CODE OF FEDERAL REGULATIONS

Title 42
Public Health

Parts 400 to 413

Revised as of October 1, 2024

Containing a codification of documents
of general applicability and future effect

As of October 1, 2024

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 400.200 *refers to title 42, part 400, section 200.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....as of January 1
Title 17 through Title 27.....as of April 1
Title 28 through Title 41.....as of July 1
Title 42 through Title 50.....as of October 1

The appropriate revision date is printed on the cover of each volume.

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OMB CONTROL NUMBERS

The Paperwork Reduction Act of 1980 (Pub. L. 96–511) requires Federal agencies to display an OMB control number with their information collection request.

Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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Provisions of the Code that are no longer in force and effect as of the revision date stated on the cover of each volume are not carried. Code users may find the text of provisions in effect on any given date in the past by using the appropriate List of CFR Sections Affected (LSA). For the convenience of the reader, a ''List of CFR Sections Affected'' is published at the end of each CFR volume. For changes to the Code prior to the LSA listings at the end of the volume, consult previous annual editions of the LSA. For changes to the Code prior to 2001, consult the List of CFR Sections Affected compilations, published for 1949-1963, 1964-1972, 1973-1985, and 1986-2000.

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The term ''[Reserved]'' is used as a place holder within the Code of Federal Regulations. An agency may add regulatory information at a ''[Reserved]'' location at any time. Occasionally ''[Reserved]'' is used editorially to indicate that a portion of the CFR was left vacant and not dropped in error.

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What is incorporation by reference? Incorporation by reference was established by statute and allows Federal agencies to meet the requirement to publish regulations in the Federal Register by referring to materials already published elsewhere. For an incorporation to be valid, the Director of the Federal Register must approve it. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register (5 U.S.C. 552(a)). This material, like any other properly issued regulation, has the force of law.

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An index to the text of ''Title 3—The President'' is carried within that volume.

The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the ''Contents'' entries in the daily Federal Register.

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OLIVER A. POTTS,
Director,
Office of the Federal Register
October 1, 2024

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, 2024.

For this volume, Christine Colaninno 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 400 to 413)

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

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 62 FR 46037, Aug. 29, 1997; 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002; and 77 FR 29028, May 16, 2012

SUBCHAPTER A—GENERAL PROVISIONS

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SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

Sec.

Subpart C [Reserved]

AUTHORITY: 42 U.S.C. 1302 and 1395hh and 44 U.S.C. Chapter 35.

Subpart A [Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

ALJ stands for administrative law judge.

Area means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

Beneficiary means a person who is entitled to Medicare benefits and/or has been determined to be eligible for Medicaid.

CMP stands for competitive medical plan.

Conditions of participation includes *requirements for participation* as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to ''level A requirements'' as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CY stands for calendar year.

DAB stands for Departmental Appeals Board.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FDA stands for the Food and Drug Administration.

FQHC means Federally qualified health center.

FR stands for FEDERAL REGISTER.

FY stands for fiscal year.

HCPP stands for health care prepayment plan.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

ICF/IID stands for intermediate care facility for individuals with intellectual disabilities.

Medicaid means medical assistance provided under a State plan approved under title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under title XVIII of the Act.

Medicare Savings Programs (MSPs) has the same meaning described in § 435.4 of this chapter.

NCD stands for national coverage determination.

OASDI stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

OIG stands for the Department's Office of the Inspector General.

Public Health Emergency (PHE) means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health

Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

QDWI stands for Qualified Disabled and Working Individual.

QIO stands for quality improvement organization.

QMB stands for Qualified Medicare Beneficiary.

Qualified Disabled and Working Individual means an individual who—

(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

Qualified Medicare Beneficiary (QMB) means an individual described in § 435.123 of this chapter.

Qualifying Individual (QI) means an individual described in § 435.125 of this chapter.

Quality improvement organization means an organization that has a contract with CMS, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

Regional Administrator means a Regional Administrator of CMS.

Regional Office means one of the regional offices of CMS.

RHC stands for rural health clinic.

RRB stands for Railroad Retirement Board.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

Specified Low-Income Medicare Beneficiary (SLMB) means an individual described in § 435.124 of this chapter.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[48 FR 12534, Mar. 25, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 400.200, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Critical access hospital (CAH) means a facility designated by HFCA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any other Board staff appointed by the Board Chair to perform a review under that part.

Entitled means that an individual meets all the requirements for Medicare benefits.

Essential access community hospital (EACH) means a hospital designated by CMS as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

GME stands for graduate medical education.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Medicare integrity program contractor means an entity that has a contract with CMS under section 1893 of the Act to perform exclusively one or more of the program integrity activities specified in that section.

Medicare Part A means the hospital insurance program authorized under Part A of title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Nonparticipating supplier means a supplier that does not have an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Payment on an assignment-related basis means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

Provider means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 400.202, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Intellectual disability means the condition that was previously referred to as mental retardation.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Nursing facility (NF), effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Services means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992; 67 FR 41094, June 14, 2002; 77 FR 29028, May 16, 2012]

Subpart C [Reserved]

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

Sec.

Subpart C [Reserved]

AUTHORITY: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5) and sec. 105, Pub. L. 114–10, 129 Stat. 87.

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

(a) The regulations in this subpart:

(1) Implement section 1106(a) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to information obtained by officers or employees of CMS in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of CMS and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart:

Act means the Social Security Act.

Freedom of Information Act rules means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department's public information regulation, 45 CFR part 5, subpart F

and by §§ 401.106 to 401.152 of this subpart.

Person means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include Federal agencies or State or Federal courts.

Record has the same meaning as that provided in 45 CFR 5.5.

Subject individual means an individual whose record is maintained by the Department in a system of records, as the terms ''individual,'' ''record'', and ''system of records'' are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

§ 401.105 Rules for disclosure.

(a) *General rule.* The Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or beneficiary of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

(b) *Application of the general rule.* Pursuant to the general rule in paragraph (a) of this section,

(1) Information shall be disclosed—

(i) To a subject individual when required by the access provision of the Privacy Act, 5 U.S.C. 552a(d), as implemented by the Department Privacy Act regulation, 45 CFR part 5b; and

(ii) To a person upon request when required by the Freedom of Information Act, 5 U.S.C. 552;

(2) Unless prohibited by any other statute (e.g., the Privacy Act of 1974, 5 U.S.C. 552a(b), the Tax Reform Act of 1976, 26 U.S.C. 6103, or section 1106(d) and (e) of the Social Security Act), information may be disclosed to any requester or beneficiary of the information, including another Federal agency or a State or Federal court, when the information would not be exempt from mandatory disclosure under Freedom of Information Act rules or when the information nevertheless would be made available under the Department's public information regulation's criteria for disclosures which are in the public interest and consistent with obligations of confidentiality and administrative necessity, 45 CFR part 5, subpart F, as supplemented by §§ 401.106 to 401.152 of this subpart.

[42 FR 14704, Mar. 16, 1977. Redesignated at 45 FR 74913, 74914, Nov. 13, 1980, and correctly redesignated at 46 FR 24551, May 1, 1981, as amended at 46 FR 55697, Nov. 12, 1981]

§ 401.106 Publication.

(a) *Methods of publication.* Materials required to be published under the provisions of The Freedom of Information Act, 5 U.S.C. 552 (a)(1) and (2) are published in one of the following ways:

(1) By publication in the FEDERAL REGISTER of CMS regulations, and by their subsequent inclusion in the Code of Federal Regulations;

(2) By publication in the FEDERAL REGISTER of appropriate general notices;

(3) By other forms of publication, when incorporated by reference in the FEDERAL REGISTER with the approval of the Director of the Federal Register; and

(4) By publication of indexes of precedential orders and opinions issued in the adjudication of claims, statements of policy and interpretations which have been adopted but have not been published in the FEDERAL REGISTER, and of administrative staff manuals and instructions to staff that affect a member of the public.

(b) *Availability for inspection.* Those materials which are published in the FEDERAL REGISTER pursuant to 5 U.S.C. 552(a)(1) shall, to the extent practicable and to further assist the public, be made available for inspection at the places specified in § 401.128.

[46 FR 55696, Nov. 12, 1981, as amended at 48 FR 22924, May 23, 1983]

§ 401.108 CMS rulings.

(a) After September 1981, a precedent final opinion or order or a statement of policy or interpretation that has not been published in the FEDERAL REGISTER as a part of a regulation or of a notice implementing regulations, but which has been adopted by CMS as having precedent, may be published in the FEDERAL REGISTER as a CMS Ruling

and will be made available in the publication entitled *CMS Rulings*.

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by CMS before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *CMS Rulings*.

(c) CMS Rulings are published under the authority of the Administrator, CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[48 FR 22924, May 23, 1983, as amended at 70 FR 11472, Mar. 8, 2005; 70 FR 37702, June 30, 2005]

§401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential. In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the FEDERAL REGISTER.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

[82 FR 5105, Jan. 17, 2017]

§401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of CMS may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.

(a) Titles 20, 42, and 45 of the Code of Federal Regulations.

(b) FEDERAL REGISTER issues.

(c) Compilation of the Social Security Laws.

(d) CMS Rulings.

(e) Social Security Handbook. The information in the Handbook is not of precedent or interpretative force.

(f) Medicare/Medicaid Directory of Medical Facilities.

§401.112 Availability of administrative staff manuals.

All CMS administrative staff manuals and instructions to staff personnel which contain policies, procedures, or interpretations that affect the public are available for inspection and copying. A complete listing of such materials is published in CMS Rulings. These manuals are generally not printed in a sufficient quantity to permit sale or other general distribution to the public. Selected material is maintained at Social Security Administration district offices and field offices and may be inspected there. See §§401.130 and 401.132 for a listing of this material.

§ 401.116 Availability of records upon request.

(a) *General.* In addition to the records made available pursuant to §§ 401.106, 401.108, 401.110 and 401.112, CMS will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of title 5, United States Code (see § 401.126), or any other provision of law.

(b) *Misappropriation, alteration, or destruction of records.* No person may remove any record made available to him for inspection or copying under this part, from the place where it is made available. In addition, no person may steal, alter, mutilate, obliterate, or destroy in whole or in part, such a record. See sections 641 and 2071 of title 18 of the United States Code.

§ 401.118 Deletion of identifying details.

When CMS publishes or otherwise makes available an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names or other identifying details will be deleted.

§ 401.120 Creation of records.

Records will not be created by compiling selected items from the files, and records will not be created to provide the requester with such data as ratios, proportions, percentages, per capitas, frequency distributions, trends, correlations, and comparisons. If such data have been compiled and are available in the form of a record, the record shall be made available as provided in this subpart.

§ 401.126 Information or records that are not available.

(a) *Specific exemptions from disclosure.* Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see subpart F of the public information regulation of the Department of Health and Human Services (45 CFR part 5) and the appendix to that regulation.

(b) *Materials exempt from disclosure by statute.* Pursuant to paragraph (b)(3) of 5 U.S.C. 552, as amended, which exempts from the requirement for disclosure matters that are exempted from disclosure by statute, provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matter to be withheld:

(1) Reports described in sections 1106 (d) and (e) of the Social Security Act shall not be disclosed, except in accordance with the provisions of sections 1106 (d) and (e). Sections 1106 (d) and (e) provide for public inspection of certain official reports dealing with the operation of the health programs established by titles XVIII and XIX of the Social Security Act (Medicare and Medicaid), but require that program validation survey reports and other formal evaluations of providers of services shall not identify individual patients, individual health care practitioners, or other individuals. Section 1106(e) further requires that none of the reports shall be made public until the contractor or provider whose performance is being evaluated has had a reasonable opportunity to review that report and to offer comments. See § 401.133 (b) and (c);

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, CMS may not disclose any accreditation survey or any information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of § 488.5 or § 493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions.* (A) CMS may release the accreditation survey of any home health agency; and

(B) CMS may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example,

denial of payment for new admissions, civil money penalties, temporary management and termination) taken by CMS; and

(3) Tax returns and return information defined in section 6103 of the Internal Revenue Code, as amended by the Tax Reform Act of 1976, shall not be disclosed except as authorized by the Internal Revenue Code.

(c) *Effect of exemption.* Neither 5 U.S.C. 552 nor this regulation directs the withholding of any record or information, except to the extent of the prohibitions in paragraph (b) of this section. Except for material required to be withheld under the statutory provisions incorporated in paragraph (b) of this section or under another statute which meets the standards in 5 U.S.C. 552(b)(3), materials exempt from mandatory disclosure will nevertheless be made available when this can be done consistently with obligations of confidentiality and administrative necessity. The disclosure of materials or records under these circumstances in response to a specific request, however, is of no precedent force with respect to any other request.

[46 FR 55696, Nov. 12, 1981, as amended at 58 FR 61837, Nov. 23, 1993; 80 FR 29834, May 22, 2015]

§401.128 Where requests for records may be made.

(a) *General.* Any request for any record may be made to—

(1) Any CMS component;

(2) Director, Office of Public Affairs, CMS 313–H, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, DC 20201; or

(3) Director of Public Affairs in any Regional Office of the Department of Health and Human Services.

The locations and service areas of these offices are as follows:

Region I—John F. Kennedy Federal Building, Boston, MA 02203. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region II—26 Federal Plaza, New York, NY 10007. New York, New Jersey, Puerto Rico, Virgin Islands.

Region III—Gateway Building, 3535 Market Street, Philadelphia, PA 19101. Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia.

Region IV—101 Marietta Street, Altanta, GA 30323. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Region V—300 South Wacker Drive, Chicago, IL 60606. Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Region VI—1200 Main Tower Building, Dallas, TX 75202. Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region VII—601 East 12th Street, Kansas City, MO 64106. Iowa, Kansas, Missouri, Nebraska.

Region VIII—Federal Office Building, 19th and Stout Streets, Denver, CO 80294. Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Region IX—Federal Office Building, 50 United Nations Plaza, San Francisco, CA 94102. Arizona, California, Hawaii, Nevada, Guam, Trust Territory of Pacific Islands, American Samoa.

Region X—Arcade Plaza Building, 1321 Second Avenue, Seattle, WA 98101. Alaska, Idaho, Oregon, Washington.

(b) *Records pertaining to individuals.* CMS maintains some records pertaining to individuals. Disclosure of such records is generally prohibited by section 1106 of the Social Security Act (42 U.S.C. 1306), except as prescribed in §401.105 (See also §401.126(b)). Requests for records pertaining to individuals may be addressed to:

Director, Office of Research, Demonstrations and Statistics, CMS, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for CMS, Office of Research, Demonstrations and Statistics; or whose records have been included by statistical sampling techniques in research and statistical studies authorized by the Social Security Act in the field of health care financing.

(c) *Requests for materials listed in §401.130 or §401.132 or indexed in the CMS Rulings.* A request to inspect and copy materials listed in §401.130 or §401.132 or indexed in CMS Rulings may be made to any district or branch office of the Social Security Administration. If the specific material requested is not available in the office receiving the request, the material will be obtained and made available promptly.

§ 401.130 Materials available at social security district offices and branch offices.

(a) *Materials available for inspection.* The following are available or will be made available for inspection at the social security district offices and branch offices:

(1) Compilation of the Social Security Laws.

(2) The Public Information Regulation of the Department of Health and Human Services (45 CFR part 5).

(3) Medicare Program regulations issued by the Centers for Medicare & Medicaid Services. 42 CFR chapter IV .

(4) CMS Rulings.

(5) Social Security Handbook.

(b) *Materials available for inspection and copying.* The following materials are available or will be made available for inspection and copying at the social security district offices and branch offices:

(1) Claims Manual of the Social Security Administration.

(2) Department Staff Manual on Organization, Department of Health and Human Services, Part F, CMS.

(3) Parts 2 and 3 of the Part A Intermediary Manual (Provider Services under Medicare CMS Pub. 13–2 and 13–3).

(4) Parts 2 and 3 of the Part B Intermediary Manual (Physician and Supplier Services).

(5) Intermediary Letters Related to Parts 2 and 3 of the Part A and Part B Intermediary Manuals.

(6) State Buy-In Handbook (State Enrollment of Eligible Individuals under the Supplementary Medical Insurance Program) and Letters.

(7) Group Practice Prepayment Plan Manual (HIM–8) and Letters.

(8) State Operations Manual (HIM–7).

(9) CMS Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (CMS Pub. 12).

(11) Hearing Officers Handbook (Supplementary Medical Insurance Program—HIM–21).

(12) Hospital Manual (HIM–10).

(13) Home Health Agency Manual (HIM–11).

(14) Outpatient Physical Therapy Provider Manual (HIM–9).

(15) Provider Reimbursement Manual (HIM–15).

(16) Audit Program Manuals for Hospital (HIM–16), Home Health Agency (HIM–17), and Extended Care Facilities (HIM–18).

(17) Statements of deficiencies based upon survey reports of health care institutions or facilities prepared after January 31, 1973, by a State agency, and such reports (including pertinent written statements furnished by such institution or facility on such statements of deficiencies), as set forth in § 401.133(a). Except as otherwise provided for at §§ 401.133 and 488.325 of this chapter for SNFs, such statements of deficiencies, reports, and pertinent written statements shall be available or made available only at the social security district office and regional office servicing the area in which the institution or facility is located, except that such statements of deficiencies and pertinent written statements shall also be available at the local public assistance offices servicing such area.

(18) Indexes to the materials listed in paragraph (a) of this section and in this paragraph (b) and an index to the Bureau of Hearings and Appeals Handbook.

[46 FR 55696, Nov. 12, 1981, as amended at 59 FR 56232, Nov. 10, 1994]

§ 401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.

(a) *Materials available for inspection.* The following materials are available for inspection in the field offices of the Office of Hearings and Appeals, SSA.

(1) Title 45 of the Code of Federal Regulations (including the public information regulation of the Department of Health and Human Services).

(2) Regulations of the Social Security Administration and CMS.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) CMS Rulings.

(6) Social Security Handbook.

(b) *Handbook available for inspection and copying.* The Office of Hearings and Appeals Handbook is available for inspection and copying in the field offices of the Office of Hearings and Appeals.

§401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Except as otherwise provided for in §488.325 of this chapter for SNFs, the following must be made available to the public under the conditions specified:

(a) *Statements of deficiencies and survey reports on providers of services prepared by State agencies.* (1) Statements of deficiencies based upon official survey reports prepared after January 31, 1973, by a State agency pursuant to its agreement entered into under section 1864 of the Social Security Act and furnished to CMS, which relate to a State agency's findings on the compliance of a health care institution or facility with the applicable provisions in section 1861 of the Act and with the regulations, promulgated pursuant to those provisions, dealing with health and safety of patients in those institutions and facilities; and (2) State agency survey reports. The statement of deficiencies or report and any pertinent written statements furnished by the institution or facility on the statement of deficiencies shall be disclosed within 90 days following the completion of the survey by the State agency, but not to exceed 30 days following the receipt of the report by CMS. (See §401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *CMS reports on providers of services.* Upon request in writing, official reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the performance of providers of services under Medicare: *Provided*, That no information identifying individual patients, physicians, or other practitioners, or other individuals shall be disclosed under this paragraph. Those reports and other evaluations shall be disclosed within 30 days following the final preparation thereof by CMS during which time the providers of services shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those providers on those reports and evaluations.

(c) *Contractor performance review reports.* Upon request in writing, official contractor performance review reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the evaluation of the performance of (1) intermediaries and carriers under their agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act and (2) State agencies under their agreements entered into pursuant to section 1864 of the Act (including comparative evaluations of the performance of those intermediaries, carriers, and State agencies). The latest Contract Performance Review Report pertaining to a particular intermediary or carrier, prepared prior to February 1, 1973, may also be disclosed to any person upon request in writing. Those reports and evaluations shall be disclosed within 30 days following their final preparation by CMS (or 30 days following the request therefor, in the case of the contract performance review report prepared prior to February 1, 1973), during which time those intermediaries, carriers, and State agencies, as the case may be, shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those intermediaries, carriers, on State agencies or those reports and evaluations.

(d) *Accreditation surveys.* Upon written request, CMS will release the accreditation survey and related information from an accreditation organization meeting the requirements of §488.5 or §493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by CMS;

(e) Upon written request, CMS will release the accreditation survey of any home health agency.

[46 FR 55696, Nov. 12, 1981; 46 FR 59249, Dec. 4, 1981, as amended at 58 FR 61838, Nov. 23, 1993; 59 FR 56232, Nov. 10, 1994; 80 FR 29834, May 22, 2015]

§ 401.134 Release of Medicare information to State and Federal agencies.

(a) Except as provided in paragraph (b) of this section, the following information may be released to an officer or employee of an agency of the Federal or a State government lawfully charged with the administration of a program receiving grants-in-aid under title V and XIX of the Social Security Act for the purpose of administration of those titles, or to any officer or employee of the Department of Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS):

(1) Information, including the identification number, concerning charges made by physicians, other practitioners, or suppliers, and amounts paid under Medicare for services furnished to beneficiaries by such physicians, other practioners, or suppliers, to enable the agency to determine the proper amount of benefits payable for medical services performed in accordance with those programs; or

(2) Information as to physicians or other practioners that has been disclosed under § 401.105.

(3) Information relating to the qualifications and certification status of hospitals and other health care facilities obtained in the process of determining whether, and certifying as to whether, institutions or agencies meet or continue to meet the conditions of participation of providers of services or whether other entities meet or continue to meet the conditions for coverage of services they furnish.

(b) The release of such information shall not be authorized by a fiscal intermediary or carrier.

(c) The following information may be released to any officer or employee of an agency of the Federal or a State government lawfully charged with the duty of conducting an investigation or prosecution with respect to possible fraud or abuse against a program receiving grants-in-aid under Medicaid, but only for the purpose of conducting such an investigation or prosecution, or to any officer or employee of the Department of the Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provided that the agency has filed an agreement with CMS that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose that information for other than program purposes:

(1) The name and address of any provider of medical services, organization, or other person being actively investigated for possible fraud in connection with Medicare, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or a program review team, to have provided unnecessary services, or of any physician or other individual found to have violated the assignment agreement on at least three occasions.

(3) The name and address of any provider of medical services, organization or other person released under paragraph (c)(1) or (2) of this section concerning which an active investigation is concluded with a finding that there is no fraud or other prosecutable offense.

§ 401.135 Release of Medicare information to the public.

The following shall be made available to the public under the conditions specified:

(a) Information as to amounts paid to providers and other organizations and facilities for services to beneficiaries under title XVIII of the Act: *Provided,* That no information identifying any particular beneficiaries shall be disclosed under this paragraph.

(b) The name of any provider of services or other person furnishing services to Medicare beneficiaries who—

(1) Has been found by a Federal court to have been guilty of submitting false claims in connection with Medicare; or

(2) Has been found by a carrier or intermediary, after consultation with a professional medical association functioning external to program administration or, if appropriate, the State medical authority, to have been engaged in a pattern of furnishing services to beneficiaries which are substantially in excess of their medical needs; except that the name of any provider or other person shall not be disclosed pursuant to a finding under this paragraph (b)(2) of this section, unless that provider or other person has first been afforded a reasonable opportunity to offer evidence on his behalf.

(c) Upon request in writing, cost reports submitted by providers of services pursuant to section 1815 of the Act to enable the Secretary to determine amounts due the providers.

§401.136 Requests for information or records.

(a) A request should reasonably identify the requested record by brief description. Requesters who have detailed information which would assist in identifying the records requested are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Freedom of Information requests. The request should include the fee or request determination of the fee. When necessary, a written request will be promptly forwarded to the proper office, and the requester will be advised of the date of the receipt and identification and address of the proper office.

(b) Determinations of whether records will be released or withheld will be made within 10 working days from date of receipt of the request in the office listed in §401.128 except where CMS extends this time and sends notice of such extension to the requester. Such extension may not exceed 10 additional working days and shall apply only where the following unusual circumstances exist:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are requested in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the request or among two or more components of CMS having a substantial interest in the subject matter of the request.

(c) If an extension is made, the requester will be notified in writing before the expiration of 10 working days from receipt of the request and will be given an explanation of why the extension was necessary and the date on which a determination will be made.

(d) Authority to extend the time limit with respect to any request for information or records is granted to the Director, Office of Public Affairs, CMS and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of CMS who are listed in §401.144(a) as having authority to deny requests for information from records maintained on individuals are granted authority to extend the time limit for responding to requests for information from such records.

§401.140 Fees and charges.

(a) *Statement of policy.* It is CMS's policy to comply with certain requests for information services without charge. Except as otherwise determined pursuant to paragraph (c) of this section, fees will be charged for the following services with respect to all other requests for information from records which are reasonably identified by the requesters:

(1) Reproduction, duplication, or copying of records;

(2) Searches for records; and

(3) Certification or authentication of records.

(b) *Fee schedules.* The fee schedule is as follows:

(1) *Search for records.* Three dollars per hour: *Provided, however,* That no

charge will be made for the first half hour.

(2) *Reproduction, duplication, or copying of records.* Ten cents per page where such reproduction can be made by commonly available photocopying machines. The cost of reproducing records which cannot be so photocopied will be determined on an individual basis at actual cost.

(3) *Certification or authentication of records.* Three dollars per certification or authentication.

(4) *Forwarding materials to destination.* Any special arrangements for forwarding which are requested shall be charged at actual cost; however, no charge will be made for postage.

(5) No charge will be made when the total amount does not exceed five dollars.

(c) *Waiver or reduction of fees.* Waiver or reduction of the fees in paragraph (b) of this section may be made upon a determination that such waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Such determination may be made by the appropriate officer or employee identified in § 401.144.

(d) *Sale of documents.* On occasion, a previously printed document may be available for sale to the public; the cost of supplying the document is one cent per page unless the document is available for sale from the Superintendent of Documents, in which case the price shall be that determined by the Superintendent.

§ 401.144 Denial of requests.

(a) *General authority.* Only the Director, Office of Public Affairs, CMS, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any CMS information or record.

(b) *Forms of denials.* (1) Oral requests may be dealt with orally, but the requester should be advised that the oral response is not an official determination and that an official determination may be obtained only by submitting the request in writing. Appropriate available assistance will be offered.

(2) Written Requests—Denials of written requests will be in writing and will contain the reasons for the denial including, as appropriate, a statement that a document requested is nonexistent or not reasonably described or is subject to one or more clearly described exemption(s). Denials will also provide the requester with appropriate information on how to exercise the right of appeal.

§ 401.148 Administrative review.

(a) *Review by the Administrator.* A person whose request has been denied may initiate a review by filing a request for review with the Administrator of CMS, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, within 30 days of receipt of the determination to deny or within 30 days of receipt of records which are in partial response to his request if a portion of a request is granted and a portion denied, whichever is later. Upon receipt of a timely request for review, the Administrator will review the decision in question and the findings upon which it was based. Upon the basis of the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Administrator or his designee will affirm or revise in whole or in part the findings and decision in question. A decision to affirm the denial will be made only upon concurrence of the Assistant Secretary for Public Affairs, or his designee, after consultation with the General Counsel or his or her designee, and the appropriate program policy official. Written notice of the decision of the Administrator will be mailed to the person who requested the review. A written decision will be made within 20 working days from receipt of the request for review. Extension of the time limit may be granted under the circumstances listed in § 401.136(b) to the extent that the maximum 10 days limit on extensions has not been exhausted on the initial determination. The decision will include the basis for it and will advise the requester of his right to judicial review.

(b) *Failure of the Administrator to comply with the time limits.* Failure of the Administrator to comply with the time

limits set forth in § 401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§ 401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subpart C [Reserved]

Subpart D—Reporting and Returning of Overpayments

SOURCE: 81 FR 7683, Feb. 12, 2016, unless otherwise noted.

§ 401.301 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII of the Act as required by section 1128J(d) of the Act.

§ 401.303 Definitions.

For purposes of this subpart—

Medicare contractor means a Part A/Part B Medicare Administrative Contractor (A/B MAC) or a Durable Medical Equipment Medicare Administrative Contractor (DME MAC).

Overpayment means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.

Person means a provider (as defined in § 400.202 of this chapter) or a supplier (as defined in § 400.202 of this chapter).

§ 401.305 Requirements for reporting and returning of overpayments.

(a) *General.* (1) A person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.

(2) A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

(b) *Deadline for reporting and returning overpayments.* (1) A person who has received an overpayment must report and return the overpayment by the later of either of the following:

(i) The date which is 60 days after the date on which the overpayment was identified.

(ii) The date any corresponding cost report is due, if applicable.

(2) The deadline for returning overpayments will be suspended when the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

(ii) CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Disclosure Protocol.

(iii) A person requests an extended repayment schedule as defined in § 401.603 and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

(c) *Applicable reconciliation.* (1) The applicable reconciliation occurs when a cost report is filed; and

(2) In instances when the provider—

(i) Receives more recent CMS information on the SSI ratio, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the provider's cost report occurs; or

(ii) Knows that an outlier reconciliation will be performed, the provider is

not required to estimate the change in reimbursement and return the estimated overpayment until the final reconciliation of that cost report.

(d) *Reporting.* (1) A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, except as provided in paragraph (d)(2) of this section. If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statistically valid sampling and extrapolation methodology in the report.

(2) A person satisfies the reporting obligations of this section by making a disclosure under the OIG's Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol resulting in a settlement agreement using the process described in the respective protocol.

(e) *Enforcement.* Any overpayment retained by a person after the deadline for reporting and returning the overpayment specified in paragraph (b) of this section is an obligation for purposes of 31 U.S.C. 3729.

(f) *Lookback period.* An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment, as defined in paragraph (a)(2) of this section, within 6 years of the date the overpayment was received.

Subpart E [Reserved]

Subpart F—Claims Collection and Compromise

SOURCE: 48 FR 39064, Aug. 29, 1983, unless otherwise noted.

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements the following statutory provisions:

(1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government.

(2) Section 1893(f)(1) of the Act regarding the use of repayment plans.

(b) *Scope.* Except as provided in paragraphs (c) through (f) of this section, the regulations in this subpart describe CMS's procedures and standards for the collection of claims in any amount, and the compromise of, or the suspension or termination of collection action on, all claims for money or property that do not exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, arising under any functions delegated to CMS by the Secretary.

(c) *Amount of claim.* CMS refers all claims that exceed $100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(d) *Related regulations*—(1) *Department regulations.* DHHS regulations applicable to CMS that generally implement the FCCA for the Department are located at 45 CFR part 30. These regulations apply only to the extent CMS regulations do not address a situation.

(2) *CMS regulations.* The following regulations govern specific debt management situations encountered by CMS and supplement this subpart:

(i) Claims against Medicare beneficiaries for the recovery of overpayments are covered in 20 CFR 404.515.

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350–405.358 of this chapter.

(iii) Claims against providers, physicians, or other suppliers of services for overpayments under Medicare and for assessment of interest are covered in §§ 405.377 and 405.378 of this chapter, respectively.

(iv) Claims against beneficiaries for unpaid hospital insurance or supplementary medical insurance premiums under Medicare are covered in § 408.110 of this chapter.

(v) State repayment of Medicaid funds by installments is covered in § 430.48 of this chapter.

(e) *Collection and compromise under other statutes and at common law.* The regulations in this subpart do not—

(1) Preclude disposition by CMS of claims under statutes, other than the FCCA, that provide for the collection or compromise of a claim, or suspension or termination of collection action.

(2) Affect any rights that CMS may have under common law as a creditor.

(f) *Fraud.* The regulations in this subpart do not apply to claims in which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of a debtor or any other party having an interest in the claim. CMS forwards these claims to the Department of Justice for disposition under 4 CFR 105.1.

(g) *Enforced collection.* CMS refers claims to the Department of Justice for enforced collection through litigation in those cases which cannot be compromised or on which collection action cannot be suspended or terminated in accordance with this subpart or the regulations issued jointly by the Attorney General and the Comptroller General.

[48 FR 39064, Aug. 29, 1983, as amended at 52 FR 48123, Dec. 18, 1987; 57 FR 56998, Dec. 2, 1992; 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996; 73 FR 36447, June 27, 2008]

§ 401.603 Definitions.

For purposes of this subpart—

Claim means any debt owed to CMS.

Debtor means any individual, partnership, corporation, estate, trust or other legal entity against which CMS has a claim.

Extended repayment schedule means installment payments to pay back a debt.

[48 FR 39064, Aug. 29, 1983, as amended at 73 FR 36447, June 27, 2008]

§ 401.605 Omissions not a defense.

The failure of CMS to comply with the regulations in this subpart, or with the related regulations listed in § 401.601(d), is not available as a defense to a debtor against whom CMS has a claim for money or property.

§ 401.607 Claims collection.

(a) *General policy.* CMS recovers amounts of claims due from debtors, including interest where appropriate, by—

(1) Direct collections in lump sums or in installments; or

(2) Offsets against monies owed to the debtor by the Federal government where possible.

(b) *Collection in lump sums.* Whenever possible, CMS attempts to collect claims in full in one lump sum. However, if CMS determines that a debtor is unable to pay the claim in one lump sum, CMS may instead enter into an agreement to accept regular installment payments.

(c) *Collection in installments.* Generally, CMS requires that all claims to be satisfied by installment payments must be liquidated in three years or less. If unusual circumstances exist, such as the possibility of debtor insolvency, an installment agreement that extends beyond three years may be approved.

(1) *Debtor request.* If a debtor desires to repay a claim in installments, the debtor must submit—

(i) A request to CMS; and

(ii) Any information required by CMS to make a decision regarding the request.

(2) *Extended repayment schedule.* (i) For purposes of this paragraph (c)(2), the following definitions apply:

Extreme hardship exists when a provider or supplier qualifies as being in ''hardship'' as defined in this paragraph and the provider's or supplier's request for an extended repayment schedule (ERS) is approved under paragraph (c)(3) of this section.

Hardship exists when the total amount of all outstanding outstanding overpayments (principal and interest and including overpayments reported in accordance with §§ 401.301 through 401.305) not included in an approved, existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report for a provider filing a cost report, or for the previous calendar year for a supplier or non cost-report provider.

(ii) CMS or its contractor reviews a provider's or supplier's request for an ERS. For a provider or a supplier not paid by Medicare during the previous year or paid only during a portion of that year, the contractor or CMS will use the last 12 months of Medicare payments. If less than a 12-month payment history exists, the number of months available is annualized to equal an approximate yearly Medicare payment level for the provider or supplier.

(iii) For a provider or supplier requesting an ERS, CMS or its contractor evaluates the request based on the definitions and information submitted under this paragraph (c)(2). For a provider or supplier whose situation does not meet the definitions in paragraph (c)(2)(i) of this section, CMS or its contractor evaluates the ERS request using the information in paragraph (c)(3) of this section in deciding to grant an ERS.

(iv) CMS or its contractor is prohibited from granting an ERS to a provider or supplier if there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program, or there is an indication of fraud or abuse committed against the Medicare program.

(v) CMS or its contractor may grant a provider or a supplier an ERS of at least 6 months if repaying an overpayment within 30 days will constitute a ''hardship'' as defined in paragraph (c)(2)(i) of this section. If a provider or supplier is granted an ERS under this paragraph, missing one installment payment constitutes a default and the total balance of the overpayment will be recovered immediately.

(vi) CMS or its contractor may grant a provider or a supplier an ERS of 36 months and up to 60 months if repaying an overpayment will constitute an ''extreme hardship'' as defined in paragraph (c)(2)(i) of this section.

(3) *CMS decision.* CMS will determine the number, amount and frequency of installment payments based on the information submitted by the debtor and on other factors such as—

(i) Total amount of the claim;

(ii) Debtor's ability to pay; and

(iii) Cost to CMS of administering an installment agreement.

(d) *Collection by offset.* (1) CMS may offset, where possible, the amount of a claim against the amount of pay, compensation, benefits or other monies that a debtor is receiving or is due from the Federal government.

(2) Under regulations at §405.350–405.358 of this chapter, CMS may initiate adjustments in program payments to which an individual is entitled under title II of the Act (Federal Old Age, Survivors, and Disability Insurance Benefits) or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to recover Medicare overpayments.

[48 FR 39064, Aug. 29, 1983, as amended at 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996; 73 FR 36447, June 27, 2008; 81 FR 7684, Feb. 12, 2016]

§ 401.613 Compromise of claims.

(a) *Amount of compromise.* HFCA requires that the amount to be recovered through a compromise of a claim must—

(1) Bear a reasonable relation to the amount of the claim; and

(2) Be recoverable through enforced collection procedures.

(b) *General factors.* After considering the bases for a decision to compromise a claim under paragraph (c) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(c) *Basis for compromise.* Bases on which CMS may compromise a claim include the following—

(1) *Inability to pay.* CMS may compromise a claim if it determines that the debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount of the claim within a reasonable time.

(2) *Litigative probabilities.* CMS may compromise a claim if it determines that it would be difficult to prevail in a case before a court of law as a result of the legal issues involved or inability of the parties to agree to the facts of

the case. The amount that CMS accepts in compromise under this provision will reflect—

(i) The likelihood that CMS would have prevailed on the legal question(s) involved;

(ii) Whether and to what extent CMS would have obtained a full or partial recovery of a judgment, depending on the availability of witnesses, or other evidentiary support for CMS's claim; and

(iii) The amount of court costs that would be assessed to CMS.

(3) *Cost of collecting the claim.* CMS may compromise a claim if it determines that the cost of collecting the claim does not justify the enforced collection of the full amount. In this case, CMS may adjust the amount it accepts as a compromise to allow an appropriate discount for the costs of collection it would have incurred but for the compromise.

(d) *Enforcement policy.* CMS may compromise statutory penalties, forfeitures, or debts established as an aid to enforcement or to compel compliance, if it determines that its enforcement policy, in terms of deterrence and securing compliance both present and future, is adequately served by acceptance of the compromise amount.

§401.615 Payment of compromise amount.

(a) *Time and manner of compromise.* Payment by the debtor of the amount that CMS has agreed to accept as a compromise in full settlement of a claim must be made within the time and in the manner prescribed by CMS. Accordingly, CMS will not settle a claim until the full payment of the compromise amount has been made.

(b) *Effect of failure to pay compromise amount.* Failure of the debtor to make payment, as provided by the compromise agreement, reinstates the full amount of the claim, less any amounts paid prior to the default.

(c) *Prohibition against grace periods.* CMS will not agree to inclusion of a provision in an installment agreement that would permit grace periods for payments that are late under the terms of the agreement.

§401.617 Suspension of collection action.

(a) *General conditions.* CMS may temporarily suspend collection action on a claim if the following general conditions are met—

(1) *Amount of future recovery.* CMS determines that future collection action may result in a recovery of an amount sufficient to justify periodic review and action on the claim by CMS during the period of suspension.

(2) *Statute of limitations.* CMS determines that—

(i) The applicable statute of limitations has been tolled, waived or has started running anew; or

(ii) Future collections may be made by CMS through offset despite an applicable statute of limitations.

(b) *Basis for suspension.* Bases on which CMS may suspend collection action on a particular claim include the following—

(1) A debtor cannot be located; or

(2) A debtor—

(i) Owns no substantial equity in property;

(ii) Is unable to make payment on CMS's claim or is unable to effect a compromise; and

(iii) Has future prospects that justify retention of the claim.

(c) *Locating debtors.* CMS will make every reasonable effort to locate missing debtors sufficiently in advance of the bar of an applicable statute of limitations to permit timely filing of a lawsuit to recover the amount of the claim.

(d) *Effect of suspension on liquidation of security.* CMS will liquidate security, obtained in partial recovery of a claim, despite a decision under this section to suspend collection action against the debtor for the remainder of the claim.

§401.621 Termination of collection action.

(a) *General factors.* After considering the bases for a decision to terminate collection action under paragraph (b) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which CMS may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* CMS may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, CMS will consider factors such as—

(i) Judicial remedies available;

(ii) The debtor's future financial prospects; and

(iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, CMS may terminate collection action if—

(i) There is no security remaining to be liquidated;

(ii) The applicable statute of limitations has run; or

(iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by CMS to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* CMS may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* CMS may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* CMS may terminate collection action if—

(i) Efforts to obtain voluntary payment are unsuccessful; and

(ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* CMS will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, CMS will not allocate the burden of claims payment among the debtors. CMS will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, CMS will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of CMS claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of CMS appeal procedures.

Subpart G—Availability of Medicare Data for Performance Measurement

SOURCE: 76 FR 76567, Dec. 7, 2011, unless otherwise noted.

§ 401.701 Purpose and scope.

The regulations in this subpart implement section 1874(e) of the Social Security Act as it applies to Medicare data made available to qualified entities for the evaluation of the performance of providers and suppliers.

§ 401.703 Definitions.

For purposes of this subpart:

(a) *Qualified entity* means either a single public or private entity, or a lead entity and its contractors, that meets the following requirements:

(1) Is qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use.

(2) Agrees to meet the requirements described in this subpart at §§ 401.705 through 401.721.

(b) *Provider of services (referred to as a provider)* has the same meaning as the term ''provider'' in § 400.202 of this chapter.

(c) *Supplier* has the same meaning as the term ''supplier'' at § 400.202 of this chapter.

(d) *Claim* means an itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests

payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D Prescription Drug Event (PDE) data.

(e) *Standardized data extract* is a subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) *Beneficiary identifiable data* is any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to postal address or telephone number.

(g) *Encrypted data* is any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

(h) *Claims data from other sources* means provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

(i) *Clinical data* is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

(j) *Authorized user* is a third party and its contractors (including, where applicable, business associates as that term is defined at 45 CFR 160.103) that need analyses or data covered by this section to carry out work on behalf of that third party (meaning not the qualified entity or the qualified entity's contractors) to whom/which the qualified entity provides or sells data as permitted under this subpart. Authorized user third parties are limited to the following entities:

(1) A provider.

(2) A supplier.

(3) A medical society.

(4) A hospital association.

(5) An employer.

(6) A health insurance issuer.

(7) A healthcare provider and/or supplier association.

(8) A state entity.

(9) A federal agency.

(k) *Employer* has the same meaning as the term ''employer'' as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974.

(l) *Health insurance issuer* has the same meaning as the term ''health insurance issuer'' as defined in section 2791 of the Public Health Service Act.

(m) *Medical society* means a nonprofit organization or association that provides unified representation and advocacy for physicians at the national or state level and whose membership is comprised of a majority of physicians.

(n) *Hospital association* means a nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national, state, or local level and whose membership is comprised of a majority of hospitals and health systems.

(o) *Healthcare Provider and/or Supplier Association* means a nonprofit organization or association that provides unified representation and advocacy for providers and suppliers at the national or state level and whose membership is comprised of a majority of suppliers or providers.

(p) *State Entity* means any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

(q) *Combined data* means, at a minimum, a set of CMS claims data provided under this subpart combined with claims data, or a subset of claims data from at least one of the other claims data sources described in §401.707(d).

(r) *Patient* means an individual who has visited the provider or supplier for

a face-to-face or telehealth appointment at least once in the past 24 months.

(s) *Marketing* means the same as the term ''marketing'' at 45 CFR 164.501 without the exception to the bar for ''consent'' based marketing.

(t) *Violation* means a failure to comply with a requirement of a CMS DUA (CMS data use agreement) or QE DUA (qualified entity data use agreement).

(u) *Required by law* means the same as the phrase ''required by law'' at 45 CFR 164.103.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 401.705 Eligibility criteria for qualified entities.

(a) *Eligibility criteria:* To be eligible to apply to receive data as a qualified entity under this subpart, an applicant generally must demonstrate expertise and sustained experience, defined as 3 or more years, in the following three areas, as applicable and appropriate to the proposed use:

(1) Organizational and governance criteria, including:

(i) Expertise in the areas of measurement that they propose to use in accurately calculating quality, and efficiency, effectiveness, or resource use measures from claims data, including the following:

(A) Identifying an appropriate method to attribute a particular patient's services to specific providers and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

(C) Using methods for risk-adjustment to account for variations in both case-mix and severity among providers and suppliers.

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A plan for a business model that is projected to cover the costs of performing the required functions, including the fee for the data.

(iii) Successfully combining claims data from different payers to calculate performance reports.

(iv) Designing, and continuously improving the format of performance reports on providers and suppliers.

(v) Preparing an understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports.

(vi) Implementing and maintaining a process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

(vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information, violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues.

(viii) Accurately preparing performance reports on providers and suppliers and making performance report information available to the public in aggregate form, that is, at the provider or supplier level.

(2) Expertise in combining Medicare claims data with claims data from other sources, including demonstrating to the Secretary's satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source.

(3) Expertise in establishing, documenting and implementing rigorous data privacy and security policies including enforcement mechanisms.

(b) *Source of expertise and experience:* An applicant may demonstrate expertise and experience in any or all of the

areas described in paragraph (a) of this section through one of the following:

(1) Activities it has conducted directly through its own staff.

(2) Contracts with other entities if the applicant is the lead entity and includes documentation in its application of the contractual arrangements that exist between it and any other entity whose expertise and experience is relied upon in submitting the application.

§ 401.707 Operating and governance requirements for qualified entities.

A qualified entity must meet the following operating and governance requirements:

(a) Submit to CMS a list of all measures it intends to calculate and report, the geographic areas it intends to serve, and the methods of creating and disseminating reports. This list must include the following information, as applicable and appropriate to the proposed use:

(1) Name of the measure, and whether it is a standard or alternative measure.

(2) Name of the measure developer/owner.

(3) If it is an alternative measure, measure specifications, including numerator and denominator.

(4) The rationale for selecting each measure, including the relationship to existing measurement efforts and the relevancy to the population in the geographic area(s) the entity would serve, including the following:

(i) A specific description of the geographic area or areas it intends to serve.

(ii) A specific description of how each measure evaluates providers and suppliers on quality, efficiency, effectiveness, and/or resource use.

(5) A description of the methodologies it intends to use in creating reports with respect to all of the following topics:

(i) Attribution of beneficiaries to providers and/or suppliers.

(ii) Benchmarking performance data, including the following:

(A) Methods for creating peer groups.

(B) Justification of any minimum sample size determinations made.

(C) Methods for handling statistical outliers.

(iii) Risk adjustment, where appropriate.

(iv) Payment standardization, where appropriate.

(b) Submit to CMS a description of the process it would establish to allow providers and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public.

(c) Submit to CMS a prototype report and a description of its plans for making the reports available to the public.

(d) Submit to CMS information about the claims data it possesses from other sources, as defined at § 401.703(h), and documentation of adequate rights to use the other claims data for the purposes of this subpart.

(e) If requesting a 5 percent national sample to calculate benchmarks for the specific measures it is using, submit to CMS a justification for needing the file to calculate benchmarks.

§ 401.709 The application process and requirements.

(a) *Application deadline.* CMS accepts qualified entity applications on a rolling basis after an application is made available on the CMS Web site. CMS reviews applications in the order in which they are received.

(b) *Selection criteria.* To be approved as a qualified entity under this subpart, the applicant must meet one of the following:

(1) *Standard approval process:* Meet the eligibility and operational and governance requirements, fulfill all of the application requirements to CMS' satisfaction, and agree to pay a fee equal to the cost of CMS making the data available. The applicant and each of its contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart.

(2) *Conditional approval process:* Meet the eligibility and operational and governance requirements, and fulfill all of the application requirements to CMS' satisfaction, with the exception of possession of sufficient claims data from

other sources. Meeting these requirements will result in a conditional approval as a qualified entity. Entities gaining a conditional approval as a qualified entity must meet the eligibility requirements related to claims data from other sources the entity intends to combine with the Medicare data, agree to pay a fee equal to the cost of CMS making the data available, and execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart before receiving any Medicare data. If the qualified entity is composed of lead entity with contractors, any contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS.

(c) *Duration of approval.* CMS permits an entity to participate as a qualified entity for a period of 3 years from the date of notification of the application approval by CMS. The qualified entity must abide by all CMS regulations and instructions. If the qualified entity wishes to continue performing the tasks after the 3-year approval period, the entity may re-apply for qualified entity status following the procedures in paragraph (f) of this section.

(d) *Reporting period.* A qualified entity must produce reports on the performance of providers and suppliers at least annually, beginning in the calendar year after they are approved by CMS.

(e) *The distribution of data*—(1) *Initial data release.* Once CMS fully approves a qualified entity under this subpart, the qualified entity must pay a fee equal to the cost of CMS making data available. After the qualified entity pays the fee, CMS will release the applicable encrypted claims data, as well as a file that crosswalks the encrypted beneficiary ID to the beneficiary name and the Medicare HICN. The data will be the most recent data available, and will be limited to the geographic spread of the qualified entity's other claims data, as determined by CMS.

(2) *Subsequent data releases.* After the first quarter of participation, CMS will provide a qualified entity with the most recent additional quarter of currently available data, as well as a table that crosswalks the encrypted beneficiary ID to the beneficiary's name and the Medicare HICN. Qualified entities are required to pay CMS a fee equal to the cost of making data available before CMS will release the most recent quarter of additional data to the qualified entity.

(f) *Re-application.* A qualified entity that is in good standing may re-apply for qualified entity status. A qualified entity is considered to be in good standing if it has had no violations of the requirements in this subpart or if the qualified entity is addressing any past deficiencies either on its own or through the implementation of a corrective action plan. To re-apply a qualified entity must submit to CMS documentation of any changes to what was included in its previously-approved application. A re-applicant must submit this documentation at least 6 months before the end of its 3-year approval period and will be able to continue to serve as a qualified entity until the re-application is either approved or denied by CMS. If the re-application is denied, CMS will terminate its relationship with the qualified entity and the qualified entity will be subject to the requirements for return or destruction of data at § 401.721(b).

§ 401.711 Updates to plans submitted as part of the application process.

(a) If a qualified entity wishes to make changes to the following parts of its previously-approved application:

(1) Its list of proposed measures—the qualified entity must send all the information referenced in § 401.707(a) for the new measures to CMS at least 30 days before its intended confidential release to providers and suppliers.

(2) Its proposed prototype report—the qualified entity must send the new prototype report to CMS at least 30 days before its intended confidential release to providers and suppliers.

(3) Its plans for sharing the reports with the public—the qualified entity must send the new plans to CMS at least 30 days before its intended confidential release to providers and suppliers.

(b) CMS will notify the qualified entity when the entity's proposed changes are approved or denied for use, generally within 30 days of the qualified entity submitting the changes to CMS. If a CMS decision on approval or disapproval for a change is not forthcoming within 30 days and CMS does not request an additional 30 days for review, the change or modification shall be deemed to be approved.

(c) If the amount of claims data from other sources available to a qualified entity decreases, the qualified entity must immediately inform CMS and submit documentation that the remaining claims data from other sources is sufficient to address the methodological concerns regarding sample size and reliability. Under no circumstances may a qualified entity use Medicare data to create a report, use a measure, or share a report after the amount of claims data from other sources available to a qualified entity decreases until CMS determines either that the remaining claims data is sufficient or that the qualified entity has collected adequate additional data to address any deficiencies.

(1) If the qualified entity cannot submit the documentation required in paragraph (c) of this section, or if CMS determines that the remaining claims data is not sufficient, CMS will afford the qualified entity up to 120 days to obtain additional claims to address any deficiencies. If the qualified entity does not have access to sufficient new data after that time, CMS will terminate its relationship with the qualified entity.

(2) If CMS determines that the remaining claims data is sufficient, the qualified entity may continue issuing reports, using measures, and sharing reports.

§401.713 Ensuring the privacy and security of data.

(a) *Data use agreement between CMS and a qualified entity*. A qualified entity must comply with the data requirements in its data use agreement with CMS (hereinafter the CMS DUA). Contractors (including, where applicable, business associates) of qualified entities that are anticipated to have access to the Medicare claims data or beneficiary identifiable data in the context of this program are also required to execute and comply with the CMS DUA. The CMS DUA will require the qualified entity to maintain privacy and security protocols throughout the duration of the agreement with CMS, and will ban the use or disclosure of Medicare data or any derivative data for purposes other than those set out in this subpart. The CMS DUA will also prohibit the use of unsecured telecommunications to transmit such data, and will specify the circumstances under which such data must be stored and may be transmitted.

(b) A qualified entity must inform each beneficiary whose beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed in accordance with the DUA.

(c) Contractor(s) must report to the qualified entity whenever there is an incident where beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed.

(d) *Data use agreement between a qualified entity and an authorized user*. In addition to meeting the other requirements of this subpart, and as a pre-condition of selling or disclosing any combined data or any Medicare claims data (or any beneficiary-identifiable derivative data of either kind) and as a precondition of selling or disclosing nonpublic analyses that include individually identifiable beneficiary data, the qualified entity must enter a DUA (hereinafter the QE DUA) with the authorized user. Among other things laid out in this subpart, such QE DUA must contractually bind the authorized user (including any contractors or business associates described in the definition of authorized user) to the following:

(1)(i) The authorized user may be permitted to use such data and non-public analyses in a manner that a HIPAA Covered Entity could do under the following provisions:

(A) Activities falling under paragraph (1) of the definition of ''health care operations'' under 45 CFR 164.501: Quality improvement activities, including care coordination activities and efforts to track and manage medical costs; patient-safety activities; population-based activities such as

those aimed at improving patient safety, quality of care, or population health, including the development of new models of care, the development of means to expand coverage and improve access to healthcare, the development of means of reducing healthcare disparities, and the development or improvement of methods of payment or coverage policies.

(B) Activities falling under paragraph (2) of the definition of ''health care operations'' under 45 CFR 164.501: Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

(C) Activities that qualify as ''fraud and abuse detection or compliance activities'' under 45 CFR 164.506(c)(4)(ii).

(D) Activities that qualify as ''treatment'' under 45 CFR 164.501.

(ii) All other uses and disclosures of such data and/or such non-public analyses must be forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure as defined at 45 CFR 164.103.

(2) The authorized user is prohibited from using or disclosing the data or non-public analyses for marketing purposes as defined at § 401.703(s).

(3) The authorized user is required to ensure adequate privacy and security protection for such data and non-public analyses. At a minimum, regardless of whether the authorized user is a HIPAA covered entity, such protections of beneficiary identifiable data must be at least as protective as what is required of covered entities and their business associates regarding protected health information (PHI) under the HIPAA Privacy and Security Rules. In all cases, these requirements must be imposed for the life of such beneficiary identifiable data or non-public analyses and/or any derivative data, that is until all copies of such data or non-public analyses are returned or destroyed. Such duties must be written in such a manner as to survive termination of the QE DUA, whether for cause or not.

(4) Except as provided for in paragraph (d)(5) of this section, the authorized user must be prohibited from re-disclosing or making public any such data or non-public analyses.

(5)(i) At the qualified entity's discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose such data and non-public analyses as a covered entity will be permitted to disclose PHI under 45 CFR 164.506(c)(4)(i), under 45 CFR 164.506(c)(2), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

(6) Authorized users who/that receive the beneficiary de-identified combined data or Medicare data as contemplated under § 401.718 are contractually prohibited from linking the beneficiary de-identified data to any other identifiable source of information, and must be contractually barred from attempting any other means of re-identifying any individual whose data is included in such data.

(7) The QE DUA must bind authorized user(s) to notifying the qualified entity of any violations of the QE DUA, and it must require the full cooperation of the authorized user in the qualified entity's efforts to mitigate any harm that may result from such violations, or to comply with the breach provisions governing qualified entities under this subpart.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 401.715 Selection and use of performance measures.

(a) *Standard measures.* A standard measure is a measure that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data and meets the following requirements:

(1) Meets one of the following criteria:

(i) Is endorsed by the entity with a contract under section 1890(a) of the Social Security Act.

(ii) Is time-limited endorsed by the entity with a contract under section 1890(a) of the Social Security Act until such time as the full endorsement status is determined.

(iii) Is developed under section 931 of the Public Health Service Act.

(iv) Can be calculated from standardized extracts of Medicare Parts A or B claims or Part D prescription drug event data, was adopted through notice-and-comment rulemaking, and is currently being used in CMS programs that include quality measurement.

(v) Is endorsed by a CMS-approved consensus-based entity. CMS will approve organizations as consensus-based entities based on review of documentation of the consensus-based entity's measure approval process. To receive approval as a consensus-based entity, an organization must submit information to CMS documenting its processes for stakeholder consultation and measures approval; an organization will only receive approval as a consensus-based entity if all measure specifications are publically available. An organization will retain CMS acceptance as a consensus-based entity for 3 years after the approval date, at which time CMS will review new documentation of the consensus-based entity's measure approval process for a new 3-year approval.

(2) Is used in a manner that follows the measure specifications as written (or as adopted through notice-and-comment rulemaking), including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(b) *Alternative measure.* (1) An alternative measure is a measure that is not a standard measure, but that can be calculated in full, or in part, from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data, and that meets one of the following criteria:

(i) *Rulemaking process:* Has been found by the Secretary, through a notice-and comment-rulemaking process, to be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as adopted through notice-and-comment rulemaking, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(ii) *Stakeholder consultation approval process:* Has been found by the Secretary, using documentation submitted by a qualified entity that outlines its consultation and agreement with stakeholders in its community, to be more valid, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as submitted, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources. If a CMS decision on approval or disapproval of alternative measures submitted using the stakeholder consultation approval process is not forthcoming within 60 days of submission of the measure by the qualified entity, the measure will be deemed approved. However, CMS retains the right to disapprove a measure if, even after 60 days, we find it to not be ''more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource'' than a standard measure.

(2) An alternative measure approved under the process at paragraph (b)(1)(i) of this section may be used by any qualified entity. An alternative measure approved under the process at paragraph (b)(1)(ii) of this section may only be used by the qualified entity that submitted the measure for consideration by the Secretary. A qualified entity may use an alternative measure up until the point that an equivalent standard measure for the particular clinical area or condition becomes available at which point the qualified entity must switch to the standard measure within 6 months or submit additional scientific justification and receive approval, via either paragraphs (b)(1)(i) or (b)(1)(ii) of this section, from

the Secretary to continue using the alternative measure.

(3) To submit an alternative measure for consideration under the notice-and-comment-rulemaking process, for use in the calendar year following the submission, an entity must submit the following information by May 31st:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) Evidence that use of the alternative measure would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures.

(4) To submit an alternative measure for consideration under the documentation of stakeholder consultation approval process described in paragraph (b)(1)(ii) of this section, for use once the measure is approved by the Secretary, an entity must submit the following information to CMS:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) A description of the process by which the qualified entity notified stakeholders in the geographic region it serves of its intent to seek approval of an alternative measure. Stakeholders must include a valid cross representation of providers, suppliers, payers, employers, and consumers.

(v) A list of stakeholders from whom feedback was solicited, including the stakeholders' names and roles in the community.

(vi) A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure.

(vii) Unless CMS has already approved the same measure for use by another qualified entity, no new scientific evidence on the measure is available, and the subsequent qualified entity wishes to rely upon the scientific evidence submitted by the previously approved applicant, an explanation backed by scientific evidence that demonstrates why the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure.

§ 401.716 Non-public analyses.

(a) *General.* So long as it meets the other requirements of this subpart, and subject to the limits in paragraphs (b) and (c) of this section, the qualified entity may use the combined data to create non-public analyses in addition to performance measures and provide or sell these non-public analyses to authorized users (including any contractors or business associates described in the definition of authorized user).

(b) *Limitations on a qualified entity.* In addition to meeting the other requirements of this subpart, a qualified entity must comply with the following limitations as a pre-condition of dissemination or selling non-public analyses to an authorized user:

(1) A qualified entity may only provide or sell a non-public analysis to a health insurance issuer as defined in § 401.703(l), after the health insurance issuer or a business associate of that health insurance issuer has provided the qualified entity with claims data that represents a majority of the health insurance issuer's covered lives, using one of the four methods of calculating covered lives established at 26 CFR 46.4375–1(c)(2), for the time period and geographic region covered by the issuer-requested non-public analyses. A qualified entity may not provide or sell a non-public analysis to a health insurance issuer if the issuer does not have any covered lives in the geographic region covered by the issuer-requested non-public analysis.

(2) Analyses that contain information that individually identifies one or more beneficiaries may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) when both of the following conditions are met:

(i) The analyses only contain identifiable information on beneficiaries with whom the provider or supplier have a patient relationship as defined at § 401.703(r).

(ii) A QE DUA as defined at §401.713(d) is executed between the qualified entity and the provider or supplier prior to making any individually identifiable beneficiary information available to the provider or supplier.

(3) Except as specified under paragraph (b)(2) of this section, all analyses must be limited to beneficiary de-identified data. Regardless of the HIPAA covered entity or business associate status of the qualified entity and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR 164.514(b).

(4) Analyses that contain information that individually identifies a provider or supplier (regardless of the level of the provider or supplier, that is, individual clinician, group of clinicians, or integrated delivery system) may not be disclosed unless one of the following three conditions apply:

(i) The analysis only individually identifies the provider or supplier that is being supplied the analysis.

(ii) Every provider or supplier individually identified in the analysis has been afforded the opportunity to appeal or correct errors using the process at §401.717(f).

(iii) Every provider or supplier individually identified in the analysis has notified the qualified entity, in writing, that analyses can be disclosed to the authorized user without first going through the appeal and error correction process at §401.717(f).

(c) *Non-public analyses agreement between a qualified entity and an authorized user for beneficiary de-identified non-public analyses disclosures.* In addition to the other requirements of this subpart, a qualified entity must enter a contractually binding non-public analyses agreement with the authorized user (including any contractors or business associates described in the definition of authorized user) as a precondition to providing or selling de-identified analyses. Such non-public analyses agreement must contain the following provisions:

(1) The authorized user may not use the analyses or derivative data for the following purposes:

(i) Marketing, as defined at §401.703(s).

(ii) Harming or seeking to harm patients or other individuals both within and outside the healthcare system regardless of whether their data are included in the analyses.

(iii) Effectuating or seeking opportunities to effectuate fraud and/or abuse in the healthcare system.

(2) If the authorized user is an employer as defined in §401.703(k), the authorized user may only use the analyses or derivative data for purposes of providing health insurance to employees, retirees, or dependents of employees or retirees of that employer.

(3)(i) At the qualified entity's discretion, it may permit an authorized user that is a provider as defined in §401.703(b) or a supplier as defined in §401.703(c), to re-disclose the de-identified analyses or derivative data, as a covered entity will be permitted under 45 CFR 164.506(c)(4)(i), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a ''required by law'' disclosure.

(4) If the authorized user is not a provider or supplier, the authorized user may not re-disclose or make public any non-public analyses or derivative data except as required by law.

(5) The authorized user may not link the de-identified analyses to any other identifiable source of information and may not in any other way attempt to identify any individual whose de-identified data is included in the analyses.

(6) The authorized user must notify the qualified entity of any DUA violations, and it must fully cooperate with the qualified entity's efforts to mitigate any harm that may result from such violations.

[81 FR 44480, July 7, 2016]

§401.717 Provider and supplier requests for error correction.

(a) A qualified entity must confidentially share measures, measurement methodologies, and measure results with providers and suppliers at least 60 calendar days before making reports public. The 60 calendar days begin on the date on which qualified entities

send the confidential reports to providers and suppliers. A qualified entity must inform providers and suppliers of the date the reports will be made public at least 60 calendar days before making the reports public.

(b) Before making the reports public, a qualified entity must allow providers and suppliers the opportunity to make a request for the data, or to make a request for error correction, within 60 calendar days after sending the confidential reports to providers or suppliers.

(c) During the 60 calendar days between sending a confidential report on measure results and releasing the report to the public, the qualified entity must, at the request of a provider or supplier and with appropriate privacy and security protections, release the Medicare claims data and beneficiary names to the provider or supplier. Qualified entities may only provide the Medicare claims and/or beneficiary names relevant to the particular measure or measure result the provider or supplier is appealing.

(d) A qualified entity must inform providers and suppliers that reports will be made public, including information related to the status of any data or error correction requests, after the date specified to the provider or supplier when the report is sent for review and, if necessary, error correction requests (at least 60 calendar days after the report was originally sent to the providers and suppliers), regardless of the status of any requests for error correction.

(e) If a provider or supplier has a data or error correction request outstanding at the time the reports become public, the qualified entity must, if feasible, post publicly the name of the appealing provider or supplier and the category of the appeal request.

(f) A qualified entity must comply with the following requirements before disclosing non-public analyses, as defined at §401.716, which contain information that individually identifies a provider or supplier:

(1) A qualified entity must confidentially notify a provider or supplier that non-public analyses that individually identify the provider or supplier are going to be released to an authorized user at least 65 calendar days before disclosing the analyses. This confidential notification must include a short summary of the analyses (including the measures calculated), the process for the provider or supplier to request the analyses, the authorized users receiving the analyses, and the date on which the qualified entity will release the analyses to the authorized user.

(2) A qualified entity must allow providers and suppliers the opportunity to opt-in to the review and correction process as defined in paragraphs (a) through (e) of this section, anytime during the 65 calendar days. If a provider or supplier chooses to opt-in to the review and correction process more than 5 days into the notification period, the time for the review and correction process is shortened from 60 days to the number of days between the provider or supplier opt-in date and the release date specified in the confidential notification.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44481, July 7, 2016]

§ 401.718 Dissemination of data.

(a) *General.* Subject to the other requirements in this subpart, the requirements in paragraphs (b) and (c) of this section and any other applicable laws or contractual agreements, a qualified entity may provide or sell combined data or provide Medicare data at no cost to authorized users defined at §401.703(b), (c), (m), and (n).

(b) *Data*—(1) *De-identification.* Except as specified in paragraph (b)(2) of this section, any data provided or sold by a qualified entity to an authorized user must be limited to beneficiary de-identified data. De-identification must be determined based on the de-identification standards for HIPAA covered entities found at 45 CFR 164.514(b).

(2) *Exception.* If such disclosure will be consistent with all applicable laws, data that individually identifies a beneficiary may only be disclosed to a provider or supplier (as defined at §401.703(b) and (c)) with whom the identifiable individuals in such data have a current patient relationship as defined at §401.703(r).

(c) *Data use agreement between a qualified entity and an authorized user.* A

qualified entity must contractually require an authorized user to comply with the requirements in § 401.713(d) prior to providing or selling data to an authorized user under § 401.718.

[81 FR 44481, July 7, 2016]

§ 401.719 Monitoring and sanctioning of qualified entities.

(a) CMS will monitor and assess the performance of qualified entities and their contractors using the following methods:

(1) Audits.

(2) Submission of documentation of data sources and quantities of data upon the request of CMS and/or site visits.

(3) Analysis of specific data reported to CMS by qualified entities through annual reports (as described in paragraph (b) of this section) and reports on inappropriate disclosures or uses of beneficiary identifiable data (as described in paragraph (c) of this section).

(4) Analysis of complaints from beneficiaries and/or providers or suppliers.

(b) A qualified entity must provide annual reports to CMS containing information related to the following:

(1) General program adherence, including the following information:

(i) The number of Medicare and private claims combined.

(ii) The percent of the overall market share the number of claims represent in the qualified entity's geographic area.

(iii) The number of measures calculated.

(iv) The number of providers and suppliers profiled by type of provider and supplier.

(v) A measure of public use of the reports.

(2) The provider and supplier data sharing, error correction, and appeals process, including the following information:

(i) The number of providers and suppliers requesting claims data.

(ii) The number of requests for claims data fulfilled.

(iii) The number of error corrections.

(iv) The type(s) of problem(s) leading to the request for error correction.

(v) The amount of time to acknowledge the request for data or error correction.

(vi) The amount of time to respond to the request for error correction.

(vii) The number of requests for error correction resolved.

(3) Non-public analyses provided or sold to authorized users under this subpart, including the following information:

(i) A summary of the analyses provided or sold, including—

(A) The number of analyses.

(B) The number of purchasers of such analyses.

(C) The types of authorized users that purchased analyses.

(D) The total amount of fees received for such analyses.

(E) QE DUA or non-public analyses agreement violations.

(ii) A description of the topics and purposes of such analyses.

(iii) The number of analyses disclosed with unresolved requests for error correction.

(4) Data provided or sold to authorized users under this subpart, including the following information:

(i) The entities who received data.

(ii) The basis under which each entity received such data.

(iii) The total amount of fees received for providing, selling, or sharing the data.

(iv) QE DUA violations.

(c) A qualified entity must inform CMS of inappropriate disclosures or uses of beneficiary identifiable data under the DUA.

(d) CMS may take the following actions against a qualified entity if CMS determines that the qualified entity violated any of the requirements of this subpart, regardless of how CMS learns of a violation:

(1) Provide a warning notice to the qualified entity of the specific concern, which indicates that future deficiencies could lead to termination.

(2) Request a corrective action plan (CAP) from the qualified entity.

(3) Place the qualified entity on a special monitoring plan.

(4) Terminate the qualified entity.

(5) In the case of a violation, as defined at § 401.703(t), of the CMS DUA or

the QE DUA, CMS will impose an assessment on a qualified entity in accordance with the following:

(i) *Amount of assessment.* CMS will calculate the amount of the assessment of up to $100 per individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under Part B of such title whose data was implicated in the violation based on the following:

(A) *Basic factors.* In determining the amount per impacted individual, CMS takes into account the following:

(*1*) The nature and the extent of the violation.

(*2*) The nature and the extent of the harm or potential harm resulting from the violation.

(*3*) The degree of culpability and the history of prior violations.

(B) *Criteria to be considered.* In establishing the basic factors, CMS considers the following circumstances:

(*1*) *Aggravating circumstances.* Aggravating circumstances include the following:

(*i*) There were several types of violations occurring over a lengthy period of time.

(*ii*) There were many of these violations or the nature and circumstances indicate a pattern of violations.

(*iii*) The nature of the violation had the potential or actually resulted in harm to beneficiaries.

(*2*) *Mitigating circumstances.* Mitigating circumstances include the following:

(*i*) All of the violations subject to the imposition of an assessment were few in number, of the same type, and occurring within a short period of time.

(*ii*) The violation was the result of an unintentional and unrecognized error and the qualified entity took corrective steps immediately after discovering the error.

(C) *Effects of aggravating or mitigating circumstances.* In determining the amount of the assessment to be imposed under paragraph (d)(5)(i)(A) of this section:

(*1*) If there are substantial or several mitigating circumstance, the aggregate amount of the assessment is set at an amount sufficiently below the maximum permitted by paragraph (d)(5)(i)(A) of this section to reflect the mitigating circumstances.

(*2*) If there are substantial or several aggravating circumstances, the aggregate amount of the assessment is set at an amount at or sufficiently close to the maximum permitted by paragraph (d)(5)(i)(A) of this section to reflect the aggravating circumstances.

(D) The standards set for the qualified entity in this paragraph are binding, except to the extent that—

(*1*) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(*2*) Nothing in this section limits the authority of CMS to settle any issue or case as provided by part 1005 of this title or to compromise any assessment as provided by paragraph (d)(5)(ii)(E) of this section.

(ii) *Notice of determination.* CMS must propose an assessment in accordance with this paragraph (d)(5), by notifying the qualified entity by certified mail, return receipt requested. Such notice must include the following information:

(A) The assessment amount.

(B) The statutory and regulatory bases for the assessment.

(C) A description of the violations upon which the assessment was proposed.

(D) Any mitigating or aggravating circumstances that CMS considered when it calculated the amount of the proposed assessment.

(E) Information concerning response to the notice, including:

(*1*) A specific statement of the respondent's right to a hearing in accordance with procedures established at Section 1128A of the Act and implemented in 42 CFR part 1005.

(*2*) A statement that failure to respond within 60 days renders the proposed determination final and permits the imposition of the proposed assessment.

(*3*) A statement that the debt may be collected through an administrative offset.

(*4*) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(F) The means by which the qualified entity may pay the amount if they do not intend to request a hearing.

(iii) *Failure to request a hearing.* If the qualified entity does not request a hearing within 60 days of receipt of the notice of proposed determination, any assessment becomes final and CMS may impose the proposed assessment.

(A) CMS notifies the qualified entity, by certified mail with return receipt requested, of any assessment that has been imposed and of the means by which the qualified entity may satisfy the judgment.

(B) The qualified entity has no right to appeal an assessment for which the qualified entity has not requested a hearing.

(iv) *When an assessment is collectible.* An assessment becomes collectible after the earliest of the following:

(A) Sixty (60) days after the qualified entity receives CMS's notice of proposed determination under paragraph (d)(5)(ii) of this section, if the qualified entity has not requested a hearing.

(B) Immediately after the qualified entity abandons or waives its appeal right at any administrative level.

(C) Thirty (30) days after the qualified entity receives the ALJ's decision imposing an assessment under §1005.20(d) of this title, if the qualified entity has not requested a review before the DAB.

(D) Sixty (60) days after the qualified entity receives the DAB's decision imposing an assessment if the qualified entity has not requested a stay of the decision under §1005.22(b) of this title.

(v) *Collection of an assessment.* Once a determination by HHS has become final, CMS is responsible for the collection of any assessment.

(A) The General Counsel may compromise an assessment imposed under this part, after consulting with CMS or OIG, and the Federal government may recover the assessment in a civil action brought in the United States district court for the district where the claim was presented or where the qualified entity resides.

(B) The United States or a state agency may deduct the amount of an assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing the qualified entity.

(C) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect an assessment.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44481, July 7, 2016]

§401.721 Terminating an agreement with a qualified entity.

(a) *Grounds for terminating a qualified entity agreement.* CMS may terminate an agreement with a qualified entity if CMS determines the qualified entity or its contractor meets any of the following:

(1) Engages in one or more serious violations of the requirements of this subpart.

(2) Fails to completely and accurately report information to CMS or fails to make appropriate corrections in response to confidential reviews by providers and suppliers in a timely manner.

(3) Fails to submit an approvable corrective action plan (CAP) as prescribed by CMS, fails to implement an approved CAP, or fails to demonstrate improved performance after the implementation of a CAP.

(4) Improperly uses or discloses claims information received from CMS in violation of the requirements in this subpart.

(5) Based on its re-application, no longer meets the requirements in this subpart.

(6) Fails to maintain adequate data from other sources in accordance with §401.711(c).

(7) Fails to ensure authorized users comply with their QE DUAs or analysis use agreements.

(b) *Return or destruction of CMS data upon voluntary or involuntary termination from the qualified entity program:*

(1) If CMS terminates a qualified entity's agreement, the qualified entity

and its contractors must immediately upon receipt of notification of the termination commence returning or destroying any and all CMS data (and any derivative files). In no instance can this process exceed 30 days.

(2) If a qualified entity voluntarily terminates participation under this subpart, it and its contractors must return to CMS, or destroy, any and all CMS data in its possession within 30 days of notifying CMS of its intent to end its participation.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44482, July 7, 2016]

§ 401.722 Qualified clinical data registries.

(a) A qualified clinical data registry that agrees to meet all the requirements in this subpart, with the exception of § 401.707(d), may request access to Medicare data as a quasi qualified entity in accordance with such qualified entity program requirements.

(b) Notwithstanding § 401.703(q) (generally defining combined data), for purposes of qualified clinical data registries acting as quasi qualified entities under the qualified entity program requirements, combined data means, at a minimum, a set of CMS claims data provided under this subpart combined with clinical data or a subset of clinical data.

[81 FR 44482, July 7, 2016]

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

Subpart A—General Provisions

Sec.

Subpart B—Civil Money Penalties and Assessments

Subpart C—Exclusions

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 63 FR 68690, Dec. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis.* This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope.* This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties.* CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(35) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)

(1) Sections 1833(h)(5)(D) and 1842(j)(2)—Any person that knowingly and willfully, and on a repeated basis, bills for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also include an assessment and cause exclusion.)

(2) Section 1833(i)(6)—Any person that knowingly and willfully presents, or causes to be presented, a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.

(3) Section 1833(q)(2)(B)—Any entity that knowingly and willfully fails to provide information about a referring physician, including the physician's name and unique physician identification number for the referring physician, when seeking payment on an unassigned basis. (This violation, if it occurs in repeated cases, may also cause an exclusion.)

(4) Sections 1834(a)(11)(A) and 1842(j)(2)—Any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A). (This violation may also include an assessment and cause exclusion.)

(5) Sections 1834(a)(18)(B) and 1842(j)(2)—Any nonparticipating durable medical equipment supplier that knowingly and willfully, in violation of section 1834(a)(18)(A), fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also include an assessment and cause exclusion.)

(6) Sections 1834(b)(5)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services. (This violation may also include an assessment and cause exclusion.)

(7) Sections 1834(c)(4)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(4)(B), for mammography screening. (This violation may also include an assessment and cause exclusion.)

(8) Sections 1834(h)(3) and 1842(j)(2)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also include an assessment and cause exclusion.)

(9) Section 1834(j)(2)(A)(iii)—Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) or fails to provide the information required under section 1834(j)(2)(A)(ii).

(10) Sections 1834(j)(4) and 1842(j)(2)—

(i) Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15); or

(C) The service is determined not to be medically necessary or reasonable.

(ii) These violations may also include an assessment and cause exclusion.

(11) Sections 1842(b)(18)(B) and 1842(j)(2)—Any practitioner specified in section 1842(b)(18)(C) (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists) or other person that

knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(12) Sections 1842(k) and 1842(j)(2)—Any physician who knowingly and willfully presents, or causes to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15). (This violation may also include an assessment and cause exclusion.)

(13) Sections 1842(l)(3) and 1842(j)(2)—Any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A). (This violation may also include an assessment and cause exclusion.)

(14) Sections 1842(m)(3) and 1842(j)(2)—(i) Any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, who knowingly and willfully fails to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program.

(ii) This violation may also include an assessment and cause exclusion.

(15) Sections 1842(n)(3) and 1842(j)(2)—Any physician who knowingly and willfully, in repeated cases, bills one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B). (This violation may also include an assessment and cause exclusion.)

(16) Section 1842(p)(3)(A)—Any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill not submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

(17) Sections 1848(g)(1)(B) and 1842(j)(2)—

(i) Any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis, that—

(A) Knowingly and willfully bills or collects in excess of the limiting charge (as defined in section 1848(g)(2)) on a repeated basis; or

(B) Fails to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv).

(ii) These violations may also include an assessment and cause exclusion.

(18) Section 1848(g)(3)(B) and 1842(j)(2)—Any person that knowingly and willfully bills for State plan approved physicians' services, as defined in section 1848(j)(3), on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may also include an assessment and cause exclusion.)

(19) Section 1848(g)(4)(B)(ii), 1842(p)(3), and 1842(j)(2)(A)—

(i) Any physician, supplier, or other person (except any person that has been excluded from the Medicare program) that, for services furnished after September 1, 1990, knowingly and willfully—

(A) Fails to submit a claim on a standard claim form for services provided for which payment is made under Part B on a reasonable charge or fee schedule basis; or

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

(ii) These violations, if they occur in repeated cases, may also cause exclusion.

(20) Section 1862(b)(6)(B)—Any entity that knowingly, willfully, and repeatedly—

(i) Fails to complete a claim form relating to the availability of other

health benefit plans in accordance with section 1862(b)(6)(A); or

(ii) Provides inaccurate information relating to the availability of other health benefit plans on the claim form.

(21) Section 1862(b)(7)(B)—Except for the situation described in paragraphs (c)(21)(ii)(A) and (B) of this section, any entity that has a reporting obligation under section 1862(b)(7) of the Act (''reporting entity'') that—

(i) Fails to report any beneficiary record within 1 year of the last acceptable reporting date, defined as 365 days from the GHP coverage effective date or the Medicare beneficiary's entitlement date, whichever is later.

(ii) A civil money penalty (CMP) is not imposed if—

(A) The incident of noncompliance is associated with a specific reporting policy or procedural change on the part of CMS that has been effective for less than 6 months following the implementation of that policy or procedural change (or for 1 year, should CMS be unable to provide a minimum of 6 months' notice prior to implementing such changes).

(B) The entity complies with any reporting thresholds or any other reporting exclusions.

(22) Section 1862(b)(8)(E)—Except for the situations described in paragraph (c)(22)(ii)(A), (B) and (C) of this section, any applicable plan that has a reporting obligation under section 1862(b)(8) of the Act (''applicable plan''), that—

(i) Fails to report any beneficiary record within 1 year from the date of the settlement, judgment, award, or other payment, or the effective date where ongoing payment responsibility for medical care has been assumed by the entity.

(ii) A CMP is not imposed in the following situations:

(A) An NGHP applicable plan fails to report required information as a result of the applicable plan's inability to obtain an individual's last name, first name, date of birth, gender, Medicare Beneficiary Identifier (MBI), Social Security Number (SSN), or the last 5 digits of the SSN, and the applicable plan has made a good faith effort to obtain this information by meeting the following:

(*1*) Has communicated the need for this information to the individual and his or her attorney, or other representative, if applicable, or both.

(*2*) Has requested the information from the individual and his or her attorney, or other representative (if applicable), at least three times—

(*i*) Once in writing (including electronic mail);

(*ii*) Then at least once more by mail; and

(*iii*) At least once more by phone or other means of contact in the absence of a response to the mailings.

(*3*) Has not received a response or has received a written response clearly indicating that the individual refuses to provide the needed information. Should the applicable plan receive a written response from the individual or their attorney or representative that clearly and unambiguously declines or refuses to provide any portion of the information specified herein, no additional communications with the individual or their attorney or other representative are required.

(*4*) Has documented its efforts to obtain the MBI or SSN (or the last 5 digits of the SSN). This documentation, including any written rejection correspondence, must be retained for a minimum of 5 years.

(B) An NGHP applicable plan complies with any reporting thresholds or any other reporting exclusions.

(C) The incident of noncompliance is associated with a specific reporting policy or procedural change on the part of CMS that has been effective for less than 6 months following the implementation of that policy or procedural change (or for 12 months, should CMS be unable to provide a minimum of 6 months' notice prior to implementing such changes).

(23) Section 1877(g)(5)—Any person that fails to report information required by HHS under section 1877(f) concerning ownership, investment, and compensation arrangements. (This violation may also include an assessment and cause exclusion.)

(24) Sections 1879(h), 1834(a)(18), and 1842(j)(2)—

(i) Any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics,

or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15) of the Act; or

(C) The service is determined not to be payable under section 1834(a)(17)(b) because of unsolicited telephone contacts.

(ii) These violations may also include an assessment and cause exclusion.

(25) Section 1882(a)(2)—Any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C). (This violation may also include an assessment and cause exclusion.)

(26) Section 1882(p)(8)—Any person that sells or issues Medicare supplemental policies, on or after July 30, 1992, that fail to conform to the NAIC or Federal standards established under section 1882(p). (This violation may also include an assessment and cause exclusion.)

(27) Section 1882(p)(9)(C)—

(i) Any person that sells a Medicare supplemental policy and—

(A) Fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits; or

(B) Fails to provide the individual, before the sale of the policy, an outline of coverage describing the benefits provided by the policy.

(ii) These violations may also include an assessment and cause exclusion.

(28) Section 1882(q)(5)(C)—

(i) Any person that fails to—

(A) Suspend a Medicare supplemental policy at the policyholder's request, if the policyholder applies for and is determined eligible for medical assistance, and the policyholder provides notice within 90 days of the eligibility determination; or

(B) Automatically reinstate the policy as of the date of termination of medical assistance if the policyholder loses eligibility for medical assistance and the policyholder provides notice within 90 days of loss of eligibility.

(ii) These violations may also include an assessment and cause exclusion.

(29) Section 1882(r)(6)(A)—Any person that fails to provide refunds or credits as required by section 1882(r)(1)(B). (This violation may also include an assessment and cause exclusion.)

(30) Section 1882(s)(4)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Does not waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare supplemental policy; or

(B) Denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A).

(ii) These violations may also include an assessment and cause exclusion.

(31) Section 1882(t)(2)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Fails substantially to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(B) Imposes premiums on enrollees in excess of the premiums approved by the State;

(C) Acts to expel an enrollee for reasons other than nonpayment of premiums; or

(D) Does not provide each enrollee at the time of enrollment with the specific information provided in section 1882(t)(1)(E)(i) or fails to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)).

(ii) These violations may also include an assessment and cause exclusion.

(32) Sections 1834(k)(6) and 1842(j)(2)—Any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(33) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(34) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.

(35) Section 1128G (b) (1) and (2)—Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

(2) CMS or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If CMS or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(g) *Time limits.* Neither CMS nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 78 FR 9520, Feb. 8, 2013; 88 FR 70372, Oct. 11, 2023]

§ 402.3 Definitions.

For purposes of this part:

Assessment means the amount described in § 402.107 and includes the plural of that term.

Assignment-related basis means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

Claim means an application for payment for a service for which the Medicare or Medicaid program may pay.

Covered means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

Exclusion means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by that person are not paid for under either program.

General Counsel means the General Counsel of HHS or his or her designees.

Initiating agency means whichever agency (CMS or the OIG) initiates the interaction with the person.

Knowingly or *knowingly and willfully* means that a person, with respect to information—

(1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information; and

(4) No proof of specific intent is required.

Medicare supplemental policy means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other limitations on payment imposed under title XVIII of the Act and will provide additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

NAIC stands for the National Association of Insurance Commissioners.

Nonparticipating describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

Participating describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

Penalty means the amount described in § 402.105 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physicians' services means the following Medicare covered professional services:

(1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.

(2) Services and supplies furnished ''incident to'' a physician's professional services.

(3) Outpatient physical and occupational therapy services.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).

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

(6) Antigens prepared by a physician.

Radiologist service means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

Request for payment means an application submitted by a person to any person for payment for a service.

Respondent means the person upon which CMS or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

Service includes—

(1) Any item, device, medical supply, or service claimed to have been furnished to a patient and listed in an itemized claim for program payment; or

(2) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Timely basis means that the adjustment to a bill or a refund is considered ''on a timely basis'' if the physician, supplier, or other person makes the adjustment or refund to the appropriate party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

[63 FR 68690, Dec. 14, 1998, as amended at 72 FR 39752, July 20, 2007]

§ 402.5 Right to a hearing before the final determination.

CMS or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

§ 402.7 Notice of proposed determination.

(a) If CMS or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment, exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If CMS or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique CMS or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that CMS or OIG considered when it determined the amount of the proposed penalty and any applicable assessment.

(6) Information concerning response to the notice, including—

(i) A specific statement of the respondent's right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

(7) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

§ 402.9 Failure to request a hearing.

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and CMS or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) CMS or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, CMS or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate quality improvement organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, CMS or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

(b) A person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

CMS or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either CMS or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *$2,000.* Except as provided in paragraphs (b) through (h) of this section, CMS or OIG may impose a penalty of not more than $2,000 as adjusted annually under 45 CFR part 102 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *$1,000.* CMS or OIG may impose a penalty of not more than $1,000 as adjusted annually under 45 CFR part 102 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

(i) Contains information concerning the medical condition of the patient; or

(ii) Fails to include cost information.

(2) For entities with reporting obligations under section 1862(b)(7) of the Act (''reporting entity''), if a reporting entity fails to report any beneficiary record within the specified period from the latter of the GHP coverage effective date or the Medicare beneficiary's entitlement date. The penalty is—

(i) Calculated on a daily basis, based on the number of recently added beneficiary records reviewed where CMS identifies that the entity submitted the required information more than 1 year after the GHP coverage effective date for the individual; and

(ii) $1,000 as adjusted annually under 45 CFR part 102 for each calendar day starting the day after 1 year (365 days) from the first instance of noncompliance, as defined in paragraph (b)(2)(i) of this section.

(3) For entities with reporting obligations under section 1862(b)(8) of the Act (''applicable plan'') as follows:

(i) If an applicable plan fails to report any NGHP beneficiary record within the specified period from the date of the settlement, judgment, award, or other payment (including the effective date of the assumption of ongoing payment responsibility for medical care). The penalty is—

(A) Calculated on a daily basis, based on the number of recently added beneficiary records reviewed where CMS identifies that the entity submitted the required information more than 1 year after the date of settlement, judgment, award, or other payment (including the effective date of the assumption of ongoing payment responsibility for medical care);

(B) $250 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance as defined in paragraph (b)(3)(i)(A) of this section for each individual for which the required information should have been submitted, but was reported more than 1 year but less than 2 years after the required reporting date;

(C) $500 (as adjusted annually under 45 CFR part 102) for each calendar day of noncompliance as defined in paragraph (b)(3)(i)(A) of this section for each individual for which the required information should have been submitted, but was reported 2 years or more, but less than 3 years, after the required reporting date; and

(D) $1,000 (as adjusted annually under 45 CFR part 102), for each calendar day of noncompliance as defined in paragraph (b)(3)(i)(A) of this section for each individual for which the required information should have been submitted, but was reported 3 years or more after the required reporting date.

(ii) The maximum penalty that may be imposed for noncompliance associated with any one individual for which the required information should have been submitted is $365,000 (as adjusted annually under 45 CFR part 102).

(c) *$5,000.* CMS or OIG may impose a penalty of not more than $5,000 as adjusted annually under 45 CFR part 102 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *$10,000.* (1) CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(ix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§ 402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

(3) CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

(5) CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to failures to report in an annual submission of information will not exceed $150,000 as annually adjusted under 45 CFR part 102.

(e) *$15,000*. CMS or OIG may impose a penalty of not more than $15,000 as adjusted annually under 45 CFR part 102 for if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2) and (f)(3) of this section (§ 402.1 (c)(25) and (c)(26)).

(f) *$25,000*. CMS or OIG may impose a penalty of not more than $25,000 as adjusted annually under 45 CFR part 102 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§ 402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§ 402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§ 402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§ 402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§ 402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in section 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)) (section 1882(t)(2)).

(g) *$100*. CMS or OIG may impose a penalty of not more than $100 as adjusted annually under 45 CFR part 102 for each violation if the person or entity does not furnish an itemized statement to a Medicare beneficiary within 30 days of the beneficiary's request.

(h) *$100,000*. CMS or OIG may impose a penalty of not more than $10,000 as adjusted annually under 45 CFR part 102 for each knowing failure of an applicable manufacturer or an applicable

group purchasing organization to report timely, accurately or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000 as annually adjusted under 45 CFR part 102.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 72 FR 39752, July 20, 2007; 72 FR 46175, Aug. 17, 2007; 78 FR 9520, Feb. 8, 2013; 81 FR 61561, Sept. 6, 2016; 88 FR 70372, Oct. 11, 2023]

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).

(9) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(10) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(11) By any nonparticipating physician, who does not accept payment for

an elective surgical procedure on an assignment-related basis and whose charge is at least $500, knowingly and willfully failing to—

(i) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(ii) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(12) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(13) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(i) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(ii) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A) (iii) or (iv) (§ 402.1(c)(17)).

(14) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(i) The supplier did not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.109 Statistical sampling.

(a) *Purpose.* CMS or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once CMS or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. CMS or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

(1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.

(2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.

(3) The resources available to the person submitting the claim or request for payment or giving the information.

(4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the factors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than $1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of CMS or OIG to settle any issue or case as provided by § 402.19 or to compromise any penalty and assessment as provided by § 402.115.

§ 402.113 When a penalty and assessment are collectible.

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives CMS's or OIG's notice of proposed determination under § 402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under § 1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under § 1005.22(b) of this title.

(f) If the ALJ grants a stay under § 1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under § 1005.22(b) of this title.

§ 402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment imposed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Subpart C—Exclusions

SOURCE: 72 FR 39752, July 20, 2007, unless otherwise noted.

§ 402.200 Basis and purpose.

(a) *Basis*. This subpart is based on the sections of the Act that are specified in § 402.1(e).

(b) *Purpose*. This subpart—

(1) Provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions of the Act provided in § 402.1(e) (and further described in § 402.1(c)); and

(2) Sets forth the appeal rights of persons subject to exclusion and the procedures for reinstatement following exclusion.

§ 402.205 Length of exclusion.

The length of exclusion from participation in Medicare, Medicaid, and, where applicable, other Federal health care programs, is contingent upon the specific violation of the Medicare statute. A full description of the specific violations identified in the sections of the Act are cross-referenced in the regulatory sections listed in the table in paragraph (a) of this section.

(a) In no event will the period of exclusion exceed 5 years for violation of the following sections of the Act:

Social Security Act paragraph	Code of Federal Regulations section
1833(h)(5)(D) in repeated cases	§ 402.1(c)(1)
1833(q)(2)(B) in repeated cases	§ 402.1(c)(3)
1834(a)(11)(A)	§ 402.1(c)(4)
1834(a)(18)(B)	§ 402.1(c)(5)
1834(b)(5)(C)	§ 402.1(c)(6)
1834(c)(4)(C)	§ 402.1(c)(7)
1834(h)(3)	§ 402.1(c)(8)
1834(j)(4)	§ 402.1(c)(10)
1834(k)(6)	§ 402.1(c)(31)
1834(l)(6)	§ 402.1(c)(32)
1842(b)(18)(B)	§ 402.1(c)(11)
1842(k)	§ 402.1(c)(12)
1842(l)(3)	§ 402.1(c)(13)
1842(m)(3)	§ 402.1(c)(14)
1842(n)(3)	§ 402.1(c)(15)
1842(p)(3)(B) in repeated cases	§ 402.1(c)(16)
1848(g)(1)(B) in repeated cases	§ 402.1(c)(17)
1848(g)(3)(B)	§ 402.1(c)(18)
1848(g)(4)(B)(ii) in repeated cases	§ 402.1(c)(19)
1879(h)	§ 402.1(c)(23)

(b) For violation of the following sections, there is no maximum time limit for the period of exclusion.

Social Security Act paragraph	Code of Federal Regulations section
1834(a)(17)(c) for a pattern of contacts.	§ 402.1(e)(2)(i)
1834(h)(3) for a pattern of contacts	§ 402.1(e)(2)(ii)
1877(g)(5)	§ 402.1(c)(22)
1882(a)(2)	§ 402.1(c)(24)
1882(p)(8)	§ 402.1(c)(25)
1882(p)(9)(C)	§ 402.1(c)(26)
1882(q)(5)(C)	§ 402.1(c)(27)
1882(r)(6)(A)	§ 402.1(c)(28)
1882(s)(4)	§ 402.1(c)(29)
1882(t)(2)	§ 402.1(c)(30)

(c) For a person excluded under any of the grounds specified in paragraph (a) of this section, notwithstanding any

other requirements in this section, reinstatement occurs—

(1) At the expiration of the period of exclusion, if the exclusion was imposed for a period of 5 years; or

(2) At the expiration of 5 years from the effective date of the exclusion, if the exclusion was imposed for a period of less than 5 years and the initiating agency did not receive the appropriate written request for reinstatement as specified in § 402.300.

§ 402.208 Factors considered in determining whether to exclude, and the length of exclusion.

(a) *General factors.* In determining whether to exclude a person and the length of exclusion, the initiating agency considers the following:

(1) The nature of the claims and the circumstances under which they were presented.

(2) The degree of culpability, the history of prior offenses, and the financial condition of the person presenting the claims.

(3) The total number of acts in which the violation occurred.

(4) The dollar amount at issue (Medicare Trust Fund dollars or beneficiary out-of-pocket expenses).

(5) The prior history of the person insofar as its willingness or refusal to comply with requests to correct said violations.

(6) Any other facts bearing on the nature and seriousness of the person's misconduct.

(7) Any other matters that justice may require.

(b) *Criteria to be considered.* As a guideline for taking into account the general factors listed in paragraph (a) of this section, the initiating agency may consider any one or more of the circumstances listed in paragraphs (b)(1) and (b)(2) of this section, as applicable. The respondent, in his or her written response to the notice of intent to exclude (that is, the proposed exclusion), may provide information concerning potential mitigating circumstances.

(1) *Aggravating circumstances.* An aggravating circumstance may be any of the following:

(i) The services or incidents were of several types and occurred over an extended period of time.

(ii) There were numerous services or incidents, or the nature and circumstances indicate a pattern of claims or requests for payment or a pattern of incidents, or whether a specific segment of the population was targeted.

(iii) Whether the person was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for health care items or services at any time before the incident or whether the person presented any claim or made any request for payment that included an item or service subject to a determination under § 402.1.

(iv) There is proof that the person engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs and in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings at section 1128A(c)(1) of the Act does not apply to proof of other wrongful conducts as an aggravating circumstance.

(v) The wrongful conduct had an adverse impact on the financial integrity of the Medicare program or its beneficiaries.

(vi) The person was the subject of an adverse action by any other Federal, State, or local government agency or board, and the adverse action is based on the same set of circumstances that serves as a basis for the imposition of the exclusion.

(vii) The noncompliance resulted in a financial loss to the Medicare program of at least $5,000.

(viii) The number of instances for which full, accurate, and complete disclosure was not made as required, or provided as requested, and the significance of the undisclosed information.

(2) *Mitigating circumstances.* A mitigating circumstance may be any of the following:

(i) All incidents of noncompliance were few in nature and of the same type, occurred within a short period of time, and the total amount claimed or

requested for the items or services provided was less than $1,500.

(ii) The claim(s) or request(s) for payment for the item(s) or service(s) provided by the person were the result of an unintentional and unrecognized error in the person's process for presenting claims or requesting payment, and the person took corrective steps promptly after the error was discovered.

(iii) Previous cooperation with a law enforcement or regulatory entity resulted in convictions, exclusions, investigations, reports for weaknesses, or civil money penalties against other persons.

(iv) Alternative sources of the type of health care items or services furnished by the person are not available to the Medicare population in the person's immediate area.

(v) The person took corrective action promptly upon learning of the noncompliance from the person's employee or contractor, or by the Medicare contractor.

(vi) The person had a documented mental, emotional, or physical condition before or during the commission of the noncompliant act(s) and that condition reduces the person's culpability for the acts in question.

(vii) The completeness and timeliness of refunding to the Medicare Trust Fund or Medicare beneficiaries any inappropriate payments.

(viii) The degree of culpability of the person in failing to provide timely and complete refunds.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interest of justice, those circumstances require either a reduction or increase in the sanction to ensure achievement for the purposes of this subpart.

(4) *Initiating agency authority.* Nothing in this section limits the authority of the initiating agency to settle any issue or case as provided by § 402.17, or to compromise any penalty and assessment as provided by § 402.115.

§ 402.209 Scope and effect of exclusion.

(a) *Scope of exclusion.* Under this title, persons may be excluded from the Medicare, Medicaid, and, where applicable, any other Federal health care programs.

(b) *Effect of exclusion on a person(s).* (1) Unless and until an excluded person is reinstated into the Medicare program, no payment is made by Medicare, Medicaid, and, where applicable, any other Federal health care programs for any item or service furnished by the excluded person or at the direction or request of the excluded person when the person furnishing the item or service knew or had reason to know of the exclusion, on or after the effective date of the exclusion as specified in the notice of exclusion.

(2) An excluded person may not take assignment of a Medicare beneficiary's claim on or after the effective date of the exclusion.

(3) An excluded person that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act. In addition, submission of claims, or the causing of claims to be submitted for items or services furnished, ordered, or prescribed, by an excluded person may serve as the basis for denying reinstatement to the Medicare program.

(c) *Exceptions.* (1) If a Medicare beneficiary or other person (including a supplier) submits an otherwise payable claim for items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person after the effective date of the exclusion, CMS pays the first claim submitted by the beneficiary or other person and immediately notifies the claimant of the exclusion. CMS does not pay a beneficiary or other person (including a supplier) for items or services furnished by, or under, the medical direction of an excluded person more than 15 days after the date on the notice to the beneficiary or other person (including a supplier), or after the effective date of the exclusion, whichever is later.

(2) Notwithstanding the other provisions of this section, payment may be made for certain emergency items or services furnished by an excluded person, or under the medical direction or

on the request of an excluded person during the period of exclusion. To be payable, a claim for the emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services, specifying the nature of the emergency and the reason that the items or services were not furnished by a person eligible to furnish or order the items or services. No claim for emergency items or services is payable if those items or services were provided by an excluded person that, through employment, contractual, or under any other arrangement, routinely provides emergency health care items or services.

§ 402.210 Notices.

(a) *Notice of proposed determination to exclude.* When the initiating agency proposes to exclude a person from participation in a Federal health care program in accordance with this part, notice of the proposed determination to exclude must be given in writing, and delivered or sent by certified mail, return receipt requested. The written notice must include, at a minimum—

(1) Reference to the statutory basis for the exclusion.

(2) A description of the claims, requests for payment, or incidents for which the exclusion is proposed.

(3) The reason why those claims, requests for payments, or incidents subject the person to an exclusion.

(4) The length of the proposed exclusion.

(5) A description of the circumstances that were considered when determining the period of exclusion.

(6) Instructions for responding to the notice, including a specific statement of the person's right to submit documentary evidence and a written response concerning whether the exclusion is warranted, and any related issues such as potential mitigating circumstances. The notice must specify that—

(i) The person has the right to request an opportunity to meet with an official of the initiating agency to make an oral presentation; and

(ii) The request to make an oral presentation must be submitted within 30 days of the receipt of the notice of intent to exclude.

(7) If a person fails, within the time permitted under § 402.212, to exercise the right to respond to the notice of proposed determination to exclude, the initiating agency may initiate actions for the imposition of the exclusion.

(b) *Notice of exclusion.* Once the initiating agency determines that the exclusion is warranted, a written notice of exclusion is sent to the person in the same manner as described in paragraph (a) of this section. The exclusion is effective 20 days from the date of the notice. The written notice must include, at a minimum, the following:

(1) The basis for the exclusion.

(2) The length of the exclusion and, when applicable, the factors considered in setting the length.

(3) The effect of exclusion.

(4) The earliest date on which the initiating agency considers a request for reinstatement.

(5) The requirements and procedures for reinstatement.

(6) The appeal rights available to the excluded person under part 1005 of this title.

(c) *Amendment to the notice of exclusion.* No later than 15 days before the final exhibit exchanges required under § 1005.8 of this title, the initiating agency may amend the notice of exclusion if information becomes available that justifies the imposition of a period of exclusion other than the one proposed in the original written notice.

§ 402.212 Response to notice of proposed determination to exclude.

(a) A person that receives a notice of intent to exclude (that is, the proposed determination) as described in § 402.210, may present to the initiating agency a written response stating whether the proposed exclusion is warranted, and may present additional supportive documentation. The person must submit this response within 60 days of the receipt of notice. The initiating agency reviews the materials presented and initiates a response to the person regarding the argument presented, and any changes to the determination, if appropriate.

(b) The person is also afforded an opportunity to make an oral presentation to the initiating agency concerning

whether the proposed exclusion is warranted and any related matters. The person must submit this request within 30 days of the receipt of notice. Within 15 days of receipt of the person's request, the initiating agency initiates communication with the person to establish a mutually agreed upon time and place for the oral presentation and discussion.

§ 402.214 Appeal of exclusion.

(a) The procedures in part 1005 of this title apply to all appeals of exclusions. References to the Inspector General in that part apply to the initiating agency.

(b) A person excluded under this subpart may file a request for a hearing before an administrative law judge (ALJ) only on the issues of whether—

(1) The basis for the imposition of the exclusion exists; and

(2) The duration of the exclusion is unreasonable.

(c) When the initiating agency imposes an exclusion for a period of 1 year or less, paragraph (b)(2) of this section does not apply.

(d) The excluded person must file a request for a hearing within 60 days from the receipt of notice of exclusion. The effective date of an exclusion is not delayed beyond the date stated in the notice of exclusion simply because a request for a hearing is timely filed (see paragraph (g) of this section).

(e) A timely filed written request for a hearing must include—

(1) A statement as to the specific issues or findings of fact and conclusions of law in the notice of exclusion with which the person disagrees.

(2) Basis for the disagreement.

(3) The general basis for the defenses that the person intends to assert.

(4) Reasons why the proposed length of exclusion should be modified.

(5) Reasons, if applicable, why the health or safety of Medicare beneficiaries receiving items or services does not warrant the exclusion going into or remaining in effect before the completion of an ALJ proceeding in accordance with part 1005 of this title.

(f) If the excluded person does not file a written request for a hearing as provided in paragraph (d) of this section, the initiating agency notifies the excluded person, by certified mail, return receipt requested, that the exclusion goes into effect or continues in accordance with the notice of exclusion. The excluded person has no right to appeal the exclusion other than as described in this section.

(g) If the excluded person files a written request for a hearing, and asserts in the request that the health or safety of Medicare beneficiaries does not warrant the exclusion going into or remaining in effect before completion of an ALJ hearing, then the initiating agency may make a determination as to whether the exclusion goes into effect or continues pending the outcome of the ALJ hearing.

§ 402.300 Request for reinstatement.

(a) An excluded person may submit a written request for reinstatement to the initiating agency no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. The written request for reinstatement must include documentation demonstrating that the person has met the standards set forth in § 402.302. Obtaining or reactivating a Medicare provider number (or equivalent) does not constitute reinstatement.

(b) Upon receipt of a written request for reinstatement, the initiating agency may require the person to furnish additional, specific information, and authorization to obtain information from private health insurers, peer review organizations, and others as necessary to determine whether reinstatement is granted.

(c) Failure to submit a written request for reinstatement or to furnish the required information or authorization results in the continuation of the exclusion, unless the exclusion has been in effect for 5 years. In this case, reinstatement is automatic.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person may request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement includes the same standards as noted in paragraph (b) of this section.

§ 402.302 Basis for reinstatement.

(a) The initiating agency authorizes reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion did not recur and will not recur; and

(3) There is no additional basis under title XVIII of the Act that justifies the continuation of the exclusion.

(b) The initiating agency does not authorize reinstatement if it determines that submitting claims or causing claims to be submitted or payments to be made by the Medicare program for items or services furnished, ordered, or prescribed, may serve as a basis for denying reinstatement. This section applies regardless of whether the excluded person has obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

(c) In making a determination regarding reinstatement, the initiating agency considers the following:

(1) Conduct of the excluded person occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion;

(2) Conduct of the excluded person after the date of the exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or, where applicable, any Federal, State, or local health care program are paid in full, or satisfactory arrangements are made to fulfill these obligations;

(4) Whether the excluded person complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and

(5) Whether the excluded person has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by Medicare, Medicaid, and, where applicable, any other Federal health care program, for items or services furnished, ordered, or prescribed, and the conditions under which these actions occurred.

(d) Reinstatement is not effective until the initiating agency grants the request and provides notices under § 402.304. Reinstatement is effective as provided in the notice.

(e) A determination for a denial of reinstatement is not appealable or reviewable except as provided in § 402.306.

(f) An ALJ may not require reinstatement of an excluded person in accordance with this chapter.

§ 402.304 Approval of request for reinstatement.

(a) If the initiating agency grants a request for reinstatement, the initiating agency—

(1) Gives written notice to the excluded person specifying the date of reinstatement; and

(2) Notifies appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person is reinstated into the Medicare program.

(b) A determination by the initiating agency to reinstate an excluded person has no effect if Medicare, Medicaid, or, where applicable, any other Federal health care program has imposed a longer period of exclusion under its own authorities.

§ 402.306 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, the initiating agency provides written notice to the excluded person. Within 30 days of the date of this notice, the excluded person may submit to the initiating agency:

(1) Documentary evidence and a written argument challenging the reinstatement denial; or

(2) A written request to present written evidence or oral argument to an official of the initiating agency.

(b) If a written request as described in paragraph (a)(2) of this section is received timely by the initiating agency, the initiating agency, within 15 days of receipt of the excluded person's request, initiates communication with the excluded person to establish a time and place for the requested meeting.

(c) After evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described in paragraph (a) of this section, if no documentary evidence or written request is submitted), the initiating agency sends written notice to the excluded person either confirming the denial, or approving the reinstatement in the manner set forth in §402.304. If the initiating agency elects to uphold its denial decision, the written notice also indicates that a subsequent request for reinstatement will not be considered until at least 1 year after the date of the written denial notice.

(d) The decision to deny reinstatement is not subject to administrative review.

§402.308 Waivers of exclusions.

(a) *Basis.* Section 1128(c)(3)(B) of the Act specifies that in the case of an exclusion from participation in the Medicare program based upon section 1128(a)(1), (a)(3), or (a)(4) of the Act, the individual may request that CMS present, on his or her behalf, a request to the OIG for a waiver of the exclusion.

(b) *Definitions.* For purposes of this section:

Excluded person has the same meaning as a ''person'' as defined in §402.3 who meets for the purposes of this subpart, the definition of the term ''exclusion'' in §402.3.

Hardship for purposes of this section means something that negatively affects Medicare beneficiaries and results from the imposition of an exclusion because the excluded person is the sole community physician or sole source of essential specialized services in the Medicare community.

Sole community physician has the same meaning as that term is defined §1001.2 of this title.

Sole source of essential specialized services in the community has the same meaning as that term defined by the §1001.2 of this title.

(c) *General rule.* If CMS determines that a hardship as defined in paragraph (b)(2) of this section results from exclusion of an affected person from the Medicare program, CMS may consider and may make a request to the Inspector General for waiver of the Medicare exclusion.

(d) *Submission and content of a waiver of exclusion request.* An excluded person must submit a request for waiver of exclusion in writing to CMS that includes the following:

(1) A copy of the exclusion notice from the OIG.

(2) A statement requesting that CMS present a waiver of exclusion request to the OIG on his or her behalf.

(3) A statement that he or she is the sole community physician or sole source of essential specialized services in the community.

(4) Documentation to support the statement in paragraph (d)(3) of this section.

(e) *Processing of waiver of exclusion requests.* CMS processes a request for a waiver of exclusion as follows:

(1) Notifies the submitter that the waiver of exclusion request has been received.

(2) Reviews and validates all submitted documents.

(3) During its analysis, CMS may require additional, specific information, and authorization to obtain information from private health insurers, peer review organizations (including, but not limited to, Quality Improvement Organizations), and others as necessary to determine validity.

(4) Makes a determination regarding whether or not to submit the waiver of exclusion request to the OIG based on review and validation of the submitted documents.

(5) If CMS elects to submit the waiver of exclusion request to the OIG, CMS copies the excluded person on the request.

(6) If CMS denies the request, then CMS notifies the excluded person of the decision and specifies the reason(s) for the decision.

(f) *Administrative or judicial review.* A determination rendered under paragraph (e)(4) of this section is not subject to administrative or judicial review.

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]

Subpart B—Medicare Supplemental Policies

Subpart C—Recognition of State Reimbursement Control Systems

Subparts D—F [Reserved]

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

Subpart A [Reserved]

Subpart B—Medicare Supplemental Policies

SOURCE: 47 FR 32400, July 26, 1982, unless otherwise noted.

§ 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures CMS will use to implement the voluntary certification program.

GENERAL PROVISIONS

§ 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—

(1) A private entity offers to a Medicare beneficiary; and

(2) Is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare

program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

(1) *Policy form.* Policy form is the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy.* Policy is the contract—

(i) Issued under the policy form; and

(ii) Held by the policy holder.

(c) If the policy otherwise meets the definition in this section, a Medicare supplemental policy includes-

(1) An individual policy;

(2) A group policy;

(3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a standalone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug Plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

[70 FR 4525, Jan. 28, 2005]

§ 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

§ 403.210 NAIC model standards.

(a) *NAIC model standards* means the National Association of Insurance Commissioners (NAIC) ''Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act'' (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows—

(1) *Policy*, for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit ''policy'' to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

[47 FR 32400, July 26, 1982; 49 FR 44472, Nov. 7, 1984]

§ 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

STATE REGULATORY PROGRAMS

§ 403.220 Supplemental Health Insurance Panel.

(a) *Membership.* The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions.* (1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

§ 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) *Policy issued in that State* means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

§ 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that CMS has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which CMS notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following—

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to CMS for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

§ 403.232 Requirements and procedures for obtaining certification.

(a) To be certified by CMS, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

(i) Issued in that State; or

(ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to CMS for review—

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the CMS/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers'

guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) CMS will review policies that the insuring organization voluntarily submits, except that CMS will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, CMS will—

(1) Certify the policy; and

(2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If CMS certifies a policy, it will inform all State Commissioners and Superintendents of Insurance of that fact.

§ 403.239 Submittal of material to retain certification.

(a) CMS certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with CMS no later than the date specified in paragraph (b) or (c) of this section—

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with CMS no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which CMS—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to CMS, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with CMS no later then the last day of that rate calculation period.

§ 403.245 Loss of certification.

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) CMS determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for submittal of material specified in § 403.239.

(b) If a policy loses its certification, CMS will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the

policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

§ 403.248 Administrative review of CMS determinations.

(a) This section provides for administrative review if CMS determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If CMS makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That CMS has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the CMS determination; and

(ii) Submit additional information to CMS for review.

(4) That, if the insuring organization requests an administrative review, CMS will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the CMS determination will go into effect 30 days from the date of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until CMS makes a final determination.

(c) If the insuring organization requests an administrative review, CMS will conduct the review as follows—

(1) A CMS official, not involved in the initial CMS determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to CMS for review, as specified in § 403.232(b) or § 403.239(a); and

(ii) Any additional information, that the insuring organization submits to CMS.

(3) Within 15 days after the administrative review is completed, CMS will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of CMS's notice informing the insuring organization of the final decision.

VOLUNTARY CERTIFICATION PROGRAM: LOSS RATIO PROVISIONS

§ 403.250 Loss ratio calculations: General provisions.

(a) *Basic formula.* The expected loss ratio is calculated by determining the ratio of benefits to premiums.

(b) *Calculations.* The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

§ 403.251 Loss ratio date and time frame provisions.

(a) *Initial calculation date* means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to CMS for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to CMS.

(b) *Loss ratio calculation period* means the period beginning with the initial calculation date and ending with the last day of the period for which the insuring organization calculates the policy's scale of premiums.

(c) To calculate ''present values'', the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

§ 403.253 Calculation of benefits.

(a) *General provisions.* (1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of ''benefits'' by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period: and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of ''benefits'' in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ratio calculation period.

(b) *Calculation of total policy reserve*—(1) *Option for calculation.* The insuring organization must calculate ''total policy reserve'' according to the provisions of paragraph (b) (2) or (3) of this section.

(2) *Total policy reserve: Federal provisions.* (i) ''Total policy reserve'' means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) *Additional reserve* means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) *Net premium* means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) *Reserve for future contingent benefits* means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions.* ''Total policy reserve'' means the total policy reserve calculated according to appropriate State law or regulation.

§ 403.254 Calculation of premiums.

(a) *General provisions.* To calculate the amount of ''premiums'', calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions.* (1) *Earned premium* for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) *Written premiums in a period* means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) *Total premium reserve* means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) *Unearned premium reserve* means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) *Advance premium reserve* means premiums received by the insuring organization that are due after the valuation date.

(6) *Reserve for rate credits* means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

§ 403.256 Loss ratio supporting data.

(a) For purposes of requesting CMS certification under § 403.232, the insuring organization must submit the following loss ratio data to CMS for review—

(1) A statement of why the policy is to be considered, for purposes of the loss ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued CMS certification under § 403.239(a), the insuring organization must submit the following to CMS—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since CMS last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since CMS first certified the policy.

§ 403.258 Statement of actuarial opinion.

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), *statement of actuarial opinion* means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) *Qualified actuary* means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

Subpart C—Recognition of State Reimbursement Control Systems

SOURCE: 51 FR 15492, Apr. 24, 1986, unless otherwise noted.

§ 403.300 Basis and purpose.

(a) *Basis.* This subpart implements section 1886(c) of the Act, which authorizes payment for Medicare inpatient hospital services in accordance with a State's reimbursement control system rather than under the Medicare reimbursement principles as described in CMS's regulations and instructions.

(b) *Purpose.* Contained in this subpart are—

(1) The basic requirements that a State reimbursement control system must meet in order to be approved by CMS;

(2) A description of CMS's review and evaluation procedures; and

(3) The conditions that apply if the system is approved.

§ 403.302 Definitions.

For purposes of this subpart—

Chief executive officer of a State means the Governor of the State or the Governor's designee.

Existing demonstration project refers to demonstration projects approved by CMS under the authority of section 402(a) 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)) and in effect on April 20, 1983 (the date of the enactment of Pub. L. 98–21 (Social Security Amendments of 1983)).

Federal hospital means a hospital that is administered by, or that is under exclusive contract with, the Department of Defense, the Veterans Administration, or the Indian Health Service.

State system or *system* refers to a State reimbursement control system that is approved by CMS under the authority of section 1886(c) of the Act and that satisfies the requirements described in this subpart.

§ 403.304 Minimum requirements for State systems—discretionary approval.

(a) *Discretionary approval by CMS.* CMS may approve Medicare payments under a State system, if CMS determines that the system meets the requirements in paragraphs (b) and (c) of this section and, if applicable paragraph (d) of this section.

(b) *Requirements for State system.* (1) An application for approval of the system must be submitted to CMS by the Chief Executive Officer of the State.

(2) The State system must apply to substantially all non-Federal acute care hospitals in the State.

(3) All hospitals covered by the system must have and maintain a utilization and quality control review agreement with a Quality Improvement Organization, as required under section 1866(a)(1)(F) of the Act and § 466.78(a) of this chapter.

(4) Federal hospitals must be excluded from the State system.

(5) Nonacute care or specialty hospital (such as rehabilitation, psychiatric, or children's hospitals) may, at the option of the State, be excluded from the State system.

(6) The State system must apply to at least 75 percent of all revenues or expenses—

(i) For inpatient hospital services in the State; and

(ii) For inpatient hospital services under the State's Medicaid plan.

(7) Under the system, HMOs and competitive medical plans (CMPs), as defined by section 1876(b) of the Act and part 417 of this chapter, must be allowed to negotiate payment rates with hospitals.

(8) The system must limit hospital charges for Medicare beneficiaries to deductibles, coinsurance or non-covered services.

(9) Unless a waiver is granted by CMS under § 489.23 of this chapter, the system must prohibit payment, as required under section 1862(a)(14) of the Act and § 405.310(m) of this chapter, for nonphysician services provided to hospital inpatients under Part B of Medicare.

(10) The system must require hospitals to submit Medicare cost reports or approved reports in lieu of Medicare cost reports as required.

(11) The system must require—

(i) Preparation, collection, or retention by the State of reports (such as financial, administrative, or statistical reports) that may be necessary, as determined by CMS, to review and monitor the State's assurances; and

(ii) Submission of the reports to CMS upon request.

(12) The system must provide hospitals an opportunity to appeal errors that they believe have been made in the determination of their payment rates. The system, if it is prospective may not permit providers to file administrative appeals that would result in a retroactive revision of prospectively determined payment rates.

(c) *Satisfactory assurances.* The State must provide to CMS satisfactory assurance as to the following:

(1) The system provides for equitable treatment of hospital patients and hospital employees.

(2) The system provides for equitable treatment of all entities that pay hospitals for inpatient hospital services, including Federal and State programs. Under the requirement, the following conditions must be met:

(i) Both the Medicare and Medicaid programs must participate under the system.

(ii) The State must assure equitable and uniform treatment under the system of third-party payors of inpatient hospital services in terms of opportunity. Equitable opportunity must include, but need not be limited to, participation in the system and availability of discounts. Criteria under which discounts are made available must be equitably and uniformly applied to all payors, except for discounts negotiated by HMOs and CMPs. Discounts available to HMOs and CMPs as result of their statutory right to negotiate payment rates independently of a State system, as described in paragraph (b)(7) of this section, need not be available to other payors.

(iii) The State must assure that all third-party payors that participate under the system share in the system's risks and benefits.

(3) The amount of Medicare payments made under the system over 36-month periods may not exceed the amount of Medicare payment that would otherwise have been made under the Medicare principles of reimbursement for Medicare items and services had the State system not been in effect. States must submit the assurance and supporting data as required by § 403.320 to document that the payment limit is not exceeded. States that have an existing Medicare demonstration project in effect on April 20, 1983, and that have requested approval of a State system under section 1886(c)(4) of the Act, may elect to have the effectiveness of the State system under this paragraph judged on the basis of the State system's rate of increase or inflation in Medicare inpatient hospital payments as compared to the national rate of increase or inflation for such payments during the three cost reporting periods of the hospitals in the State beginning on or after October 1, 1983.

(d) *Additional cost-effectiveness assurance.* If the assurances and supporting data required under paragraph (c)(3) of this section are insufficient to provide assurance satisfactory to CMS regarding the cost-effectiveness of a State system, the State may additionally submit one of the following assurances in order to meet the cost-effectiveness test:

(1) *State responsibility for excess payments.* The State must agree that each month Medicare intermediaries will disburse to the State's hospital Federal funds that in the aggregate equal no more than would have been disbursed in the absence of the State system. Any additional funds necessary to pay hospitals for Medicare services required by the State system will be paid to the intermediaries by the State. These additional amounts will be refunded to the State by the intermediaries to the extent that, in subsequent months, the State system requires a smaller aggregate payment for Medicare services than would have been paid in the absence of the State system.

(2) *Limitations on payments.* (i) The State must agree that if its projections exceed what Medicare would pay in any particular period, the State and CMS will establish and agreed upon payment schedule that will limit payments under the State system based on a predetermined percentage relationship between projected State payments and what payments would have been under Medicare.

(ii) If deviation from the predetermined relationship described in paragraph (d)(2)(i) of this section occurs, the State must further agree that—

(A) Medicare payments would be capped automatically at payment levels based on the rates used for the Medicare prospective payment system and the State would be required to pay the difference to individual hospitals in its system; or

(B) The State may provide by legislation or legally binding regulations that any reduced payments to hospitals under the system that result from this cost-effectiveness assurance will constitute full and final payment for hospital services furnished to Medicare beneficiaries for the period covered by these reduced payments.

§ 403.306 Additional requirements for State systems—mandatory approval.

(a) *General policy*—(1) *Mandatory approval.* HFCA will approve an application for Medicare reimbursement under

a State system if the system meets all of the requirements of § 403.304 and of paragraph (b) of this section.

(2) *Exception.* CMS may approve an application if the State system meets all of the requirements of § 403.304 but only some of the requirements of paragraph (b) of this section.

(b) *Additional requirements*—(1) *Operation of system.* The system must—

(i) Be operated directly by the State or by entity designated under State law;

(ii) Provide for payments to hospitals using a methodology under which—

(A) Prospectively determined payment rates are established; and

(B) Exceptions, adjustments, and methods for changes in methodology are set forth;

(iii) Provide that a change by the State in the system that has the effect of materially changing payments to hospitals can take effect only upon 60 days notice to CMS and to the hospitals likely to be materially affected by the change and upon CMS's approval of the change.

(2) *Satisfactory assurances*—(i) *Admissions practice.* The State must assure that the operation of the system will not result in any change in hospital admission practices that result in—

(A) A significant reduction in the proportion of patients receiving hospital services covered under the system who have no third-party coverage and who are unable to pay for hospital services;

(B) A significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is less, or is likely to be less, than the anticipated charges for or cost of the services;

(C) A refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital; or

(D) A refusal to provide emergency services to any person who is in need of emergency services, if the hospital provides the services.

(ii) *Consultation with local government officials.* The State must provide documentation that it has consulted with local government officials concerning the impact of the system on publicly owned or operated hospitals.

§ 403.308 State systems under demonstration projects—mandatory approval.

CMS will approve an application from a State for a State system if—

(a) The system was in effect prior to April 20, 1983 under an existing demonstration project; and

(b) The minimum requirements and assurances for approval of a State system are met under § 403.304 (b)(1)–(10) and § 403.304(c), and, if appropriate § 403.304(d).

§ 403.310 Reduction in payments.

(a) *General rule.* If CMS determines that the satisfactory assurances required of a State under § 403.304(c) and, if applicable, § 403.304(d) have not been met, or will not be met, with respect to any 36-month period, CMS will reduce Medicare payments to individual hospitals being reimbursed under the State's system or, if applicable, under the Medicare payment system, in an amount equal to the amount by which the Medicare payments under the system exceed the amount of Medicare payments to such hospitals that otherwise would have been made not using the State system. The amount of the recoupment will include, when appropriate, interest charges computed in accordance with § 405.378 of this chapter.

(b) *Recoupment procedures.* The amount of the overpayment will be recouped on a proportionate basis from each of those hospitals that received payments under the State system that exceeded the payments they would have received under the Medicare payment system. Each hospital's share of the aggregate excess payment will be determined on the basis of a comparison of the hospital's proportionate share of the aggregate payment received under the State system that is in excess of what the aggregate payment would have been under the Medicare payment system. Recoupments may be accomplished by a hospital's direct payment to the Medicare program or by offsets to future payments made to the hospital.

(c) *Alternative recoupment procedures.* As an alternative to the recoupment procedures described in paragraph (b) of this section and subject to CMS's acceptance, the State may provide, by legislation or legally binding regulations, procedures for the recoupment of the amount of payments that exceed the amount of payments that otherwise would have been paid by Medicare if the State system had not been in effect.

(d) *Rule for existing Medicare demonstration projects.* In cases of existing Medicare demonstration projects where the expenditure test is to be applied by a rate of increase factor, the amount of the excess payment will be determined, for the three hospital cost reporting periods beginning before October 1, 1986, by a comparison of the State system's rate of increase to the national rate of increase. Recoupment of excessive payments will be assessed and recouped as described in this section.

[51 FR 15492, Apr. 24, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 403.312 Submittal of application.

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to CMS for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

§ 403.314 Evaluation of State systems.

CMS will evaluate all State applications for approval of State systems and notify the State of its determination within 60 days.

§ 403.316 Reconsideration of certain denied applications.

(a) *Request for reconsideration.* If CMS denies an application for a State system, the State may request that CMS reconsider the denial if the State believes that its system meets all of the requirements for mandatory approval under §§ 403.304 and 403.306 or, in the case of a State with a system operating under an existing demonstration project, the applicable requirements of §§ 403.304 and 403.308.

(b) *Time limit.* (1) The State must submit its request for reconsideration within 60 days after the date of CMS's notice that the application was denied.

(2) CMS will notify the State of the results of its reconsideration within 60 days after it receives the request for reconsideration.

§ 403.318 Approval of State systems.

(a) *Approval agreement.* If CMS approves a State system, a written agreement will be executed between CMS and the Chief Executive Officer of the State. The agreement must incorporate any terms of the State's application for approval of the system as agreed to by the parties and, as a minimum, must contain provisions that require the following:

(1) The system is operated directly by the State or an entity designated by State law.

(2) For purposes of the Medicare program, the State's system applies only to Medicare payments for inpatient, and if applicable, outpatient hospital services.

(3) The system conforms to applicable Medicare law and regulations other than those relating to the amount of reimbursement for inpatient hospital services, or for inpatient and outpatient services, whichever the State system covers. Applicable regulations include, for example, those describing Medicare benefits and entitlement requirements for program beneficiaries, as explained in parts 406 and 409 of this chapter; the requirements at part 405, subpart J of this chapter specifying conditions of participation for hospitals; the requirements at part 405, subparts A, G, and S of this chapter on Medicare program administration; and all applicable fraud and abuse regulations contained in titles 42 and 45 of the CFR.

(4) The State must obtain CMS's approval of the State's reporting forms and of provider cost reporting forms or other forms that have not been approved by CMS but that are necessary for the collection of required information.

(b) *Effective date.* An approved State system may not be effective earlier than the date of the approval agreement, which may not be retroactive.

§ 403.320 CMS review and monitoring of State systems.

(a) *General rule.* The State must submit an assurance and detailed and quantitative studies of provider cost and financial data and projections to support the effectiveness of its system, as required by paragraphs (b) and (c) of this section.

(b) *Required information.* (1) Under § 403.304(c)(3) an assurance is required that the system will not result in greater payments over a 36-month period than would have otherwise been made under Medicare not using such system. If a State that has an existing demonstration project in effect on April 20, 1983 elects under § 403.304(c)(3) to have the effectiveness of its system judged on the basis of a rate of increase factor, the State must submit an assurance that its rate of increase or inflation in inpatient hospital payments does not exceed, for that portion of the 36-month period that is subject to this test, the national rate of increase or inflation in Medicare inpatient hospital payments. The election of the rate of increase test applies only to the three cost reporting periods beginning on or after October 1, 1983. At the end of these cost reporting periods, the State must assure, beginning with the first month after the expiration of the third cost reporting period beginning after October 1, 1983, that payments under its system will not exceed over the remainder of the 36-month period what Medicare payments would have been.

(2) Estimates and data are required to support the State's assurance, required under § 403.304(c)(3), that expenditures under the State system will not exceed what Medicare would have paid over a 36-month period. The estimates and projections of what Medicare would have otherwise paid must take into account all the Medicare reimbursement principles in effect at the time and, for any period in which payments either exceed or are less than Medicare levels, the values of interest the Medicare Trust Fund earned, or would have earned, on these amounts. Upon application for approval, the State must submit projections for each hospital for the first 12-month period covered by the assurance, in both the aggregate and on a per discharge basis, of Medicare inpatient expenditures under Medicare principles of reimbursement and parallel projections of Medicare inpatient expenditures under the State's system and the resulting cost or savings to Medicare. The State must also submit separate statewide projections for each year of the 36-month period, in both the aggregate and on a weighted average discharge basis, of inpatient expenditures under the State system and under the Medicare principles of reimbursement.

(3) The projection submitted under paragraph (b)(2) of this section must include a detailed description of the methodology and assumptions used to derive the expenditure amounts under both systems. In instances where the assumptions are different under the projections cited in paragraph (b)(2) of this section, the State must provide a detailed explanation of the reasons for the differences. At a minimum, the following separate data and assumptions are to be included in the projections for the Medicare principles and for the State's system.

(i) The State system base year and the Medicare allowable and reimbursable cost of each hospital that the State used to develop the projections, including the amount of estimated pass through costs.

(ii) The categories of costs that are included in the State system and are reimbursed differently under the State system than under the Medicare system.

(iii) The number of Medicare and total base year discharges and admissions for each hospital.

(iv) The rate of change factor (and the method of application of this factor) used to project the base year costs over the 36-month period to which the assurance would apply.

(v) Any allowance for anticipated growth in the amount of services from the base year (if applicable, the allowance must be presented in separate estimates for population increases or for increases in rates of admissions or both).

(vi) Any adjustment in which the State is permitted by CMS to take into account previous reductions in the Medicare payment amounts that were

the result of the effectiveness of the State's system even though Medicare was not a part of that system.

(vii) Appropriate recognition and projection of the time value of trust fund expenditures for the period the State system expenditures were either less than or exceeded the Medicare system payments.

(viii) States applying under a rate of increase effectiveness test under § 403.304(c)(3) must also submit data projecting the parallel rates of increase during the requisite period.

(4) The projections must include both the aggregate payments and the payments per discharge for the individual hospitals and for the State as a whole.

(5) On a case-by-case basis. CMS may require additional data and documentation as needed to complete its review and monitoring.

(6) For existing Medicare demonstration projects in effect on April 20, 1983, the assurance and data as required by paragraphs (a) and (b) of this section, if appropriate, may be based on aggregate payments or payments per inpatient admission or discharge. CMS will judge the effectiveness of these systems on the basis of the rate of increase or inflation in Medicare inpatient hospital payments compared to the national rate of increase or inflation for such payments during the State's hospitals' three cost reporting periods beginning on or after October 1, 1983. The data submitted by the State for the period subject to the rate of increase test must include the rate of increase projection for that particular period of time. For the subsequent period of time, the State must assure that payments under its system will not exceed what Medicare payments would have been, as described in § 403.304(c)(3).

(7) If the amount of Medicare payments under the State system exceeds what would have been paid under the Medicare reimbursement principles in any given year, the State must also submit quantitative evidence that the system will result in expenditures that do not exceed what Medicare expenditures would have been over the 36 month period beginning with the first month that the State system is operating. For a State that has an existing demonstration project in effect on April 20, 1983, and that elects under § 403.304(c)(3) to have a rate of increase test apply, if the State's rate of increase or inflation exceeds the national rate of increase or inflation in a given year, the State must submit quantitative evidence that, over 36 months, its payments will not exceed the national rate of increase or inflation. Furthermore, if payments under the State's system must be compared to actual Medicare expenditures, at the end of the third cost reporting period, as described in paragraph (b)(1) of this section, and payments under the State's system exceed what Medicare would have paid in a given year, the State must submit quantitative evidence that, over 36 months, payments under its system will not exceed what Medicare would have paid.

(c) *Review of assurances regarding expenditures.* CMS will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. CMS will compare the State's projections of payment amounts to CMS data in order to determine if the State's assurance is reasonable and fully supportable. If the CMS data indicate that the State's system would result in payment amounts that would be more then that which would have been paid under the Medicare principles, the State's assurances would not be acceptable. For States applying in accordance with § 403.308, if CMS data indicate that the State's system would result in a rate of increase or inflation that would be more than the national rate of increase or inflation, the State's assurances would not be acceptable.

(d) *Medicaid upper limit.* In accordance with § 447.253 of this chapter, the State system may not result in aggregate payments for Medicaid inpatient hospital services that would exceed the amount that would have otherwise have been paid under the Medicare principles as applied through the State system.

(e) *Monitoring of Medicare expenditures.* CMS will monitor on a quarterly basis expenditures under the State's system as compared to what Medicare expenditures would have been if the system had not been in effect. If CMS

determines at any time that the payments made under the State's system exceed the States' projections, as established by the satisfactory assurances required under § 403.304(c) and, if appropriate, the predetermined percentage relationship of the payments as required under § 403.304(d). CMS will—

(1) Conclude that payments under the State system over a 36-month period will exceed what Medicare would have paid:

(2) Terminate the waiver; and

(3) Recoup overpayments to the affected hospitals in accordance with the procedures described in § 403.310.

§ 403.321 State systems for hospital outpatient services.

CMS may approve a State's application for approval of an outpatient system if the following conditions are met:

(a) The State's inpatient system is approved.

(b) The State's outpatient application meets the requirements and assurances for an inpatient system described in §§ 403.304 (b) and (c), and 403.306 (b)(1) and (b)(2)(ii).

(c) The State submits a separate application that provides separate assurances and estimates and data in further support of its assurance submitted under paragraph (b)(1) of § 403.320, as follows:

(1) Upon application for approval, the State must submit estimates and data that include, but are not limited to, projections for the first 12-month period covered by the assurance for each hospital, in both the aggregate and on an average cost per service and payment basis, of Medicare outpatient expenditures under Medicare principles of reimbursement; parallel projections of Medicare outpatient expenditures under the State system; and the resulting cost or savings to Medicare independent of the State system for hospital inpatient services.

(2) The State must submit separate statewide projections for each year of the 36-month period of the aggregate outpatient expenditures for each system. The projections submitted under this paragraph must—

(i) Comply with the requirements of paragraphs (b) (3) and (5) of § 403.320 regarding a detailed description of the methodology used to derive the expenditure amounts:

(ii) Include the data and assumptions set forth in paragraphs (b)(3) (i), (ii), (iii), (iv), and (v) of § 403.320; and

(iii) Include any assumption the State has adopted for establishing the number of Medicare and total base year outpatient services for each hospital.

(3) The State must provide a detailed explanation of the reasons for any difference between the data or assumptions used for the separate projections.

§ 403.322 Termination of agreements for Medicare recognition of State systems.

(a) *Termination of agreements.* (1) CMS may terminate any approved agreement if it finds, after the procedures described in this paragraph are followed that the State system does not satisfactorily meet the requirements of section 1886(c) of the Act or the regulations in this subpart. A termination must be effective on the last day of a calendar quarter.

(2) CMS will give the State reasonable notice of the proposed termination of an agreement and of the reasons for the termination at least 90 days before the effective date of the termination.

(3) CMS will give the State the opportunity to present evidence to refute the finding.

(4) CMS will issue a final notice of termination upon a final review and determination on the State's evidence.

(b) *Termination by State.* A State may voluntarily terminate a State system by giving CMS notice of its intent to terminate. A termination must be effective on the last day of a calendar quarter. The State must notify CMS of its intent to terminate at least 90 days before the effective date of the termination.

Subparts D—F [Reserved]

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

SOURCE: 64 FR 67047, Nov. 30, 1999, unless otherwise noted.

§ 403.700 Basis and purpose.

This subpart implements sections 1821; 1861(e), (y), and (ss); 1869; and 1878 of the Act regarding Medicare payment for inpatient hospital or posthospital extended care services furnished to eligible beneficiaries in religious nonmedical health care institutions.

§ 403.702 Definitions and terms.

For purposes of this subpart, the following definitions and terms apply:

Election means a written statement signed by the beneficiary or the beneficiary's legal representative indicating the beneficiary's choice to receive nonmedical care or treatment for religious reasons.

Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local laws.

FFY stands for Federal fiscal year.

Medical care or treatment means health care furnished by or under the direction of a licensed physician that can involve diagnosing, treating, or preventing disease and other damage to the mind and body. It may involve the use of pharmaceuticals, diet, exercise, surgical intervention, and technical procedures.

Nonexcepted medical care means medical care (other than excepted medical care) that is sought by or for a beneficiary who has elected religious nonmedical health care institution services.

Religious nonmedical care or religious method of healing means health care furnished under established religious tenets that prohibit conventional or unconventional medical care for the treatment of a beneficiary, and the sole reliance on these religious tenets to fulfill a beneficiary's total health care needs.

RNHCI stands for ''religious nonmedical health care institution,'' as defined in section 1861(ss)(1) of the Act.

Religious nonmedical nursing personnel means individuals who are grounded in the religious beliefs of the RNHCI, trained and experienced in the principles of nonmedical care, and formally recognized as competent in the administration of care within their religious nonmedical health care group.

§ 403.720 Conditions for coverage.

Medicare covers services furnished in an RNHCI if the following conditions are met:

(a) The provider meets the definition of an RNHCI as defined in section 1861(ss)(1) of the Act. That is, it is an institution that:

(1) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a).

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of religious beliefs, through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in, a provider of medical treatment or services. (Permissible affiliations are described at § 403.738(c).)

(8) Has in effect a utilization review plan that sets forth the following:

(i) Provides for review of the admissions to the institution, the duration of stays, and the need for continuous extended duration of stays in the institution, and the items and services furnished by the institution.

(ii) Requires that reviews be made by an appropriate committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the review committee.

(iv) Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan.

(9) Provides information CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions.

(10) Meets other requirements CMS finds necessary in the interest of the health and safety of the patients who receive services in the institution. These requirements are the conditions of participation in this subpart.

(b) The provider meets the conditions of participation cited in §§ 403.730 through 403.746. (A provider may be deemed to meet conditions of participation in accordance with part 488 of this chapter.)

(c) The provider has a valid provider agreement as a hospital with CMS in accordance with part 489 of this chapter and for payment purposes is classified as an extended care hospital.

(d) The beneficiary has a condition that would make him or her eligible to receive services covered under Medicare Part A as an inpatient in a hospital or SNF.

(e) The beneficiary has a valid election as described in § 403.724 in effect for Medicare covered services furnished in an RNHCI.

§ 403.724 Valid election requirements.

(a) *General requirements.* An election statement must be made by the Medicare beneficiary or his or her legal representative.

(1) The election must be a written statement that must include the following statements:

(i) The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment.

(ii) The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs.

(iii) The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.

(iv) The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS.

(v) The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs.

(2) The election must be signed and dated by the beneficiary or his or her legal representative.

(3) The election must be notarized.

(4) The RNHCI must keep a copy of the election statement on file and submit the original to CMS with any information obtained regarding prior elections or revocations.

(5) The election becomes effective on the date it is signed.

(6) The election remains in effect until revoked.

(b) *Revocation of election.* (1) A beneficiary's election is revoked by one of the following:

(i) The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested.

(ii) The beneficiary voluntarily revokes the election and notifies CMS in writing.

(2) The receipt of excepted medical treatment as defined in § 403.702 does not revoke the election made by a beneficiary.

(c) *Limitation on subsequent elections.* (1) If a beneficiary's election has been made and revoked twice, the following limitations on subsequent elections apply:

(i) The third election is not effective until 1 year after the date of the most recent revocation.

(ii) Any succeeding elections are not effective until 5 years after the date of the most recent revocation.

(2) CMS will not accept as the basis for payment of any claim any elections executed on or after January 1 of the calendar year in which the sunset provision described in § 403.756 becomes effective.

§ 403.730 Condition of participation: Patient rights.

An RNHCI must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* The RNHCI must do the following:

(1) Inform each patient of his or her rights in advance of furnishing patient care.

(2) Have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources.

(b) *Standard: Exercise of rights.* The patient has the right to:

(1) Be informed of his or her rights and to participate in the development and implementation of his or her plan of care.

(2) Make decisions regarding his or her care, including transfer and discharge from the RNHCI. (See § 403.736 for discharge and transfer requirements.)

(3) Formulate advance directives and expect staff who furnish care in the RNHCI to comply with those directives, in accordance with part 489, subpart I of this chapter. For purposes of conforming with the requirement in § 489.102 that there be documentation in the patient's medical records concerning advanced directives, the patient care records of a beneficiary in an RNHCI are equivalent to medical records held by other providers.

(c) *Standard: Privacy and safety.* The patient has the right to the following:

(1) Personal privacy.

(2) Care in a safe setting.

(3) Freedom from verbal, psychological, and physical abuse, and misappropriation of property.

(4) Freedom from the use of restraints.

(5) Freedom from involuntary seclusion.

(d) *Standard: Confidentiality of patient records.* For any patient care records or election information it maintains on patients, the RNHCI must establish procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular patient. Information from, or copies of, records may be released only to authorized individuals, and the RNHCI must ensure that unauthorized individuals cannot gain access to or alter patient records. Original patient care records must be released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain the records and information in an accurate and timely manner.

(3) Ensure timely access by patients to the records and other information that pertains to that patient.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for patient care records and election information.

§ 403.732 Condition of participation: Quality assessment and performance improvement.

The RNHCI must develop, implement, and maintain a quality assessment and performance improvement program.

(a) *Standard: Program scope.* (1) The quality assessment and performance improvement program must include, but is not limited to, measures to evaluate:

(i) Access to care.

(ii) Patient satisfaction.

(iii) Staff performance.

(iv) Complaints and grievances.

(v) Discharge planning activities.

(vi) Safety issues, including physical environment.

(2) In each of the areas listed in paragraph (a)(1) of this section, and any other areas the RNHCI includes, the RNHCI must do the following:

(i) Define quality assessment and performance improvement measures.

(ii) Describe and outline quality assessment and performance improvement activities appropriate for the services furnished by or in the RNHCI.

(iii) Measure, analyze, and track performance that reflect care and RNHCI processes.

(iv) Inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program.

(3) The RNHCI must set priorities for performance improvement, considering the prevalence of and severity of identified problems.

(4) The RNHCI must act to make performance improvements and must track performance to assure that improvements are sustained.

(b) *Standard: Program responsibilities.* (1) The governing body, administration, and staff are responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities in the RNHCI and are responsible for the development, implementation, maintenance, and performance improvement of assessment actions.

(2) The RNHCI must include all programs, departments, functions, and contracted services when developing, implementing, maintaining, and evaluating the program of quality assessment and performance improvement.

§ 403.734 Condition of participation: Food services.

The RNHCI must have an organized food service that is directed and adequately staffed by qualified personnel.

(a) *Standard: Sanitary conditions.* The RNHCI must furnish food to the patient that is obtained, stored, prepared, distributed, and served under sanitary conditions.

(b) *Standard: Meals.* The RNHCI must serve meals that furnish each patient with adequate nourishment in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The RNHCI must do the following:

(1) Furnish food that is palatable, attractive, and at the proper temperature and consistency.

(2) Offer substitutes of similar nourishment to patients who refuse food served or desire alternative choices.

(3) Furnish meals at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.

(4) The RNHCI must offer snacks at bedtime.

§ 403.736 Condition of participation: Discharge planning.

(a) *Discharge planning and instructions.* The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. The RNHCI must assess the need for a discharge plan for any patient likely to suffer adverse consequences if there is no planning.

(1) Discharge instructions must be provided at the time of discharge to the patient or the patient's caregiver as necessary.

(2) If the patient assessment indicates a need for a discharge plan, the discharge plan must include instructions on post-RNHCI care to be used by the patient or the caregiver in the patient's home, as identified in the discharge plan.

(3) If the RNHCI's patient assessment does not indicate a need for a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

(b) *Standard: Transfer or referral.* The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with § 403.730(b)(2).

(c) *Standard: Reassessment.* The RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003; 84 FR 51813, Sept. 30, 2019]

§ 403.738 Condition of participation: Administration.

An RNHCI must have written policies regarding its organization, services, and administration.

(a) *Standard: Compliance with Federal, State, and local laws.* The RNHCI must

operate in compliance with all applicable Federal, State, and local laws, regulations, and codes including, but not limited to, those pertaining to the following:

(1) Protection against discrimination on the basis of race, color, national origin, age, or handicap (45 CFR parts 80, 84, and 91).

(2) Protection of human research subjects (45 CFR part 46).

(3) Application of all safeguards to protect against the possibility of fraud and abuse (42 CFR part 455).

(4) Privacy of individually identifiable health information (45 CFR part 164).

(b) *Standard: Governing body.* (1) The RNHCI must have a governing body, or a person designated to function as a governing body, that is legally responsible for establishing and implementing all policies regarding the RNHCI's management and operation.

(2) The governing body must appoint the administrator responsible for the management of the RNHCI.

(c) *Standard: Affiliations and disclosure.* (1) An affiliation is permissible if it is between one of the following:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(ii) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

(2) The RNHCI complies with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(3) The RNHCI furnishes written notice, including the identity of each new individual or company, to CMS at the time of a change, if a change occurs in any of the following:

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter.

(ii) The officers, directors, agents, or managing employees.

(iii) The religious entity, corporation, association, or other company responsible for the management of the RNHCI.

(iv) The RNHCI's administrator or director of nonmedical nursing services.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003]

§ 403.740 Condition of participation: Staffing.

The RNHCI must be staffed with qualified experienced personnel who are present in sufficient numbers to meet the needs of the patients.

(a) *Standard: Personnel qualifications.* The RNHCI must ensure that staff who supervise or furnish services to patients are qualified to do so and that staff allowed to practice without direct supervision have specific training to furnish these services.

(b) *Standard: Education, training, and performance evaluation.* (1) The RNHCI must ensure that staff (including contractors and other individuals working under arrangement) have the necessary education and training concerning their duties so that they can furnish services competently. This education includes, but is not limited to, training related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities.

(2) Staff must demonstrate, in practice, the skills and techniques necessary to perform their duties and responsibilities.

(3) The RNHCI must evaluate the performance of staff and implement measures for improvement.

§ 403.742 Condition of participation: Physical environment.

A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public.

(a) *Standard: Buildings.* The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:

(1) Procedures for the proper storage and disposal of trash.

(2) Proper ventilation and temperature control and appropriate lighting

levels to ensure a safe and secure environment.

(3) An effective pest control program.

(4) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.

(5) A working call system for patients to summon aid or assistance.

(b) *Standard: Patient rooms.* Patient rooms must be designed and equipped for adequate care, comfort, and privacy of the patient.

(1) Patient rooms must meet the following conditions:

(i) Accommodate no more than four patients.

(ii) Measure at least 80 square feet per patient in multiple patient rooms and at least 100 square feet in single patient rooms.

(iii) Have direct access to an exit corridor.

(iv) Be designed or equipped to assure full visual privacy for each patient.

(v) Have at least one window to the outside.

(vi) Have a floor at or above grade level.

(2) The RNHCI must furnish each patient with the following:

(i) A separate bed of proper size and height for the convenience of the patient.

(ii) A clean, comfortable mattress.

(iii) Bedding appropriate to the weather and climate.

(iv) Functional furniture appropriate to the patient's needs and individual closet space with clothes racks and shelves accessible to the patient.

(3) CMS may permit variances in requirements specified in paragraphs (b)(1)(i) and (ii) of this section relating to rooms on an individual basis when the RNHCI adequately demonstrates in writing that the variances meet the following:

(i) Are in accordance with the special needs of the patients.

(ii) Will not adversely affect patients' health and safety.

[64 FR 67047, Nov. 30, 1999, as amended at 81 FR 64021, Sept. 16, 2016]

§ 403.744 Condition of participation: Life safety from fire.

(a) *General.* An RNHCI must meet the following conditions:

(1) Except as otherwise provided in this section—

(i) The RNHCI 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 (a)(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) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.

(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(4) The RNHCI 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 RHNCI 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) Building 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.

(b) *Exceptions.* (1) 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 RNHCI facility, but only if the waiver will not adversely affect the health and safety of the patients.

(2) If CMS finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.

(c) 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 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(ii) TIA 12–1 to NFPA 101, issued August 11, 2011.

(iii) TIA 12–2 to NFPA 101, issued October 30, 2012.

(iv) TIA 12–3 to NFPA 101, issued October 22, 2013.

(v) TIA 12–4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 69 FR 49240, Aug. 11, 2004; 70 FR 15237, Mar. 25, 2005; 70 FR 71007, Nov. 25, 2005; 71 FR 55339, Sept. 22, 2006; 81 FR 26896, May 4, 2016]

§ 403.745 Condition of participation: Building safety.

(a) *Standard: Building Safety*. Except as otherwise provided in this section the RNHCI 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).

(b) Standard: Exceptions. Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a RNHCI.

(c) *Waiver*. If application of the Health Care Facilities Code required under paragraph (a) of this section would result in unreasonable hardship for the RNHCI, 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 individuals.

(d) *Incorporation by reference*. 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.

(2) [Reserved]

[81 FR 26896, May 4, 2016]

§ 403.746 Condition of participation: Utilization review.

The RNHCI must have in effect a written utilization review plan to assess the necessity of services furnished. The plan must provide that records be maintained of all meetings, decisions, and actions by the utilization review committee.

(a) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating the following:

(1) Admissions.

(2) Duration of care.

(3) Continuing care of an extended duration.

(4) Items and services furnished.

(b) *Standard: Utilization review committee.* The committee is responsible for evaluating each admission and ensuring that the admission is necessary and appropriate. The utilization review plan must be carried out by the utilization review committee, consisting of the governing body, administrator or other individual responsible for the overall administration of the RNHCI, the supervisor of nursing staff, and other staff as appropriate.

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in paragraphs (a) and (b) of this section, the utilization review committee is responsible for:

(1) The admission, and at least every 30 days, the continued care review of each patient in the RHNCI home services program.

(2) Oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment items for beneficiaries in the program.

[64 FR 67047, Nov. 30, 1999, as amended at 69 FR 66419, Nov. 15, 2004]

§ 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal, State, and local emergency preparedness requirements. The RNHCI 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 RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do all of 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, persons at-risk; the type of services the RNHCI 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 RNHCI 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) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the RNHCI's care during an emergency. If on-duty staff and sheltered patients

are relocated during the emergency, the RNCHI must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the RNHCI, which includes the following:

(i) Consideration of care 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.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCIs and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The RNHCI 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) Next of kin, guardian or custodian.

(iv) Other RNHCIs.

(v) 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) RNHCI's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative.

(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 RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The RNHCI 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 RNHCI must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing 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 RNHCI must conduct training on the updated policies and procedures.

(2) *Testing.* The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

[81 FR 64021, Sept. 16, 2016, as amended at 84 FR 51813, Sept. 30, 2019]

§ 403.750 Estimate of expenditures and adjustments.

(a) *Estimates.* CMS estimates the level of expenditures for services provided under this subpart before the start of each FFY beginning with FFY 2000.

(b) *Adjustments to payments.* When the level of estimated expenditures is projected to exceed the FFY trigger level as described in paragraph (d) of this section, for the year of the projection, payments to RNHCIs will be reduced by a proportional percentage to prevent estimated expenditures from exceeding the trigger level. In addition to reducing payments proportionally, CMS may impose alternative adjustments.

(c) *Notification of adjustments.* CMS notifies participating RNHCIs before the start of the FFY of the type and level of expenditure reductions to be made and when these adjustments will apply.

(d) *Calculation of trigger level.* The trigger level for FFY 1998 is $20,000,000. For subsequent FFYs, the trigger level is the unadjusted trigger level increased or decreased by the carry forward as described in § 403.754(b). The unadjusted trigger level is the base year amount (the unadjusted trigger level dollar amount for the prior FFY) increased by the average consumer price index (the single numerical value published monthly by the Bureau of Labor Statistics that presents the relationship in United States urban areas for the current cost of goods and services compared to a base year, to represent the change in spending power) for the 12-month period ending on July 31 preceding the beginning of the FFY.

§ 403.752 Payment provisions.

(a) *Payment to RNHCIs.* Payment for services may be made to an RNHCI that meets the conditions for coverage described in § 403.720 and the conditions of participation described in §§ 403.730 through 403.746. Payment is made in accordance with § 413.40 of this chapter to an RNHCI meeting these conditions.

(b) *Review of estimates and adjustments.* There is no administrative or judicial review of the level of estimated expenditures or the adjustments in payments described in § 403.750(a) and (b).

(c) *Effect on beneficiary liability.* When payments are reduced in accordance with § 403.750(b), the RNHCI may bill the beneficiary the amount of the Medicare reduction attributable to his or her covered services.

(d) *Notification of beneficiary liability.* (1) The RNHCI must notify the beneficiary in writing at the time of admission of any proposed or current proportional Medicare adjustment. A beneficiary currently receiving care in the RNHCI must be notified in writing at least 30 days before the Medicare reduction is to take effect. The notification must inform the beneficiary that the RNHCI can bill him or her for the proportional Medicare adjustment.

(2) The RNHCI must, at time of billing, provide the beneficiary with his or her liability for payment, based on a calculation of the Medicare reduction pertaining to the beneficiary's covered services permitted by § 403.750(b).

§ 403.754 Monitoring expenditure level.

(a) *Tracking expenditures.* Starting in FFY 1999 CMS begins monitoring Medicare payments to RNHCIs.

(b) *Carry forward.* The difference between the trigger level and Medicare expenditures for a FFY results in a carry forward that either increases or decreases the unadjusted trigger level described in § 403.750(d). In no case may

the carry forward exceed $50,000,000 for an FFY.

§ 403.756 Sunset provision.

(a) *Effective date.* Beginning with FFY 2002, if the level of estimated expenditures for all RNHCIs exceeds the trigger level for 3 consecutive FFYs, CMS will not accept as the basis for payment of any claim any election executed on or after January 1 of the following calendar year.

(b) *Notice of activation.* A notice in the FEDERAL REGISTER will be published at least 60 days before January 1 of the calendar year that the sunset provision becomes effective.

(c) *Effects of sunset provision.* Only those beneficiaries who have a valid election in effect before January 1 of the year in which the sunset provision becomes effective will be able to claim Medicare payment for care in an RNHCI, and only for RNCHI services furnished during that election.

§ 403.764 Basis and purpose of religious nonmedical health care institutions providing home service.

(a) *Basis.* This subpart implements sections 1821, 1861, 1861(e), 1861(m), 1861(y), 1861(ss) and 1861(aaa), 1869 and 1878 of the Act regarding Medicare payment for items and services provided in the home setting furnished to eligible beneficiaries by religious nonmedical health care institutions (RNHCIs).

(b) *Purpose.* The home benefit provides for limited durable medical equipment (DME) items and RNHCI services in the home setting that are fiscally limited to $700,000 per calendar year, with an expiration date of December 31, 2006, or the date on which the 2006 spending limit is reached.

[69 FR 66419, Nov. 15, 2004]

§ 403.766 Requirements for coverage and payment of RNHCI home services.

(a) Medicare Part A pays for RNHCI home services if the RNHCI provider does the following:

(1) Submit a notice of intent to CMS to exercise the option of providing home service.

(2) Provide RNHCI services to eligible beneficiaries,

(3) Arrange with suppliers to furnish appropriate DME items as required to meet documented eligible beneficiary needs.

(4) Arrange for RNHCI nurse home visits to eligible beneficiaries.

(5) Have a utilization committee that assumes the additional responsibility for the oversight and monitoring of the items and RNHCI nursing services provided under the home benefit.

(6) Meet all applicable requirements set forth in subpart G of this part.

(b) To be an eligible beneficiary to RNHCI home services the beneficiary must:

(1) Have an effective election in place.

(2) Be confined to the home, as specified in § 409.42(a) of this chapter.

(3) Have a condition that makes him or her eligible to receive services covered under Medicare home health.

(4) Receive home services and DME items from a RNHCI.

(5) Be responsible for deductible and coinsurance for DME, as specified in § 409.50 of this chapter.

[69 FR 66419, Nov. 15, 2004, as amended at 70 FR 16721, Apr. 1, 2005]

§ 403.768 Excluded services.

In addition to items and services excluded in § 409.49 of this chapter, items and services are also excluded if they are provided by:

(a) A HHA that is not a RNHCI.

(b) A supplier who is not providing RNHCI designated items under arrangement with a RNHCI.

(c) A nurse who is not providing RNHCI home nursing services under arrangement with a RNHCI.

[69 FR 66419, Nov. 15, 2004]

§ 403.770 Payments for home services.

(a) The RNHCI nursing visits are paid at the modified low utilization payment adjusted (LUPA) rate used under the home health prospective payment system at § 484.230 of this chapter.

(b) Appropriate DME items are paid as priced by Medicare, minus the deductible and coinsurance liability of the beneficiary.

[69 FR 66419, Nov. 15, 2004]

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

SOURCE: 68 FR 69915, Dec. 15, 2003, unless otherwise noted.

§ 403.800 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D–31 of the Social Security Act (the Act).

(b) *Scope.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

§ 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

Affiliated organization means an organization that is a legally separate entity from the endorsed drug card sponsor and meets one of the following conditions:

(1) The organization and the endorsed drug card sponsor are under common control. Common control exists if another entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of the organization and the endorsed drug card sponsor.

(2) The organization is under the control of the endorsed drug card sponsor or the organization controls the endorsed drug card sponsor. Control exists if an entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of another entity.

(3) The organization possesses an ownership or equity interest of 5 percent or more in the endorsed drug card sponsor on both the date on which the endorsed drug card sponsor markets the organization's Part D plan, and the date on which the endorsed drug card sponsor signed its endorsement contract with CMS.

Annual coordinated election period means the period beginning on November 15, 2004 and ending on December 31, 2004, during which a discount card enrollee may elect to disenroll from their current endorsed discount card program and elect enrollment in another endorsed discount card program effective January 1, 2005.

Applicant means the non-governmental, single legal organization or entity doing business in the United States that is applying for Medicare endorsement of its prescription drug discount card program, as described in its application, to be operated by itself or in coordination with subcontractors.

Application means the document submitted to CMS by an applicant that seeks to demonstrate the applicant's compliance with the requirements specified in this subpart in order to obtain Medicare endorsement of the applicant's prescription drug discount card program.

Authorized representative means a person with legal authority to act on behalf of an individual in making decisions related to the individual's health care or the individual's enrollment in, disenrollment from, and access to negotiated prices and transitional assistance under the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

Covered discount card drug means any of the following: 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; a biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; insulin described in section 1927(k)(2)(C) of the Act; the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; a vaccine licensed under section 351 of the Public Health Service Act; or any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition of covered discount card drug excludes the following: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; outpatient drugs for which the manufacturer seeks to require that associated tests

or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; barbiturates; and benzodiazepines.

Discount card enrollee or enrollee or card enrollee means an individual described in § 403.810(a) who elects to enroll in a Medicare-endorsed prescription drug discount card program.

Effective date means the date on which an enrollment or disenrollment transaction becomes effective.

Enrollment period means the period beginning on the initial enrollment date and ending on December 31, 2005.

Exclusive card program means an endorsed discount card program that is offered by an exclusive card sponsor.

Exclusive card sponsor means an endorsed sponsor that also operates one or more Medicare managed care plans and limits enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrollees in one of the Medicare managed care plans it offers.

Family size means one for individuals who are single, and two for individuals who are married.

Federal Employee's Health Benefits Program plan means a plan under chapter 89 of title 5 of the United States Code including the Retired Federal Employee's Health Benefits Program.

Formulary means the list of specific drugs from among covered discount card drugs for which an endorsed sponsor offers negotiated prices to Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program.

Group enrollment means simultaneous enrollment of all or some of the individuals described in section 403.810(a) who are members of a Medicare managed care plan into the exclusive card program offered by the Medicare managed care organization.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d and section 264 of Public Law 104–191.

Income means the components of an individual's adjusted gross income (AGI), as defined under 26 U.S.C. section 62, and, to the extent not included in the components of AGI, retirement and disability benefits, or, if he or she is married, the sum of such income for the individual and his or her spouse.

Initial enrollment date means the date established by the Secretary on which endorsed sponsors may begin accepting beneficiaries' standard enrollment forms.

Initial enrollment year means the period beginning on the initial enrollment date and ending on December 31, 2004.

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 nursing facility, as defined in section 1919(a) 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.

Medicare cost plan means an organization that offers enrollment under a reasonable cost reimbursement contract under section 1876(h) of the Act.

Medicare managed care organization means a Part C organization offering a Part C plan described in section 1851(a)(2)(A) of the Act or a Medicare cost plan.

Medicare managed care plan means a plan described in section 1851(a)(2)(A) of the Act offered by a Part C organization or a Medicare cost plan.

Medicare Prescription Drug Discount Card and Transitional Assistance Program or Medicare Drug Discount Card Program means the program established under section 1860D–31 of the Act.

Medicare-endorsed prescription drug discount card program, or endorsed program, or endorsed discount card program means any prescription drug discount card program that has received Medicare endorsement and whose endorsed sponsor has entered into a contract with CMS.

Medicare-endorsed prescription drug discount card sponsor, or endorsed sponsor, or endorsed discount card sponsor means any applicant that has received

endorsement from Medicare and entered into a contract with CMS to operate an approved Medicare-endorsed discount card program.

Negotiated price means the discounted price for a covered discount card drug offered by an endorsed sponsor, including any dispensing fee, which takes into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with an endorsed sponsor to provide negotiated prices to its card enrollees and accept transitional assistance as payment for covered discount card drugs provided to its transitional assistance enrollees.

New Medicare managed care organization means an entity applying for approval to enter into a new contract with CMS to offer a new, coordinated care plan or plans as described in section 1851(a)(2)(A) of the Act under Medicare Part C and an exclusive card program under the Medicare Drug Discount Card Program.

Over-the-counter drug means a nonprescription drug.

Part C organization means an organization offering a Part C plan.

Part C plan means a plan described in section 1859(b)(1) of the Act.

Part D plan has the meaning given the term at § 423.4.

Pharmacy network means the group of network pharmacies under contract with an endorsed sponsor.

Poverty line means the income level defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section, applicable to the family size involved.

Rural means a five-digit zip code in which the population density is less than 1000 persons per square mile.

Second enrollment year means the period beginning on January 1, 2005 and ending on December 31, 2005.

Solicitation means the application materials identified in the notice CMS publishes in the FEDERAL REGISTER announcing its intention to accept and consider applications from applicants seeking Medicare endorsement for their prescription drug discount card programs.

Special election period means the period beginning the day after the effective date of an individual's disenrollment from an endorsed discount card program for one of the reasons listed in § 403.811(b)(2). The length of any given election period will be specified by CMS in a form and manner that supports the goals of the Medicare Drug Discount Card Program.

Special endorsed sponsor means an endorsed sponsor who has received special endorsement by CMS.

Special endorsement means an endorsement granted under § 403.816 or § 403.817.

Standard enrollment form means an enrollment form or other approved process for enrolling individuals into an endorsed program that incorporates the standard elements provided by CMS.

Subcontractor means an organization or entity doing business in the United States with which an applicant or endorsed sponsor enters into a contract or other legal arrangement in connection with the operation of a prescription drug discount card program.

Suburban means a five-digit zip code in which the population density is between 1000 and 3000 persons per square mile.

Transition period means the period beginning on January 1, 2006 and ending, for individuals enrolled for coverage under Part D, on the effective date of the individual's coverage, and for individuals not so enrolled, on the last day of the initial Part D open enrollment period.

Transitional assistance means a subsidy that transitional assistance enrollees may apply toward the cost of covered discount card drugs in the manner described in § 403.808(d).

Transitional assistance effective date means the date on which a transitional assistance enrollee can access transitional assistance.

Transitional assistance enrollee means an individual described in § 403.810(b) who has applied for and been determined eligible for transitional assistance and has enrolled in a discount card program.

Urban means a five-digit zip code in which the population density is greater than 3000 persons per square mile.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52022, Sept. 1, 2005]

§ 403.804 General rules for solicitation, application and Medicare endorsement period.

(a) *Application.* (1) Except as provided in paragraph (a)(2) of this section, an applicant must submit an application to CMS by the deadline announced in the solicitation to be eligible for Medicare endorsement of its prescription drug discount card program. The applicant must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(2) A new Medicare managed care organization may simultaneously apply to offer a new Part C plan or plans and an exclusive card program after the deadline announced in the solicitation. New Medicare managed care organizations seeking endorsement of their prescription drug discount card programs must submit an application to CMS at the time that they submit their Part C applications. New Medicare managed care organizations will be eligible for endorsement provided CMS approves their Part C application, the new Medicare managed care organizations demonstrate to CMS that they meet the criteria under paragraph (b) of this section, and the new Medicare managed care organizations demonstrate that they will meet the requirements of paragraph (e)(2) of this section.

(b) *Eligibility to receive endorsement.* Except as specified in §§ 403.814, 403.816 and 403.817, an applicant will be eligible for endorsement if its application demonstrates to CMS's satisfaction that the applicant meets the requirements of § 403.806(a) and § 403.806(b)(1) and that it would operate its endorsed program in a manner consistent with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m). An applicant that submits a complete application that meets all of the requirements of this subpart will be eligible to enter into a contract with CMS to operate a Medicare-endorsed prescription drug discount card program. Following the receipt of its Medicare endorsement, an endorsed sponsor must comply with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m) through the end of the transition period.

(c) *Ability to subcontract with other organizations and entities.* (1) An applicant for endorsement may demonstrate that it meets the requirements of this subpart by combining with subcontractors.

(2) Any subcontracts must be in final form satisfactory to CMS, signed by all applicable parties, and filed with CMS before an endorsed sponsor will be permitted to engage in any enrollment or information and outreach.

(3) Once endorsed, an endorsed sponsor must ensure that its subcontractors comply with all applicable requirements of this subpart.

(d) *Period of endorsement.* An applicant eligible to receive endorsement will be required to sign a contract with CMS agreeing to operate its approved Medicare-endorsed prescription drug discount card program(s) until the end of the transition period.

(e)(1) Except as provided in paragraph (e)(2) of this section, we expect an endorsed sponsor to be ready by June 8, 2004, to initiate enrollment and fully operate its endorsed program in compliance with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m).

(2) A new Medicare managed care organization must be ready to initiate enrollment and fully operate its exclusive card program in compliance with the requirements of §§ 403.806(b)(2) and (b)(3) through § 403.806(m) upon approval of its Part C application and application for Medicare endorsement of its prescription drug discount card program.

§ 403.806 Sponsor requirements for eligibility for endorsement.

Except as specified in §§ 403.814, 403.816, and 403.817, an endorsed sponsor must meet the following requirements:

(a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.

(2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean—

(i) Adjudicating and processing claims for drugs at the point of sale;

(ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and

(iii) Administering and tracking individuals' subsidies or benefits in real time.

(3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

(b) *Financial stability and business integrity.* (1) An applicant must demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.

(2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.

(3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.

(c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

(d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and formulary requirements:

(1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.

(2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

(3) Offer a negotiated price on a generic drug in at least 55 percent of the lowest level categories in each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS.

(4) In setting negotiated prices under this section, an endorsed sponsor may vary its prices and the drugs included on the formulary by pharmacy contract and enrollee characteristics, such as transitional assistance eligibility status.

(5) Synchronize changes in the list of, and negotiated prices for, covered discount card drugs included in the endorsed sponsor's formulary with formulary and negotiated prices published on a price comparison Web site, as described in paragraph (i)(4)(v) of this section.

(6) Obtain rebates, discounts, or other price concessions from manufacturers on covered discount card drugs and pass a share of such concessions to enrollees through negotiated prices.

(7) Guarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale.

(8) Guarantee that a network pharmacy, at the point of sale, inform a discount card enrollee of any differential

between the price of a prescribed drug (if it is a covered discount card drug) and the price of the lowest priced generic covered discount card drug that is therapeutically equivalent and bioequivalent and available at such pharmacy. Mail order pharmacies are to provide this information at the time of delivery of the drug.

(9) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), ensure that any increase in the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy.

(e) *Transitional assistance administration.* An endorsed sponsor must administer transitional assistance funds, including any roll-over funds as described in § 403.808(f), for transitional assistance enrollees, through the following procedures:

(1) Establish accounting procedures to manage the transitional assistance funds for each transitional assistance enrollee.

(2) Ensure that transitional assistance funds are applicable to, and only to, all covered discount card drugs available at the endorsed sponsors' network and mail order pharmacies, regardless of formulary.

(3) Ensure that, at network and mail order pharmacies, transitional assistance funds are applied at the lower of negotiated price (if any) and the pharmacy's usual and customary price.

(4) Ensure that network pharmacies make available to the transitional assistance enrollee, electronically or by telephone, at the point-of-sale of covered discount card drugs, the amount of transitional assistance remaining available to the transitional assistance enrollee. Mail order pharmacies are to make this information available by telephone.

(5) Maintain a toll-free telephone number that discount card enrollees may use to determine their transitional assistance balances.

(6) Enforce coinsurance requirements described in § 403.808(e) and ensure that the portion of the price paid through coinsurance is not deducted from the total transitional assistance funds available to the discount card enrollee.

(f) *Service area and pharmacy access.* An endorsed sponsor must meet the following requirements for its service area and its pharmacy network:

(1) The service area must cover one or more States.

(2) The endorsed sponsor's discount card program must be available to all eligible individuals residing in each State in the endorsed sponsor's service area and may not be offered to individuals residing outside of the United States.

(3) The endorsed sponsor must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the endorsed sponsor's service area the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the endorsed program, live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the endorsed program, live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the endorsed program, live within 15 miles of a network pharmacy.

(4) The endorsed sponsor's pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (f)(3) of this section are met.

(g) *Information and outreach and customer service.* (1) An endorsed sponsor must provide through the Internet and some other tangible medium (such as a mailing) to Medicare beneficiaries information and outreach materials describing its endorsed drug card program, including the following information—

(i) The enrollment fee;

(ii) Negotiated prices offered for covered discount card drugs;

(iii) If offered, discounts on over-the-counter drugs;

(iv) Any other products or services offered under the endorsement; and

(v) Any other information that CMS determines is necessary for a full description of the endorsed discount drug card program.

(2) An endorsed sponsor must include on a Web site the following:

(i) Information regarding when the Web site was last updated; and

(ii) A disclaimer that the information on the Web site may not be current.

(3) An endorsed sponsor must use the following forms which incorporate standard elements provided by CMS:

(i) An enrollment form (except as may be modified for an exclusive card sponsor as discussed in § 403.814(b)(5)(iii); and

(ii) An eligibility determination notice.

(4) An endorsed sponsor must provide to each enrollee a card that complies with National Council for Prescription Drug Programs standards.

(5) An endorsed sponsor must meet the following requirements for the review and approval of information and outreach materials:

(i) Comply with the Information and Outreach Guidelines published by CMS except as provided in paragraph (g)(5)(vi) of this section.

(ii) Except as provided in paragraph (g)(5)(iii) of this section, not distribute any information and outreach materials until or unless they are approved by CMS.

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, the materials are deemed approved under paragraph (g)(5)(ii) of this section.

(iv) Information and outreach materials may discuss only products or services inside the scope of endorsement, as described in paragraph (h) of this section.

(v) Information and outreach materials include the same kinds of materials described in 42 CFR 422.80(b), as well as the enrollment form, eligibility determination form, and membership card described in paragraphs (g)(3) and (g)(4) of this section, Web site content, and information regarding discounts for over-the-counter drugs.

(vi) All materials related to products and services that are Part D plans must comply with the requirements specified in § 423.50 of this chapter.

(6) An endorsed sponsor must maintain a toll-free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practices. The endorsed sponsor must inform enrollees that the toll-free telephone number provides information on the amount of remaining transitional assistance, in accordance with paragraph (e)(5) of this section.

(7) An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use.

(h) *Products and services inside and outside the scope of the endorsement.* (1) An endorsed sponsor may provide, under the endorsement, only those products and services inside the scope of the endorsement, including conducting enrollment. An endorsed sponsor must ensure that discount card enrollees are not charged any additional fee (other than the enrollment fee allowed under § 403.811(c)) for products or services inside the scope of the endorsement.

(2) Products and services inside the scope of the endorsement are limited to—

(i) Products or services offered for no additional fee, other than the enrollment fee allowed under § 403.811(c), that are directly related to a covered discount card drug; or

(ii) A discounted price for an over-the-counter drug.

(i) *Reporting.* (1) An endorsed sponsor must report to CMS on a periodic basis information on the major features of the endorsed sponsor's programs that correspond to the qualifications for endorsement, including, but not limited to, information concerning—

(i) Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;

(ii) Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;

(iii) Dispensing fees;

(iv) Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;

(v) Participant utilization and spending statements;

(vi) Utilization and spending for selected drugs;

(vii) Performance on customer service metrics such as call center performance;

(viii) Grievance logs; and

(ix) Endorsed sponsor's compliance with the pharmacy network access standards.

(2) An endorsed sponsor must provide notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

(3) An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(4) Through a price comparison Web site, an endorsed sponsor must report the following information:

(i) Customer service hours;

(ii) Customer service contact information;

(iii) Endorsed program Web site address;

(iv) Annual enrollment fee; and

(v) Negotiated prices (including any applicable dispensing fee), for every covered discount card drug included in the discount card program's offering.

(5) CMS may require endorsed sponsors to submit, in standard terminology, descriptions of other discount card related services they provide, such as pharmacist services.

(j) *Grievance process.* An endorsed sponsor must establish and maintain a grievance process. This process must be designed to track and appropriately address in a timely manner enrollees' complaints about any aspect of their endorsed program for which the endorsed sponsor is responsible.

(k) *Eligibility, enrollment, and disenrollment.* (1) An endorsed sponsor must make preliminary eligibility determinations in accordance with § 403.810 and conduct enrollment and disenrollment in accordance with § 403.811.

(l) *Authorized representative.* An endorsed sponsor must treat an individual's authorized representative as the individual, if under applicable law, the authorized representative has the legal authority to act on behalf of the individual with respect to the action at issue.

(m) *Other.* An endorsed sponsor must meet the requirements of §§ 403.812, 403.813, and 403.822 of this subpart.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.808 Use of transitional assistance funds.

(a) *Individuals determined eligible for transitional assistance in 2004.* Subject to paragraph (d) of this section, an individual who, in calendar year 2004, is determined eligible for transitional assistance under § 403.810(b) is entitled to the following:

(1) $600 in calendar year 2004; and

(2) $600 in calendar year 2005.

(b) *Individuals determined eligible for transitional assistance in 2005.* Subject to paragraph (d) of this section, an individual who, in calendar year 2005, is determined eligible for transitional assistance under § 403.810(b) is entitled to one of the following amounts for calendar year 2005:

(1) If the complete application for the individual's transitional assistance eligibility is received on or after January 1, 2005 and before April 1, 2005, $600.

(2) If the complete application for the individual's transitional assistance eligibility is received on or after April 1, 2005 and before July 1, 2005, $450.

(3) If the complete application for the individual's transitional assistance eligibility is received on or after July 1, 2005 and before October 1, 2005, $300.

(4) If the complete application for the individual's transitional assistance eligibility is received on or after October 1, 2005 and on or before December 31, 2005, $150.

(c) *Payment of enrollment fee.* An individual found eligible for transitional assistance is entitled to have CMS pay the annual enrollment fee to the endorsed sponsor on his or her behalf.

(d) *Conditions on use of transitional assistance.* A transitional assistance enrollee may access the transitional assistance described in paragraphs (a) and (b) of this section only if the following conditions are met:

(1) Except as provided in § 403.814(b)(3)(v), the transitional assistance funds are applied toward the cost of a covered discount card drug obtained under the Medicare Prescription Drug Discount Card and Transitional Assistance Program;

(2) The individual pays a coinsurance amount in accordance with § 403.808(e);

(3) The individual purchases the covered discount card drug on or after the individual's transitional assistance effective date; and

(4) The individual is enrolled in the Medicare Prescription Drug Discount Card and Transitional Assistance Program on the date the individual's claim for the covered discount card drug is adjudicated.

(e) *Coinsurance.* If sufficient transitional assistance funds are available, transitional assistance funds must be expended in accordance with the following:

(1) For beneficiaries with incomes at or below 100 percent of the poverty line, 95 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(2) For beneficiaries with incomes greater than 100 percent but at or below 135 percent of the poverty line, 90 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(f) *Rollover.* An individual with transitional assistance retains access to any balance of transitional assistance not expended in a calendar year during the next calendar year, up to and including the transition period, if the individual—

(1) Remains in his or her current endorsed discount card program;

(2) Elects a new endorsed program in an Annual Coordinated Election Period; or

(3) Is eligible for a Special Election Period under § 403.811(b)(2) and elects a new endorsed discount card program during such Special Election Period.

§ 403.810 Eligibility and reconsiderations.

(a) *Eligibility for an endorsed discount card program.* An individual is eligible to enroll in an endorsed discount card program only if such individual meets the following conditions:

(1) The individual is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B; and

(2) The individual, at the time of applying to enroll in an endorsed discount card program, is not enrolled in a State medical assistance program under Title XIX of the Act or under a waiver pursuant to section 1115 of the Act, under which the individual is entitled to any medical assistance for outpatient prescribed drugs as described in section 1905(a)(12) of the Act, except as allowed in § 403.817(d).

(b) *Eligibility for transitional assistance.* An individual is eligible to receive transitional assistance if, at the time of applying for transitional assistance, the individual meets the following conditions:

(1) The individual meets the conditions in paragraph (a) of this section;

(2) The individual resides in one of the 50 States or the District of Columbia;

(3) The individual's income is not more than 135 percent of the poverty line applicable to the individual's family size;

(4) The individual does not have coverage for covered discount card drugs under one or more of the following sources:

(i) A group health plan or health insurance coverage, as these terms are defined under section 2791 of the Public Health Service Act, other than a Part C plan or a group health plan consisting solely of excepted benefits (such as a Medigap plan) as the term is defined under section 2791 of the Public Health Service Act;

(ii) Coverage provided under Chapter 55 of Title 10, United States Code, including TRICARE; or

(iii) A Federal Employee's Health Benefits Program plan; and

(5) The individual (or the individual's authorized representative) completes a standard enrollment form and signs and dates the form in accordance with § 403.811(a)(4). By signing the form, the individual (or the individual's authorized representative) certifies, under penalty of perjury, that, to the best of the individual's knowledge, the information he or she provides on the form is accurate.

(c) *Special rule for QMBs, SLMBs and QIs.* An individual is deemed to meet the income requirements in paragraph (b)(3) of this section if the individual is enrolled under Title XIX of the Act as a—

(1) Qualified Medicare Beneficiary (QMB);

(2) Specified Low-Income Medicare Beneficiary (SLMB); or

(3) Qualified Individual (QI).

(d) *Duration of eligibility determinations.* An individual determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance, shall remain eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance for the duration of the individual's enrollment in the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(e) *Drug card and transitional assistance benefits not treated as benefits under other Federal programs.* Any benefits received under the Medicare Prescription Drug Discount Card and Transitional Assistance Program must not be taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(f) *Verification of eligibility.* (1) CMS will verify eligibility to enroll in an endorsed discount card program or to receive transitional assistance.

(2) If CMS is unable to verify an individual's eligibility or ineligibility for transitional assistance, CMS can require the individual to provide additional income information in a form and manner specified by CMS as one condition of eligibility for transitional assistance.

(g) *Reconsideration.* (1) If an individual is determined ineligible to enroll in an endorsed discount card program under paragraph (a) of this section or determined ineligible to receive transitional assistance under paragraph (b) of this section, the individual (or the individual's authorized representative) has a right to request that an independent review entity under contract with CMS reconsider the determination.

(2) Reconsideration requests must be filed within 60 days from date of notice of an ineligibility determination, unless the individual (or the individual's authorized representative) can demonstrate good cause for why the 60-day time frame should be extended.

(3) An individual (or the individual's authorized representative) may submit additional documentary evidence or an explanation about his or her eligibility in writing to the independent review entity, as part of the reconsideration process.

(4) Reconsideration decisions shall be issued by the independent review entity in writing and contain an explanation of the reasoning of the decision.

§ 403.811 Enrollment and disenrollment and associated endorsed sponsor requirements.

(a) *Enrollment process.* (1) An individual (or an individual's authorized representative) applying to enroll in an endorsed discount card program must complete a standard enrollment form or other method allowed by CMS and provide such information to the endorsed discount card program in which the individual wishes to enroll.

(2) An individual electing to join an endorsed discount card program that charges an annual enrollment fee, and who is not applying for transitional assistance, must agree to pay the annual enrollment fee, if any, in a form and manner determined by the endorsed card sponsor.

(3) An individual applying for transitional assistance at the time that they apply for enrollment in an endorsed discount card program may only enroll in the endorsed discount card program at that time if CMS determines that

the individual is eligible for transitional assistance. Individuals not found eligible for transitional assistance may enroll in an endorsed discount card program without applying for transitional assistance after being notified of their ineligibility for transitional assistance.

(4) An individual applying for transitional assistance must complete a standard enrollment form and sign and date the form, certifying, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the standard enrollment form.

(5) Except as provided in §403.811(b)(4), an individual who is not currently enrolled in an endorsed card program seeking to enroll in the Medicare Prescription Drug Discount Card and Transitional Assistance Program may do so at any time during the enrollment period.

(6) An individual may not be enrolled in more than one endorsed discount card program at a time.

(7) An individual may enroll in only one endorsed discount card program per year during the enrollment period. An individual enrolling during the initial enrollment year, with the exception of the circumstances under paragraph (b)(2) of this section, may change election for the second enrollment year during the annual coordinated election period. During the second enrollment year, an individual may enroll in only one endorsed discount card program, unless the individual meets the circumstances described in paragraph (b)(2) of this section.

(8) An individual remains enrolled in an endorsed discount card program elected unless—

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual elects a new program during the Annual Coordinated Election Period; or

(iii) The endorsed sponsor terminates its endorsed discount card program, or is terminated.

(9) No new enrollment in an endorsed discount card program or changing election of an endorsed discount card program is allowed during the transition period.

(10) Except as specified in §403.814(b)(6)(i), an individual may enroll in any endorsed discount card program, and only those endorsed discount card programs, offered in the individual's State of residence.

(11) In order to access negotiated prices or transitional assistance, if applicable, an individual must be enrolled in an endorsed discount card program. Access to negotiated prices begins with the effective date of enrollment and ends with disenrollment. Access to transitional assistance begins with the transitional assistance effective date and ends for claims finalized on the date of disenrollment.

(12) Except as provided in paragraph (b)(5) of this section, an individual may apply for transitional assistance at any time during the enrollment period.

(b) *Disenrollment process.* (1) An enrollee may voluntarily disenroll at any time by notifying (or by having his authorized representative notify) the endorsed sponsor.

(2) An enrolled individual who disenrolls during the enrollment period under the following circumstances is granted a Special Election Period in which the individual may enroll in another endorsed discount card program during the enrollment period:

(i) A move of residence outside the service area of the current program;

(ii) A change in residence to or from a long-term care facility;

(iii) Enrollment in or disenrollment from a Part C plan or Medicare cost plan;

(iv) An individual's current endorsed discount card program is terminated or terminates; or

(v) Other exceptional circumstances, as defined by the Secretary.

(3) Notification in order to effect a disenrollment is not required for an individual disenrolling from a terminating endorsed discount card program or enrolling in or disenrolling from a Medicare managed care plan offering an exclusive card program, or for individuals changing endorsed discount card programs during the Annual Coordinated Election Period.

(4) A drug discount card enrollee who disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of

this section will no longer be determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, if he or she disenrolls in 2004, must reapply for the Medicare Prescription Drug Discount Card and Transitional Assistance Program should he or she wish to enroll in another endorsed discount card program for the second enrollment year.

(5) An individual receiving transitional assistance who voluntarily disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will forfeit any transitional assistance remaining available to the individual on the date of disenrollment, and, if he or she disenrolls in 2004, must re-apply for transitional assistance for 2005 in order to receive transitional assistance in 2005.

(6) A discount card enrollee other than a transitional assistance enrollee may be involuntarily disenrolled from his or her endorsed discount card program for failure to pay the annual enrollment fee on a timely basis.

(7) A discount drug card enrollee other than a transitional assistance enrollee may be charged another annual enrollment fee each time the individual disenrolls from one endorsed discount card program and enrolls in another endorsed discount card program during the calendar year.

(c) *Enrollment fees.* (1) An endorsed sponsor may charge an annual enrollment fee of no more than $30 to each individual enrolled in its endorsed discount card program.

(2) An endorsed sponsor may not collect an enrollment fee from any individual applying for or receiving transitional assistance.

(3) The annual enrollment fee must not be prorated for portions of the year.

(4) An endorsed sponsor must charge a uniform enrollment fee to every discount card eligible individual, or to the Secretary in the case of individuals receiving transitional assistance, residing in a State.

(5) An endorsed sponsor must refund any enrollment fee collected from a discount card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, during the calendar year during which the individual is determined eligible to receive transitional assistance.

(6) An endorsed sponsor may not charge an annual enrollment fee during the transition period.

§ 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

(a) *HIPAA covered entities.* An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of an endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) *HIPAA privacy requirements.* An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) *Security requirements*—(1) *Standard.* An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) *Attestation.* An applicant in its application shall—

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards,

implementation specifications, and requirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) *Administrative data standards.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) *Unique identifiers.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) *Applicability of other regulations.* Nothing in this paragraph or in § 403.813 shall be deemed a modification of parts 160, 162 and 164 of title 45, Code of Federal Regulations or otherwise modify the applicability of such regulations to other organizations or covered entities independently subject to the mandates of HIPAA. If an endorsed sponsor is also a health plan, health care provider, or health care clearinghouse, nothing is this paragraph shall impair or otherwise affect the application of HIPAA or parts 160, 162 and 164 of title 45, Code of Federal Regulations to such entity and its performance of those functions which make such entity a health plan, health care provider, or health care clearinghouse.

§ 403.813 Marketing limitations and record retention requirements.

(a) *Marketing limitations.* (1) An endorsed sponsor may only market the following:

(i) Those products and services offered under the endorsed program that are inside the scope of endorsement defined in § 403.806(h) and permitted under § 403.812(b).

(ii) A Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

(2) An endorsed sponsor may not request that a drug card enrollee or an individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for purposes of marketing any product or service not allowed under paragraph (a)(1) of this section.

(3) An endorsed sponsor may not comingle any materials related to the marketing of products and services allowed under paragraph (a)(1) of this section with other marketing materials.

(4) Following termination of an endorsed sponsor's endorsement under §§ 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service.

(b) *Record retention standard.* (1) An endorsed sponsor must retain records that it creates, collects, or maintains while participating in the Medicare Drug Discount Card and Transitional Assistance Program as part of its operations of an endorsed program for at least 6 years following termination of such program, or, in the event the endorsed sponsor's endorsement is terminated under § 420.820(c), (d), or (e) of this chapter at least 6 years following termination of such endorsement. The Secretary may extend the six-year retention period if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(2) For the period during which an endorsed sponsor retains records as specified in paragraph (b)(1) of this section, an endorsed sponsor must continue to apply security and privacy protections to such records and the information contained therein to the same extent endorsed sponsors are required to do so under §§ 403.812(b) and 403.812(c)(1) prior to termination.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.

(a) *General requirements.* (1) A Part C organization and Medicare cost plan may not require enrollment in an endorsed discount card program as a condition for enrollment in its Part C plan or Medicare cost plan.

(2) A Part C organization may subsidize the enrollment fee for an endorsed discount card program, whether operated by the Part C organization or another endorsed sponsor, for individuals described in § 403.810(a), provided that any such benefit is reflected in the Part C organization's Adjusted Community Rate filing.

(b) *Exclusive card sponsors.* (1) A Medicare managed care organization may elect to become an exclusive card sponsor by limiting enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrolled in any of its Medicare managed care plans. The Medicare managed care organization must be the applicant for endorsement in order to offer an exclusive card program. Such an election must be made at the time of application for endorsement.

(2) Except as noted in paragraphs (b)(3) and (b)(4) of this section, an exclusive card sponsor must comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(3) An exclusive card sponsor is deemed to meet or is exempt from certain specific requirements listed in § 403.806 as follows:

(i) An exclusive card sponsor is deemed to meet the pharmacy network requirement in § 403.806(f)(3) if its pharmacy network is not limited to mail-order pharmacies and is equivalent to the pharmacy network used in its Medicare managed care plan and such pharmacy network has been approved by the Secretary, or, if its Medicare managed care plan does not use a pharmacy network, the Secretary determines that the pharmacy network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees under the standard set forth under 42 CFR 422.112 for a Part C organization described in section 1851(a)(2)(A) of the Act, or under 42 CFR 417.416(e) for a Medicare cost plan.

(ii) An exclusive card sponsor is deemed to meet the service area requirements in § 403.806(f)(1) and (f)(2) if it operates in a service area equivalent to its Medicare managed care plan's service area.

(iii) An exclusive card sponsor is deemed to meet the requirement for financial stability and business integrity in § 403.806(b) through compliance with § 422.400 of this chapter (if a Part C organization described in section 1851(a)(2)(A) of the Act) or compliance with §§ 417.120 and 417.122 of this chapter (if a Medicare cost plan).

(iv) An exclusive card sponsor is deemed to meet the covered lives requirement in § 403.806(a)(3).

(v) An exclusive card sponsor is deemed to meet the requirements of § 403.806(e)(2) if it ensures that transitional assistance funds are applied to, and only to, the cost to transitional assistance enrollees of any covered discount card drugs obtained from a network or mail order pharmacy included in the exclusive card sponsor's pharmacy network, and at the option of the exclusive card sponsor, any covered discount card drug obtained under an outpatient prescription drug benefit offered under the affiliated Medicare managed care plan, including any deductibles, co-payments, coinsurance, and other cost-sharing amounts for which transitional assistance enrollees are responsible under the Medicare managed care plan's outpatient prescription drug benefit.

(4) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of an exclusive card sponsor if:

(i) The requirements are duplicative of or conflict with the requirements that a Medicare managed care organization must meet either under Part C or under section 1876 of Title XVIII of the Act; or

(ii) The waiver or modification is necessary to improve coordination between benefits under the Medicare Prescription Drug Discount Card and Transitional Assistance Program and

the benefits either under Part C or under section 1876 of Title XVIII of the Act.

(iii) The applicant seeking to become an exclusive card sponsor requests such waivers or modifications in writing in a manner required by the Secretary.

(5) An exclusive card sponsor may conduct group enrollment according to the following rules:

(i) The exclusive card sponsor must seek CMS verification that its Medicare managed care members are individuals described in § 403.810(a) and enroll such individuals as a group into its exclusive card program.

(ii) The exclusive card sponsor must give all individuals it is enrolling as a group the opportunity to decline enrollment, and the opportunity to apply for transitional assistance.

(iii) The exclusive card sponsor may use a modified version of the standard enrollment form described in § 403.806(g)(3) or other CMS-approved process for group enrollment in its endorsed discount card program.

(6) An individual enrolled in a Medicare managed care plan offered by a Medicare managed care organization offering an exclusive card program to individuals enrolled in such Medicare managed care plan is subject to the following requirements:

(i) The individual may enroll only in the endorsed discount card program offered by his or her Medicare managed care organization.

(ii) If the exclusive card sponsor group elects to group enroll into an exclusive card program members of the Medicare managed plan, the individual must actively decline enrollment to avoid enrollment in the exclusive card program.

(c) *Non-uniformity of Benefits.* Implementation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program, including the provision of transitional assistance and the payment or waiver of any enrollment fee by a Part C organization, will not be taken into account in applying the uniform premium and uniform benefits requirement in sections 1854(c) and 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2) and 42 CFR 422.312(b)(2).

§ 403.815 Special rules concerning States.

(a) *Optional State payment of enrollment fee.* (1) A State may enter into payment arrangements with endorsed sponsors to provide payment of some or all of endorsed discount card programs' enrollment fees for some or all of the State's individuals described in § 403.810(a) who are not transitional assistance enrollees, provided the enrollment fees are paid directly by the State to the endorsed sponsor.

(2) Expenditures made by a State for enrollment fees described in paragraph (a)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(b) *Optional State payment of coinsurance.* (1) A State may enter into payment arrangements with pharmacies to provide payment of some or all of coinsurance amounts described in § 403.808(e) for some or all of the State's transitional assistance enrollees, provided the coinsurance amounts are paid directly by the State to the pharmacy.

(2) Expenditures made by a State for coinsurance described in paragraph (b)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(c) *Coinsurance for Qualified Medicare Beneficiaries.* For transitional assistance enrollees who are qualified Medicare beneficiaries, any coinsurance liability under § 403.808(e) must not be treated as Medicare cost-sharing coinsurance, under section 1905(p)(3)(B) of the Act, for which a State would otherwise be required to pay.

(d) *State data.* (1) A State must provide data on a monthly basis in an electronic format as determined necessary by the Secretary to effectuate the verification of beneficiary eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(2) Expenditures made by a State in complying with the requirements of paragraph (d)(1) of this section will be treated as State expenditures for which Federal matching payments are available under section 1903(a)(7) of the Act.

§ 403.816 Special rules concerning long-term care and I/T/U pharmacies.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for long-term care and/or for I/T/U pharmacies.

(2) Of qualified applicants, the Secretary will select at least two of the best-qualified applicants for special endorsement for long-term care and at least two of the best-qualified applicants for special endorsement for I/T/U pharmacies.

(3) Applicants for special endorsement for long-term care must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(4) Applicants for special endorsement for I/T/U pharmacies must demonstrate in their applications that they meet the requirements in paragraph (d) of this section.

(b) *Long-term care.* A special endorsed sponsor for long-term care must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who reside in long-term care facilities and who receive such prescription drugs through long-term care pharmacies;

(2) Offer contractual arrangements to any long-term care pharmacy seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who reside in long-term care facilities;

(3) Process any submitted claims from network pharmacies and out-of-network long-term care pharmacies that supply covered discount card drugs to transitional assistance enrollees who reside in long-term care facilities, when such enrollees have unspent transitional assistance remaining;

(4) Include special terms and conditions in its contracts with network pharmacies that are long-term care pharmacies to facilitate access to and the administration of transitional assistance to transitional assistance enrollees residing in long-term care facilities, including, but not limited to the following—

(i) Waiving penalties against long-term care pharmacies for submitting late claims to the special endorsed sponsor due to the pharmacy's coordination of benefits activities; and

(ii) Permitting a long-term care pharmacy to limit its services to only transitional assistance enrollees who reside in a long-term care facility served by the long-term care pharmacy.

(5) Except as noted in paragraph (c) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(c) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance to long-term care residents:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to long-term care pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to long-term care pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for long-term care if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of long-term care pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for long-term care must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *I/T/U pharmacies.* A special endorsed sponsor for I/T/U pharmacies must—

(1) Apply transitional assistance toward the cost of covered discount card

drugs obtained by transitional assistance enrollees who are American Indians and Alaska Natives and who receive prescription drugs through I/T/U pharmacies as allowed under paragraph (d)(2) of this section;

(2) Offer contractual arrangements to any I/T/U pharmacy that is in the special endorsed sponsor's service area and seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who are also American Indians/Alaska Natives;

(3) Include special terms and conditions in its contracts with network I/T/U pharmacies to facilitate access to and the administration of transitional assistance for transitional assistance enrollees who are American Indians/Alaska Natives, including, but not limited to the following:

(i) Permitting an I/T/U pharmacy to limit its services to only those transitional assistance enrollees who are American Indians/Alaska Natives, and

(ii) Allowing an I/T/U pharmacy to select which drugs to stock, which may be a more limited set than other retail pharmacies.

(4) Except as noted in paragraph (e) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(e) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance through I/T/U pharmacies:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for I/T/U pharmacies if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of I/T/U pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for I/T/U pharmacies must request such waivers or modifications in writing in a manner required by the Secretary.

§ 403.817 Special rules concerning the territories.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for all of the territories.

(2) Of qualified applicants, the Secretary will select at least one of the best-qualified applicants to receive a special endorsement for the territories.

(3) Applicants for special endorsement for the territories must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(b) *Requirements*—(1) *Negotiated prices.* A special endorsed sponsor for residents of the territories must provide access to negotiated prices in the territories.

(2) *Transitional assistance.* Any transitional assistance in the territories must be in accordance with paragraph (e) of this section.

(3) *Requirements, exception.* Except as specified in paragraph (c) of this section, a special endorsed sponsor for the territories must meet the requirements of §§ 403.804 and 403.806.

(c) *Waiver of requirements and alternative requirements.* (1) Section 403.806(d)(8) (requiring information about price differentials) shall not apply to pharmacies located in the territories and which are in the special endorsed sponsor's pharmacy network.

(2) Sections 403.806(f)(2) and (f)(3) will be deemed met if the special endorsed sponsor makes a good faith effort to secure the participation of retail and mail order pharmacies throughout a territory.

(3)(i) As the Secretary determines appropriate on a case-by-case basis, any

additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for the territories if—

(A) Such waiver is necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D–31 of the Act, or accommodate the unique needs of pharmacies in the territories; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for the territories must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *Other exceptions.* A special endorsed sponsor for the territories may enroll in its endorsed discount card program Medicaid enrollees with coverage for outpatient prescription drugs, as described in § 403.810(a)(2).

(e) *Transitional assistance provided by Territories.* (1) Transitional assistance in the territories may be administered only according to a plan submitted by a territory and approved by CMS.

(2) Territories choosing to provide transitional assistance must submit a plan to CMS within 90 days of the publication of this regulation. The plan must—

(i) Describe how funds allocated to the territory are to be used to cover the cost of covered discount card drugs obtained by individuals who reside in the territory, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and

(ii) Describe how the territory will ensure that amounts received under the allotment are to be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance, as described in paragraph (e)(2)(i) of this section, and

(iii) Provide such written assurance for the requirements in paragraph (e)(2)(ii) of this section.

(3) CMS will review and approve plans submitted and make allotments to territories with approved plans.

(4) CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

§ 403.820 Sanctions, penalties, and termination.

(a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:

(i) Suspension of enrollment of Medicare beneficiaries.

(ii) Suspension of information and outreach activities to Medicare beneficiaries.

(2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

(3) *Sanctionable violations.* The violations for which intermediate sanctions may be imposed are as follows:

(i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);

(ii) Substantial failure to comply with CMS Information and Outreach Guidelines;

(iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;

(iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);

(v) Charging drug card enrollees additional fees beyond a $30 enrollment fee;

(vi) Charging transitional assistance enrollees any enrollment fee;

(vii) Charging a coinsurance more than 5 percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;

(viii) Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees;

(ix) Substantial failure to provide CMS or its designees with requested information related to the endorsed sponsor's endorsed discount card operations; or

(x) Failure to otherwise substantially comply with the requirements of this subpart, including failing to perform the operational requirements of this program or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

(4) *Written notice of proposed sanctions.* (i) Prior to imposing sanctions, CMS will send a written notice to the endorsed sponsor stating the nature and basis of the proposed sanction.

(ii) CMS will send a copy of the notice in paragraph (a)(4)(i) of this section to the Office of the Inspector General.

(iii) CMS will allow the endorsed sponsor 15 days from the receipt of notice to provide evidence that it has not committed an act or omission that may fairly be characterized as a basis for sanction.

(iv) Should an endorsed sponsor present evidence described in paragraph (a)(4)(iii) of this section and by the time limit described in that paragraph, a CMS official not involved in the original sanction determination shall review the evidence and provide the endorsed sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(5) *Effective date of sanction.* (i) A sanction is effective 15 days after the date that the endorsed sponsor is notified of the sanction or, if the endorsed sponsor timely seeks reconsideration of that sanction decision, on the date specified in the notice of CMS's reconsideration determination.

(ii) The sanction remains in effect until CMS notifies the endorsed sponsor that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(b) *Civil monetary penalties*—(1) *OIG penalties.* The Office of the Inspector General (OIG) may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, sanctions that CMS may impose, as described in paragraph (a) of this section, against an endorsed sponsor whom it determines has knowingly—

(i) Misrepresented or falsified information in information and outreach or comparable material provided to program enrollee or other persons;

(ii) Charged a program enrollee in violation of the terms of the endorsement contract; or

(iii) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

(2) *CMS penalties.* If CMS determines that an endorsed sponsor has engaged in conduct that it knows or should know constitutes a violation as described in paragraph (a)(3) of this section, where the failure to perform involves the operational requirements of the program, CMS may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, the sanctions that CMS may impose, as described in paragraph (a) of this section.

(3) CMS or the OIG may impose civil monetary penalties of no more than $10,000 for each violation.

(c) *Termination of endorsement by CMS.* (1) CMS may terminate the endorsement contract at any time with notice on the following bases:

(i) Any of the bases for the imposition of intermediate sanctions as stated in paragraph (a)(3) of this section; or

(ii) The endorsed sponsor engaged in false or misleading information and outreach practices; or

(iii) The endorsed sponsor fails to comply with the requirement of § 403.804(e).

(2) CMS shall provide the endorsed sponsor written notice of termination 30 days prior to the CMS-determined effective date of the termination at

which time the endorsed sponsor must do the following:

(i) Provide its discount card enrollees notice of the termination within 10 days of receiving notice from CMS;

(ii) Continue to provide services to its discount card enrollees for 90 days after the discount card enrollees were sent the notice of termination from the endorsed sponsor; and

(iii) Suspend all information and outreach and enrollment activities once enrollees have received the notice of termination.

(3) *Corrective action plan.* Before terminating a contract, CMS shall provide the endorsed sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(d) *Termination by endorsed sponsor*—(1) *Cause for termination.* The endorsed sponsor may terminate its endorsement contract if CMS fails substantially to carry out the terms of the contract.

(2) *Card sponsor notice.* The endorsed sponsor must give advance notice as follows:

(i) To CMS, at least 90 days prior to the intended date of termination. This notice must specify the reasons why the endorsed sponsor is requesting contract termination; and

(ii) To its discount card enrollees, by mail, at least 60 days prior to the termination effective date. This notice must include a written description of alternative endorsed discount card programs that serve the discount card enrollee's address.

(3) *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 endorsed sponsor's notice of intent to terminate.

(e) *Termination by mutual consent.* (1) A contract may be modified or terminated at any time by written mutual consent.

(2) If the contract is terminated by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees as provided in paragraph (d)(2) of this section.

(3) If the contract is modified by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(f) *Appeal of contract determinations*—(1) *Scope.* This section establishes the procedures for reviewing the following contract determinations:

(i) A determination that an applicant is not qualified to enter into a contract with CMS under section 1860D–31 of the Act; and

(i) A determination to terminate a contract with an endorsed sponsor in accordance with paragraph (c) of this section.

(2) *Notice of determination.* When CMS makes an initial contract determination, it gives the endorsed sponsor or applicant written notice specifying—

(i) The reasons for the determination; and

(ii) The endorsed sponsor's or applicant's right to request reconsideration.

(3) *Effect of contract determination.* The contract determination is final and binding unless a timely request for a reconsideration hearing is filed under this section.

(4) *Right to reconsideration.* An endorsed sponsor whose contract is terminated or an applicant denied endorsement may request a hearing for reconsideration of the CMS contract determination.

(5) *Method and place for filing a request.* A request for a reconsideration hearing must be made in writing and filed with the CMS Central Office.

(6) *Time for filing a request.* The request for a reconsideration hearing must be filed within 15 days from the date of the notice of the initial determination.

(7) *Appointment of hearing officer.* CMS shall appoint a hearing officer to conduct the reconsideration. The hearing officer shall be a representative of the Administrator and not otherwise a party to the contract determination.

(8) *Conduct of hearing.* The endorsed sponsor or applicant may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings will be made and transcribed.

(9) *Reconsideration determination.* A reconsideration determination is a new determination that—

(i) Is based on a review of the contract determination, the evidence and findings upon which it was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the endorsed sponsor subsequent to the contract determination; and

(ii) Affirms, reverses, or modifies the initial contract determination.

(10) *Notice of reconsidered determination.* As soon as practicable after the close of the hearing, the hearing officer issues a written reconsideration determination that contains the following:

(i) Findings with respect to the applicant's qualifications to enter into or an endorsed sponsor's qualifications to remain under a contract with CMS under section 1860D–31 of the Act;

(ii) A statement of the specific reasons for the reconsidered determination.

(11) *Effect of reconsidered determination.* A reconsidered determination is final and binding on the parties and is not subject to judicial review.

(g) *Compliance with HIPAA.* Failure of an endorsed sponsor to comply with HIPAA and/or the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164, as established in § 403.812, shall be a violation of HIPAA and may be enforced under sections 1176 and 1177 of the Act.

§ 403.822 Reimbursement of transitional assistance and associated sponsor requirements.

(a) A Transitional Assistance Account is created within the Federal Supplementary Medical Insurance Trust Fund and kept separate from all other funds within that fund.

(b) The Managing Trustee of the Transitional Assistance Account shall pay on a monthly basis from the Account the amounts certified by CMS as necessary to make payments for transitional assistance as allowed in § 403.808.

(c) Endorsed sponsors must routinely account to CMS for the transitional assistance provided to the transitional assistance enrollees for finalized (not pending, or denied) claims up to the allowed balance provided by CMS to the sponsor.

(d) Payment transactions will be audited by the Secretary or his agent.

(e) Federal funding in excess of the amount of the balance included in CMS's system is not permitted.

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

SOURCE: 78 FR 9521, Feb. 8, 2013, unless otherwise noted.

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

§ 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

(1) Operates in the United States; and

(2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

(1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the

entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Certified nurse midwife means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

Certified registered nurse anesthetist means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Clinical nurse specialist means, an individual who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(2) Holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a—

(1) Drug or biological, by law, requires a prescription to be dispensed; or

(2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Covered recipient means— (1) Any physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, or certified nurse-midwife who is not a bona fide employee of the applicable manufacturer that is reporting the payment; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year

for which such information is available.

Device identifier is the mandatory, fixed portion of a unique device identifier (UDI) that identifies the specific version or model of a device and the labeler of that device (as described at 21 CFR 801.3 in paragraph (1) of the definition of ''Unique device identifier'').

Employee means an individual who is considered to be ''employed by'' or an ''employee'' of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

(1) Spouse.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of a grandparent or grandchild.

Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization) requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).

Know, knowing, or knowingly—(1) Means that a person, with respect to information—

(i) Has actual knowledge of the information;

(ii) Acts in deliberate ignorance of the truth or falsity of the information; or

(iii) Acts in reckless disregard of the truth or falsity of the information; and

(2) Requires no proof of a specific intent to defraud.

Long term medical supply or device loan means the loan of supplies or a device for 91 days or longer.

Non-teaching hospital covered recipient means a person who is one or more of the following: Physician; physician assistant; nurse practitioner; clinical nurse specialist; certified registered nurse anesthetist; or certified nurse-midwife.

NPPES stands for the National Plan & Provider Enumeration System.

Nurse practitioner means a nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

Operating in the United States means that an entity—

(1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or

(2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.

Ownership or investment interest—(1) Includes, but is not limited to the following:

(i) Stock, stock option(s) (other than those received as compensation, until they are exercised).

(ii) Partnership share(s);

(iii) Limited liability company membership(s).

(iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

(i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.

(ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iv) An unsecured loan subordinated to a credit facility.

(v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under section 401(a) of the Internal Revenue Code of 1986.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Physician assistant means a physician assistant who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

Physician-owned distributorship, for the purposes of determining the existence of a reportable ownership or investment interest under this subpart, means an entity that:

(1) Meets the definition of an applicable manufacturer or applicable group purchasing organization as defined in this section, and

(2) Meets at least one of the following two conditions:

(i) Has a minimum of 5 percent direct or indirect ownership or investment interest in the applicable manufacturer or applicable group purchasing organization held by a physician or a physician's immediate family member, or

(ii) A physician or a physician's immediate family member receives compensation from the applicable manufacturer or group purchasing organization in the form of a commission, return on investment, profit sharing, profit distribution, or other remuneration directly or indirectly derived from the sale or distribution of devices by the applicable manufacturer or group purchasing organization in which the physician or physician's immediate family member has ownership.

(3) This physician owned distributor definition does not apply for purposes of any other laws or regulations, including, but not limited to, section 1877 of the Act, the regulations at 42 CFR part 411, subpart J, section 1128B of the Act, or the regulations at 42 CFR 1001.952.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Short term medical supply or device loan means the loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 cumulative days per calendar year or a quantity of 90 cumulative days of average daily use per calendar year, to permit evaluation of the device or medical supply by the covered recipient.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

Unique device identifier means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 801.40 and 830.3.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014; 84 FR 63185, Nov. 15, 2019; 85 FR 10, Jan 2, 2020; 86 FR 65659, Nov. 19, 2021]

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(3) An applicable manufacturer or applicable group purchasing organization that has reported payments or transfers of value under the scope of this section may not remove, delete, or alter any record/(s) unless an error is discovered in the information that had been furnished, or the record is otherwise believed to meet exceptions for reporting.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For non-teaching hospital covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (NPPES) (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3*) Identifiers for non-teaching hospital covered recipients.* In the case of a covered recipient the following identifiers:

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a non-teaching hospital covered recipient, the field may be left blank, indicating that the applicable manufacturer could not find one.

(iii) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* Report the marketed or brand name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals—

(A) If the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(B) Any regularly used identifiers must be reported, including, but not limited to, national drug codes.

(ii) For devices, if the device has a unique device identifier (UDI), then the device identifier (DI) portions of it must be reported, as applicable.

(iii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iv) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(v) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment

or other transfer of value (if made to an entity) or indicate ''individual'' (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

(1) Cash or cash equivalent.

(2) In-kind items or services.

(3) Stock.

(4) Stock option.

(5) Any other ownership interest.

(6) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xviii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

(i) Consulting fee.

(ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.

(iii) Honoraria.

(iv) Gift.

(v) Entertainment.

(vi) Food and beverage.

(vii) Travel and lodging (including the specified destinations).

(viii) Education.

(ix) Research.

(x) Charitable contribution.

(xi) Debt forgiveness.

(xii) Royalty or license.

(xiii) Current or prospective ownership or investment interest.

(xiv) Compensation for serving as faculty or as a speaker for a medical education program.

(xv) Long term medical supply or device loan.

(xvi) Grant.

(xvii) Space rental or facility fees (teaching hospital only).

(xviii) Acquisitions.

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of research in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients, including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information

(in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a non-teaching hospital covered recipient, all of the following must be provided:

(*1*) The non-teaching hospital covered recipient's name as listed in the NPPES (if applicable).

(*2*) National Provider Identifier.

(*3*) State professional license number(s) (for at least one State where the non-teaching hospital covered recipient maintains a license) and State(s) in which the license is held.

(*4*) Specialty.

(*5*) Primary business address of the non-teaching hospital covered recipient(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section); for drugs and biologicals, the relevant National Drug Code(s), if any; and for devices and medical supplies, the relevant device identifier, if any, and the therapeutic area or product category if a marketed name is not available.

(v) Information about each non-teaching hospital covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(ii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(h) *Exclusions from reporting.* The following are excluded from the reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient exceeds $100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (h)(2)(i) of this section must

be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than $10 in CY 2013 (or less than the amount described in paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the $100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the $10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

(5) Short term medical supply or device loan.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a non-teaching hospital covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a non-teaching hospital covered recipient, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the context of a personal, non-business-related relationship.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014; 84 FR 63186, Nov. 15, 2019; 86 FR 65659, Nov. 19, 2021]

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family

member of a physician during the preceding calendar year.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

(i) Street address.

(ii) Suite or office number (if applicable).

(iii) City.

(iv) State.

(v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

(i) The specialty.

(ii) National Provider Identifier (if applicable and as listed in NPPES).

(iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in § 403.904(c) through (h). The terms ''applicable manufacturer and applicable group purchasing organization'' must be substituted for ''applicable manufacturer,'' and ''physician owner or investor'' must be substituted for ''covered recipient'' in each place they appear.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68001, Nov. 13, 2014]

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician's immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician's immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information. These points of contact must be updated for 2 years following record submission.

(4) An applicable manufacturer or applicable group purchasing organization that meets the definition of physician-

owned distributorship as defined in § 403.902 must identify its status as a physician-owned distributorship when registering or recertifying.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the

public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Covered recipients—

(A) Are notified using an online posting and notifications on CMS's listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the Web site at least once annually with corrected information.

[78 FR 9521, Feb. 8, 2013, as amended at 84 FR 63187, Nov. 15, 2019; 86 FR 65659, Nov. 19, 2021]

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site.

Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $1,000, but not more than $10,000, as adjusted annually under 45 CFR part 102 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed $150,000 as adjusted annually under 45 CFR part 102.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that knowingly fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, as adjusted annually under 45 CFR part 102 for each payment or other

transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed $1,000,000 as adjusted annually under 45 CFR part 102.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

(1) Aggregated separately;

(2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of $1,150,000 as adjusted annually under 45 CFR part 102.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

[78 FR 9521, Feb. 8, 2013, as amended at 81 FR 61561, Sept. 6, 2016; 82 FR 42749, Sept. 12, 2017]

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

SOURCE: 79 FR 68001, Nov. 13, 2014, unless otherwise noted.

§ 403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§ 403.1105 Definitions.

For purposes of this subpart—

Applicable titles means Titles XVIII, XIX, or XXI of the Act.

§ 403.1110 Evaluation of models.

(a) *Evaluation.* The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) *Information.* Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including ''protected health information'' as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

SOURCE: 84 FR 20757, May 10, 2019, unless otherwise noted.

§ 403.1200 Scope.

(a) *Covered pharmaceuticals.* Except as specified in paragraph (b) of this section, this subpart applies to advertisements for a prescription drug or biological product distributed in the United States for which payment is available, directly or indirectly, under titles XVIII or XIX of the Social Security Act.

(b) *Excepted pharmaceuticals.* An advertisement for any prescription drug or biological product that has a list price, as defined in § 403.1201, less than $35 per month for a 30-day supply or typical course of treatment shall be exempt from the requirements of this subpart.

§ 403.1201 Definitions.

For the purposes of this subpart, the following definitions apply:

(a) *Biological product.* Biological product means any biological product, as that term is defined in Public Health Service Act (''PHS Act'') section 351(i), that is licensed by the Food and Drug Administration pursuant to section 351 and is subject to the requirements of

Federal Food, Drug, and Cosmetic Act (FDCA) section 503(b)(1).

(b) *Prescription drug.* Prescription drug means any drug, as defined in the FDCA section 201(g), that has been approved by the Food and Drug Administration pursuant to FDCA section 505 and is subject to the requirements of FDCA section 503(b)(1).

(c) *List price.* List price means the wholesale acquisition cost, as defined in paragraph (d) of this section.

(d) *Wholesale acquisition cost.* Wholesale acquisition cost means, with respect to a prescription drug or biological product, the manufacturer's list price for the prescription drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological product pricing data.

§ 403.1202 Pricing information.

Any advertisement for any prescription drug or biological product on television (including broadcast, cable, streaming, or satellite) must contain a textual statement indicating the current list price for a typical 30-day regimen or for a typical course of treatment, whichever is most appropriate, as determined on the first day of the quarter during which the advertisement is being aired or otherwise broadcast, as follows: ''The list price for a [30-day supply of] [typical course of treatment with] [name of prescription drug or biological product] is [insert list price]. If you have health insurance that covers drugs, your cost may be different.'' Where the price is related to the typical course of treatment and that typical course of treatment varies depending on the indication for which a prescription drug or biological product is prescribed, the list price to be used is the one for the typical course of treatment associated with the primary indication addressed in the advertisement.

§ 403.1203 Specific presentation requirements.

The textual statement described in § 403.1202 shall be presented at the end of an advertisement in a legible manner, meaning that it is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily.

§ 403.1204 Compliance.

(a) *Identification of non-compliant products.* The Secretary will maintain a public list that will include the prescription drugs and biological products identified by the Secretary to be advertised in violation of this subpart.

(b) *State or local requirements.* No State or political subdivision of any State may establish or continue in effect any requirement concerning the disclosure in a television advertisement of the pricing of a prescription drug or biological product which is different from, or in addition to, any requirement imposed by this subpart.

SUBCHAPTER B—MEDICARE PROGRAM

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

Sec.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

GENERAL PROVISIONS

LIABILITY FOR PAYMENTS TO PROVIDERS AND SUPPLIERS, AND HANDLING OF INCORRECT PAYMENTS

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

REPAYMENT OF SCHOLARSHIPS AND LOANS

Subpart D—Private Contracts

Subpart E—Criteria for Determining Reasonable Charges

Subpart R—Provider Reimbursement Determinations and Appeals

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which ''absolute risk'' of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health's National Library of Medicine's online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national non-coverage decision) that are furnished during a clinical study and that would

be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013; 86 FR 3009, Jan. 14, 2021; 86 FR 62958, Nov. 15, 2021]

§ 405.203 FDA categorization of investigational devices.

(a) The FDA assigns a device with an FDA-approved IDE to one of two categories:

(1) Category A (Experimental) devices.

(2) Category B (Nonexperimental/investigational) devices.

(b) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category A (Experimental) or Category B (Nonexperimental).

(c) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013

§ 405.205 Coverage of a Category B (Nonexperimental/investigational) device.

(a) For any device that meets the requirements of the exception at § 411.15(o) of this chapter, the following procedures apply:

(1) The FDA notifies CMS, when it notifies the sponsor, that the device is categorized by FDA as Category B (Nonexperimental/investigational).

(2) CMS uses the categorization of the device as a factor in making Medicare coverage decisions.

(b) If the FDA becomes aware that a categorized device no longer meets the requirements of the exception at § 411.15(o) of this chapter, the FDA notifies the sponsor and CMS and the procedures described in paragraph (a)(2) of this section apply.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74809, Dec. 10, 2013

§ 405.207 Services related to a noncovered device.

(a) *When payment is not made.* Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act or because it is excluded from coverage for other reasons. These services include all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services.

(b) *When payment is made.* Medicare payment may be made for—

(1) Covered services to treat a condition or complication that arises due to the use of a noncovered device or a noncovered device-related service; or

(2) Routine care items and services related to Category A (Experimental) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

(3) Routine care items and services related to Category B (Nonexperimental/investigational) devices as defined in § 405.201(b), and furnished in conjunction with FDA-approved clinical studies that meet the coverage requirements in § 405.211.

[60 FR 48423, Sept. 19, 1995, as amended at 69 FR 66420, Nov. 15, 2004; 78 FR 74809, Dec. 10, 2013]

§ 405.209 Payment for a Category B (Nonexperimental/investigational) device.

Payment under Medicare for a Category B (Nonexperimental/investigational) device is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.

[78 FR 74809, Dec. 10, 2013]

§ 405.211 Coverage of items and services in FDA-approved IDE studies.

(a) *Coverage of routine care items and services for Category A (Experimental) devices.* Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.

(b) *Coverage of Category B (Nonexperimental/investigational) IDE devices and routine care items and services.* Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B (Nonexperimental/investigational) IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria in § 405.212 are met.

(c) CMS (or its designated entity) must review the following to determine if the Medicare coverage IDE study criteria in § 405.212 are met for purposes of coverage of items and services described in paragraphs (a) and (b) of this section:

(1) FDA approval letter of the IDE.

(2) IDE study protocol.

(3) IRB approval letter.

(4) NCT number.

(5) Supporting materials, as needed.

(d) *Notification.* A listing of all CMS-approved Category A (Experimental) IDE studies and Category B (Nonexperimental/investigational) IDE studies shall be posted on the CMS Web site and published in the FEDERAL REGISTER.

[78 FR 74809, Dec. 10, 2013]

§ 405.212 Medicare Coverage IDE study criteria.

(a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:

(1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.

(2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

(3) The study results are not anticipated to unjustifiably duplicate existing knowledge.

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.

(5) The study is sponsored by an organization or individual capable of successfully completing the study.

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812 and 45 CFR part 46.

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

(8) The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

(b) [Reserved]

[78 FR 74809, Dec. 10, 2013]

§ 405.213 Re-evaluation of a device categorization.

(a) *General rules.* (1) Any sponsor that does not agree with an FDA decision that categorizes its device as Category A (experimental) may request re-evaluation of the categorization decision.

(2) A sponsor may request review by CMS only after the requirements of paragraph (b) of this section are met.

(3) No reviews other than those described in paragraphs (b) and (c) of this section are available to the sponsor.

(4) Neither the FDA original categorization or re-evaluation (described

in paragraph (b) of this section) nor CMS's review (described in paragraph (c) of this section) constitute an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H, or parts 417, 473, or 498 of this chapter.

(b) *Request to FDA.* A sponsor that does not agree with the FDA's categorization of its device may submit a written request to the FDA at any time requesting re-evaluation of its original categorization decision, together with any information and rationale that it believes support recategorization. The FDA notifies both CMS and the sponsor of its decision.

(c) *Request to CMS.* If the FDA does not agree to recategorize the device, the sponsor may seek review from CMS. A device sponsor must submit its request in writing to CMS. CMS obtains copies of relevant portions of the application, the original categorization decision, and supplementary materials. CMS reviews all material submitted by the sponsor and the FDA's recommendation. CMS reviews only information in the FDA record to determine whether to change the categorization of the device. CMS issues a written decision and notifies the sponsor of the IDE and the FDA.

[60 FR 48423, Sept. 19, 1995, as amended at 78 FR 74810, Dec. 10, 2013

§ 405.215 Confidential commercial and trade secret information.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

Subpart C—Suspension of Payment, Recovery of Overpayments, and Repayment of Scholarships and Loans

AUTHORITY: Secs. 1102, 1815, 1833, 1842, 1862, 1866, 1870, 1871, 1879 and 1892 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp and 1395ccc) and 31 U.S.C. 3711.

SOURCE: 31 FR 13534, Oct. 20, 1966, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

EDITORIAL NOTE: Nomenclature changes to subpart C of part 405 appear at 76 FR 5961, Feb. 2, 2011.

GENERAL PROVISIONS

§ 405.301 Scope of subpart.

This subpart sets forth the policies and procedures for handling of incorrect payments and recovery of overpayments.

[54 FR 41733, Oct. 11, 1989]

LIABILITY FOR PAYMENTS TO PROVIDERS OR SUPPLIERS AND HANDLING OF INCORRECT PAYMENTS

§ 405.350 Individual's liability for payments made to providers and other persons for items and services furnished the individual.

Any payment made under title XVIII of the Act to any provider of services or other person with respect to any item or service furnished an individual shall be regarded as a payment to the individual, and adjustment shall be made pursuant to §§ 405.352 through 405.358 where:

(a) More than the correct amount is paid to a provider of services or other person and the Secretary determines that:

(1) Within a reasonable period of time, the excess over the correct amount cannot be recouped from the provider of services or other person, or

(2) The provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(b) A payment has been made under the provisions described in section 1814(e) of the Act, to a provider of services for items and services furnished the individual.

(c) For purposes of paragraph (a)(2) of this section, a provider of services or other person must, in the absence of evidence to the contrary, be deemed to be without fault if the determination of the carrier, the intermediary, or the Centers for Medicare & Medicaid Services that more than the correct amount was paid was made subsequent to the fifth year following the year in

which notice was sent to such individual that such amount had been paid.

[41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 61 FR 49271, Sept. 19, 1996; 78 FR 74810, Dec. 10, 2013]

§ 405.351 Incorrect payments for which the individual is not liable.

Where an incorrect payment has been made to a provider of services or other person, the individual is liable only to the extent that he has benefited from such payment.

§ 405.352 Adjustment of title XVIII incorrect payments.

Where an individual is liable for an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

[31 FR 13534, Oct. 20, 1966, as amended at 41 FR 1492, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.354 Procedures for adjustment or recovery—title II beneficiary.

The procedures applied in making an adjustment or recovery in the case of a title II beneficiary are the applicable procedures of 20 CFR 404.502.

[31 FR 13534, Oct. 20, 1966, as amended at 32 FR 18027, Dec. 16, 1967. Redesignated at 42 FR 52826, Sept. 30, 1977]

§ 405.355 Waiver of adjustment or recovery.

(a) The provisions of § 405.352 may not be applied and there may be no adjustment or recovery of an incorrect payment (i.e., a payment made under § 405.350(a) or § 405.350(b)) in any case where such incorrect payment has been made with respect to an individual who is without fault, or where such adjustment or recovery would be made by decreasing payments to which another person who is without fault is entitled as provided in section 1870(b) of the Act where such adjustment or recovery would defeat the purpose of title II or title XVIII of the Act or would be against equity and good conscience. (See 20 CFR 404.509 and 404.512.)

(b) Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as may be determined to be inconsistent with the purposes of Title XVIII of the Act) against an individual who is without fault will be deemed to be against equity and good conscience if the incorrect payment was made for items and services that are not payable under section 1862(a)(1) or (a)(9) of the Act and if the determination that such payment was incorrect was made subsequent to the fifth year following the year in which notice of such payment was sent to such individual.

[41 FR 1493, Jan. 8, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977; 78 FR 74810, Dec. 10, 2013]

§ 405.356 Principles applied in waiver of adjustment or recovery.

The principles applied in determining waiver of adjustment or recovery (§ 405.355) are the applicable principles of § 405.358 and 20 CFR 404.507–404.509, 404.510a, and 404.512.

[61 FR 49271, Sept. 19, 1996]

§ 405.357 Notice of right to waiver consideration.

Whenever an initial determination is made that more than the correct

amount of payment has been made, notice of the provisions of section 1870(c) of the Act regarding waiver of adjustment or recovery shall be sent to the overpaid individual and to any other individual against whom adjustment or recovery of the overpayment is to be effected (see § 405.358).

[61 FR 49271, Sept. 19, 1996]

§ 405.358 When waiver of adjustment or recovery may be applied.

Section 1870(c) of the Act provides that there shall be no adjustment or recovery in any case where an incorrect payment under title XVIII (hospital and supplementary medical insurance benefits) has been made (including a payment under section 1814(e) of the Act with respect to an individual:

(a) Who is without fault, and

(b) Adjustment or recovery would either:

(1) Defeat the purposes of title II or title XVIII of the Act, or

(2) Be against equity and good conscience.

[61 FR 49271, Sept. 19, 1996]

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355), or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

SUSPENSION AND RECOUPMENT OF PAYMENT TO PROVIDERS AND SUPPLIERS AND COLLECTION AND COMPROMISE OF OVERPAYMENTS

§ 405.370 Definitions.

(a) For purposes of this subpart, the following definitions apply:

Credible allegation of fraud. A credible allegation of fraud is 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.

Fraud hotline tip. 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.

Medicare contractor. Unless the context otherwise requires, includes, but is not limited to the any of following:

(1) A fiscal intermediary.

(2) A carrier.

(3) Program safeguard contractor.

(4) Zone program integrity contractor.

(5) Part A/Part B Medicare administrative contractor.

Offset. The recovery by Medicare of a non-Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness. (Examples are Public Health Service debts or Medicaid debts recovered by CMS).

Recoupment. The recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare payments and applying the amount withheld to the indebtedness.

Resolution of an investigation. An investigation of credible allegations of fraud will be considered resolved when legal action is terminated by settlement, judgment, or dismissal, or when the case is closed or dropped because of insufficient evidence to support the allegations of fraud.

Suspension of payment. The withholding of payment by a Medicare contractor from a provider or supplier of an approved Medicare payment amount before a determination of the amount of the overpayment exists, or until the resolution of an investigation of a credible allegation of fraud.

(b) For purposes of §§ 405.378 and 405.379, the following terms apply:

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does

not in itself convey standing to appeal the determination in question.

Fiscal intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

Medicare Appeals Council means the council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Medicare contractor, unless the context otherwise requires, includes, but is not limited to, a fiscal intermediary, carrier, recovery audit contractor, and Medicare administrative contractor.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Qualified Independent Contractor (QIC) Qualified Independent Contractor (QIC) means an entity which contracts with the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Vacate means to set aside a previous action.

[61 FR 63745, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 76 FR 5961, Feb. 2, 2011; 86 FR 6093, Jan. 19, 2021]

§ 405.371 Suspension, offset, and recoupment of Medicare payments to providers and suppliers of services.

(a) *General rules*—Medicare payments to providers and suppliers, as authorized under this subchapter (excluding payments to beneficiaries), may be one of the following:

(1) Suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor possesses reliable information that an overpayment exists or that the payments to be made may not be correct, although additional information may be needed for a determination.

(2) In cases of suspected fraud, suspended, in whole or in part, by CMS or a Medicare contractor if CMS or the Medicare contractor has consulted with the OIG, and, as appropriate, the Department of Justice, and determined that a credible allegation of fraud exists against a provider or supplier, unless there is good cause not to suspend payments.

(3) Offset or recouped, in whole or in part, by a Medicare contractor if the Medicare contractor or CMS has determined that the provider or supplier to whom payments are to be made has been overpaid.

(4) Suspended, in whole or in part, by CMS or a Medicare contractor if the provider or supplier has been subject to a Medicaid payment suspension under § 455.23(a)(1) of this chapter.

(b) *Good cause exceptions applicable to payment suspensions.* (1) CMS may find that good cause exists not to suspend payments or not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud if—

(i) OIG or other law enforcement agency has specifically requested that a payment suspension not be imposed because such a payment suspension may compromise or jeopardize an investigation;

(ii) It is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health;

(iii) It is determined that other available remedies implemented by CMS or a Medicare contractor more effectively or quickly protect Medicare funds than would implementing a payment suspension; or

(iv) CMS determines that a payment suspension or a continuation of a payment suspension is not in the best interests of the Medicare program.

(2) Every 180 days after the initiation of a suspension of payments based on credible allegations of fraud, CMS will—

(i) Evaluate whether there is good cause to not continue such suspension under this section; and

(ii) Request a certification from the OIG or other law enforcement agency that the matter continues to be under

investigation warranting continuation of the suspension.

(3) Good cause not to continue to suspend payments to an individual or entity against which there are credible allegations of fraud must be deemed to exist if a payment suspension has been in effect for 18 months and there has not been a resolution of the investigation, except CMS may extend a payment suspension beyond that point if—

(i) The case has been referred to, and is being considered by, the OIG for administrative action (for example, civil money penalties); or such administrative action is pending or

(ii) The Department of Justice submits a written request to CMS that the suspension of payments be continued based on the ongoing investigation and anticipated filing of criminal or civil action or both or based on a pending criminal or civil action or both. At a minimum, the request must include the following:

(A) Identification of the entity under suspension.

(B) The amount of time needed for continued suspension in order to conclude the criminal or civil proceeding or both.

(C) A statement of why or how criminal or civil action or both may be affected if the requested extension is not granted.

(c) *Steps necessary for suspension of payment, offset, and recoupment.* (1) Except as provided in paragraphs (d) and (e) of this section, CMS or the Medicare contractor suspends payments only after it has complied with the procedural requirements set forth at § 405.372.

(2) The Medicare contractor offsets or recoups payments only after it has complied with the procedural requirements set forth at § 405.373.

(d) *Suspension of payment in the case of unfiled cost reports.* (1) If a provider has failed to timely file an acceptable cost report, payment to the provider is immediately suspended in whole or in part until a cost report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled cost report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

(e) *Suspension of payment in the case of unfiled hospice cap determination reports.* (1) If a provider has failed to timely file an acceptable hospice cap determination report, payment to the provider is immediately suspended in whole or in part until a cap determination report is filed and determined by the Medicare contractor to be acceptable.

(2) In the case of an unfiled hospice cap determination report, the provisions of § 405.372 do not apply. (See § 405.372(a)(2) concerning failure to furnish other information.)

[76 FR 5961, Feb. 2, 2011, as amended at 79 FR 50509, Aug. 22, 2014; 84 FR 47852, Sept. 10, 2019]i

§ 405.372 Proceeding for suspension of payment.

(a) *Notice of intention to suspend*—(1) *General rule.* Except as provided in paragraphs (a)(2) through (a)(4) of this section, if the Medicare contractor, or CMS has determined that a suspension of payments under § 405.371(a)(1) should be put into effect, the Medicare contractor must notify the provider or supplier of the intention to suspend payments, in whole or in part, and the reasons for making the suspension.

(2) *Failure to furnish information.* The notice requirement of paragraph (a)(1) of this section does not apply if the Medicare contractor suspends payments to a provider or supplier in accordance with section 1815(a) or section 1833(e) of the Act, respectively, because the provider or supplier has failed to submit information requested by the Medicare contractor that is needed to determine the amounts due the provider or supplier. (See § 405.371(c) concerning failure to file timely acceptable cost reports.)

(3) *Harm to trust funds.* A suspension of payment may be imposed without prior notice if CMS, the intermediary, or carrier determines that the Medicare Trust Funds would be harmed by giving prior notice. CMS may base its determination on an intermediary's or carrier's belief that giving prior notice would hinder the possibility of recovering the money.

(4) *Fraud.* If the intended suspension of payment involves credible allegations of fraud under § 405.371(a)(2), CMS—

(i) In consultation with OIG and, as appropriate, the Department of Justice, determines whether to impose the suspension and if prior notice is appropriate;

(ii) Directs the Medicare contractor as to the timing and content of the notification to the provider or supplier; and

(iii) Is the real party in interest and is responsible for the decision.

(b) *Rebuttal*—(1) *If prior notice is required.* If prior notice is required under paragraph (a) of this section, the Medicare contractor must give the provider or supplier an opportunity for rebuttal in accordance with § 405.374. If a rebuttal statement is received within the specified time period, the suspension of payment goes into effect on the date stated in the notice, and the procedures and provisions set forth in § 405.375 apply. If by the end of the period specified in the notice no statement has been received, the suspension goes into effect automatically, and the procedures set forth in paragraph (c) of this section are followed.

(2) *If prior notice is not required.* If, under the provisions of paragraphs (a)(2) through (a)(4) of this section, a suspension of payment is put into effect without prior notice to the provider or supplier, the Medicare contractor must, once the suspension is in effect, give the provider or supplier an opportunity to submit a rebuttal statement as to why the suspension should be removed.

(c) *Subsequent action.* (1) If a suspension of payment is put into effect under § 405.371(a)(1), CMS or the Medicare contractor takes timely action after the suspension to obtain the additional information it may need to make a determination as to whether an overpayment exists or the payments may be made.

(i) CMS or the Medicare contractor makes all reasonable efforts to expedite the determination.

(ii) As soon as the determination is made, CMS or the Medicare contractor informs the provider or supplier and, if appropriate, the suspension is rescinded or any existing recoupment or offset is adjusted to take into account the determination.

(2)(i) If a suspension of payment is based upon credible allegations of fraud in accordance with § 405.371(a)(2), subsequent action must be taken by CMS or the Medicare contractor to make a determination as to whether an overpayment exists.

(ii) The rescission of the suspension and the issuance of a final overpayment determination to the provider or supplier may be delayed until resolution of the investigation.

(d) *Duration of suspension of payment*—(1) *General rule.* Except as provided in paragraphs (d)(2) and (d)(3) of this section, a suspension of payment is limited to 180 days, starting with the date the suspension begins.

(2) *180-day extension.* (i) An intermediary, a carrier, or, in cases of fraud and misrepresentation, OIG or a law enforcement agency, may request a one-time only extension of the suspension period for up to 180 additional days if it is unable to complete its examination of the information or investigation, as appropriate, within the 180-day time limit. The request must be submitted in writing to CMS.

(ii) Upon receipt of a request for an extension, CMS notifies the provider or supplier of the requested extension. CMS then either extends the suspension of payment for up to an additional 180 days or determines that the suspended payments are to be released to the provider or supplier.

(3) *Exceptions to the time limits.* (i) The time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply if the suspension of payments is based upon credible allegations of fraud under § 405.371(a)(2).

(ii) Although the time limits specified in paragraphs (d)(1) and (d)(2) of this section do not apply to suspensions based on credible allegations of fraud, all suspensions of payment in accordance with § 405.371(a)(2) will be temporary and will not continue after the resolution of an investigation, unless a suspension is warranted because of reliable evidence of an overpayment or that the payments to be made may not be correct, as specified in § 405.371(a)(1).

(e) *Disposition of suspended payments.* Payments suspended under the authority of § 405.371(a) are first applied to reduce or eliminate any overpayments determined by the Medicare contractor, or CMS, including any interest assessed under the provisions of § 405.378, and then applied to reduce any other obligation to CMS or to HHS. In the absence of a legal requirement that the excess be paid to another entity, the excess is released to the provider or supplier.

[61 FR 63746, Dec. 2, 1996, as amended at 76 FR 5962, Feb. 2, 2011]

§ 405.373 Proceeding for offset or recoupment.

(a) *General rule.* Except as specified in paragraphs (b) and (f) of this section, if the Medicare Administrative Contractor or CMS has determined that an offset or recoupment of payments under § 405.371(a)(3) should be put into effect, the Medicare Administrative Contractor must—

(1) Notify the provider or supplier of its intention to offset or recoup payment, in whole or in part, and the reasons for making the offset or recoupment; and

(2) Give the provider or supplier an opportunity for rebuttal in accordance with § 405.374.

(b) *Exception to recouping payment.* Paragraph (a) of this section does not apply if the Medicare Administrative Contractor, after furnishing a provider a written notice of the amount of program reimbursement in accordance with § 405.1803, recoups payment under paragraph (c) of § 405.1803. (For provider rights in this circumstance, see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843.)

(c) *Actions following receipt of rebuttal statement.* If a provider or supplier submits, in accordance with § 405.374, a statement as to why an offset or recoupment should not be put into effect on the date specified in the notice, the Medicare contractor must comply with the time limits and notification requirements of § 405.375.

(d) *No rebuttal statement received.* If, by the end of the time period specified in the notice, no statement has been received, the recoupment or offset goes into effect automatically.

(e) *Duration of recoupment or offset.* Except as provided in § 405.379, if a recoupment or offset is put into effect, it remains in effect until the earliest of the following:

(1) The overpayment and any assessed interest are liquidated.

(2) The Medicare contractor obtains a satisfactory agreement from the provider or supplier for liquidation of the overpayment.

(3) The Medicare contractor, on the basis of subsequently acquired evidence or otherwise, determines that there is no overpayment.

(f) *Exception to offset or recoupment of payments for shared Taxpayer Identification Number.* Paragraph (a) of this section does not apply in instances where the Medicare Administrative Contractor intends to offset or recoup payments to the applicable provider of services or supplier to satisfy an amount due from an obligated provider of services or supplier when the applicable and obligated provider of services or supplier share the same Taxpayer Identification Number.

[61 FR 63747, Dec. 2, 1996, as amended at 74 FR 47468, Sept. 16, 2009; 81 FR 80551, Nov. 15, 2016]

§ 405.374 Opportunity for rebuttal.

(a) *General rule.* If prior notice of the suspension of payment, offset, or recoupment is given under § 405.372 or § 405.373, the Medicare contractor must give the provider or supplier an opportunity, before the suspension, offset, or recoupment takes effect, to submit any statement (to include any pertinent information) as to why it should not be put into effect on the date specified in the notice. Except as provided in paragraph (b) of this section, the provider or supplier has at least 15 days following the date of notification to submit the statement.

(b) *Exception.* The Medicare contractor may for cause—

(1) Impose a shorter period for rebuttal; or

(2) Extend the time within which the statement must be submitted.

[61 FR 63747, Dec. 2, 1996]

§ 405.375 Time limits for, and notification of, administrative determination after receipt of rebuttal statement.

(a) *Submission and disposition of evidence.* If the provider or supplier submits a statement, under § 405.374, as to why a suspension of payment, offset, or recoupment should not be put into effect, or, under § 405.372(b)(2), why a suspension should be terminated, CMS, the intermediary, or carrier must within 15 days, from the date the statement is received, consider the statement (including any pertinent evidence submitted), together with any other material bearing upon the case, and determine whether the facts justify the suspension, offset, or recoupment or, if already initiated, justify the termination of the suspension, offset, or recoupment. Suspension, offset, or recoupment is not delayed beyond the date stated in the notice in order to review the statement.

(b) *Notification of determination.* The Medicare contractor must send written notice of the determination made under paragraph (a) of this section to the provider or supplier. The notice must—

(1) In the case of offset or recoupment, contain rationale for the determination; and

(2) In the case of suspension of payment, contain specific findings on the conditions upon which the suspension is initiated, continued, or removed and an explanatory statement of the determination.

(c) *Determination is not appealable.* A determination made under paragraph (a) of this section is not an initial determination and is not appealable.

[61 FR 63747, Dec. 2, 1996]

§ 405.376 Suspension and termination of collection action and compromise of claims for overpayment.

(a) *Basis and purpose.* This section contains requirements and procedures for the compromise of, or suspension or termination of collection action on, claims for overpayments against a provider or a supplier under the Medicare program. It is adopted under the authority of the Federal Claims Collection Act (31 U.S.C. 3711). Collection and compromise of claims against Medicare beneficiaries are explained at 20 CFR 404.515.

(b) *Definitions.* As used in this section, *debtor* means a provider of services or a physician or other supplier of services that has been overpaid under title XVIII of the Social Security Act. It includes an individual, partnership, corporation, estate, trust, or other legal entity.

(c) *Basic conditions.* A claim for recovery of Medicare overpayments against a debtor may be compromised, or collection action on it may be suspended or terminated, by the Centers for Medicare & Medicaid Services (CMS) if;

(1) The claim does not exceed $100,000, or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest; and

(2) There is no indication of fraud, the filing of a false claim, or misrepresentation on the part of the debtor or any director, partner, manager, or other party having an interest in the claim.

(d) *Basis for compromise.* A claim may be compromised for one or more of the following reasons:

(1) The debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount within a reasonable time;

(2) The debtor refuses to pay the claim in full and the United States is unable to collect the full amount within a reasonable time by legal proceedings;

(3) There is real doubt the United States can prove its case in court; or

(4) The cost of collecting the claim does not justify enforced collection of the full amount.

(e) *Basis for termination of collection action.* Collection action may be terminated for one or more of the following reasons:

(1) The United States cannot enforce collection of any significant sum;

(2) The debtor cannot be located, there is no security to be liquidated, the statute of limitations has run, and the prospects of collecting by offset are too remote to justify retention of the claim;

(3) The cost of further collection action is likely to exceed any recovery;

(4) It is determined the claim is without merit; or

(5) Evidence to substantiate the claim is no longer available.

(f) *Basis for suspension of collection action.* Collection action may be suspended for either of the following reasons if future collection action is justified based on potential productivity, including foreseeable ability to pay, and size of claim:

(1) The debtor cannot be located; or

(2) The debtor is unable to make payments on the claim or to fulfill an acceptable compromise.

(g) *Factors considered.* In determining whether a claim will be compromised, or collection action terminated or suspended, CMS will consider the following factors:

(1) Age and health of the debtor, present and potential income, inheritance prospects, possible concealment or fraudulent transfer of assets, and the availability of assets which may be reached by enforced collection proceedings, for compromise under paragraph (d)(1) of this section, termination under paragraph (e)(1) of this section, and suspension under paragraph (f)(2) of this section;

(2) Applicable exemptions available to a debtor and uncertainty concerning the price of the property in a forced sale, for compromise under paragraph (d)(2) of this section and termination under paragraph (e)(1) of this section; and

(3) The probability of proving the claim in court, the probability of full or partial recovery, the availability of necessary evidence, and related pragmatic considerations, for compromise under paragraph (d)(3) of this section.

(h) *Amount of compromise.* The amount accepted in compromise will be reasonable in relation to the amount that can be recovered by enforced collection proceedings.

Consideration shall be given to the following:

(1) The exemptions available to the debtor under State or Federal law;

(2) The time necessary to collect the overpayment;

(3) The litigative probabilities involved; and

(4) The administrative and litigative costs of collection where the cost of collecting the claim is a basis for compromise.

(i) *Payment of compromise*—(1) *Time and manner.* Payment of the amount that CMS has agreed to accept as a compromise in full settlement of a Medicare overpayment claim must be made within the time and in the manner prescribed by CMS. An overpayment claim is not compromised or settled until the full payment of the compromised amount has been made within the time and in the manner prescribed by CMS.

(2) *Failure to pay compromised amount.* Failure of the debtor or the estate to make payment as provided by the comprise reinstates the full amount of the overpayment claim, less any amounts paid prior to the default.

(j) *Effect of compromise, or suspension, or termination of collection action.* Any action taken by CMS under this section regarding the compromise of an overpayment claim, or termination or suspension of collection action on an overpayment claim, is not an initial determination for purposes of the appeal procedures under subparts G, H, and R of this part.

[43 FR 59381, Dec. 20, 1978, as amended at 57 FR 56998, Dec. 2, 1992. Redesignated and amended at 61 FR 63745, 63747, Dec. 2, 1996]

§ 405.377 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* This section implements section 1885 of the Act, which provides for withholding Medicare payments to certain Medicaid providers that have not arranged to repay Medicaid overpayments as determined by the Medicaid State agency or have failed to provide information necessary to determine the amount (if any) of overpayments.

(b) *When withholding may be used.* CMS may withhold Medicare payment to offset Medicaid overpayments that a Medicaid agency has been unable to collect if—

(1) The Medicaid agency has followed the procedure specified in § 447.31 of this chapter; and

(2) The institution or person is one described in paragraph (c) of this section and either—

(i) Has not made arrangements satisfactory to the Medicaid agency to repay the overpayment; or

(ii) Has not provided information to the Medicaid agency necessary to enable the agency to determine the existence or amount of Medicaid overpayment.

(c) *Institutions or persons affected.* Withholding under paragraph (b) of this section may be made with respect to any of the following entities that has or had in effect an agreement with a Medicaid agency to furnish services under an approved Medicaid State plan:

(1) An institutional provider that has in effect an agreement under section 1866 of the Act. (Part 489 (Provider and Supplier Agreements) implements section 1866 of the Act.)

(2) A physician or supplier that has accepted payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act. (Section 424.55 sets forth the conditions a supplier agrees to in accepting assignment.)

(d) *Amount to be withheld.* (1) CMS contacts the appropriate Medicare contractor to determine the amount of Medicare payment to which the institution or person is entitled.

(2) CMS may require the Medicare contractor to withhold Medicare payments to the institution or person by the lesser of the following amounts:

(i) The amount of the Medicare payments to which the institution or person would otherwise be entitled.

(ii) The total Medicaid overpayment to the institution or person.

(e) *Notice of withholding.* If CMS intends to withhold payments under this section, it notifies by certified mail, return receipt requested, the institution or person and the appropriate Medicare contractor of the intention to withhold Medicare payments and follows the procedure in § 405.374. The notice includes—

(1) Identification of the institution or person; and

(2) The amount of Medicaid overpayment to be withheld from payments to which the institution or person would otherwise be entitled under Medicare.

(f) *Termination of withholding.* CMS terminates the withholding if—

(1) The Medicaid overpayment is completely recovered;

(2) The institution or person enters into an agreement satisfactory to the Medicaid agency to repay the overpayment; or

(3) The Medicaid agency determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(g) *Disposition of funds withheld.* CMS releases amounts withheld under this section to the Medicaid agency to be applied against the Medicaid overpayment made by the State agency.

[61 FR 63747, Dec. 2, 1996]

§ 405.378 Interest charges on overpayment and underpayments to providers, suppliers, and other entities.

(a) *Basis and purpose.* This section, which implements sections 1815(d), 1833(j) and 1893(f)(2)(B) of the Act and common law, and authority granted under the Federal Claims Collection Act, provides for the charging and payment of interest on overpayments and underpayments to Medicare providers, suppliers, HMOs, competitive medical plans (CMPs), and health care prepayment plans (HCPPs).

(b) *Basic rules.* (1) CMS will charge interest on overpayments, and pay interest on underpayments, to providers and suppliers of services (including physicians and other practitioners), except as specified in paragraphs (f) and (h) of this section.

(2) Except as provided in paragraph (j) of this section, interest accrues from the date of the final determination as defined in paragraph (c) of this section, and either is charged on the overpayment balance or paid on the underpayment balance for each full 30-day period that payment is delayed.

(c) *Definition of final determination.* (1) For purposes of this section, any of the following constitutes a final determination:

(i) A Notice of Amount of Program Reimbursement (NPR) is issued, as discussed in §§ 405.1803, 417.576, and 417.810, and either—

(A) A written demand for payment is made; or

(B) A written determination of an underpayment is made by the intermediary after a cost report is filed.

(ii) In cases in which an NPR is not used as a notice of determination (that

is, primarily under part B), one of the following constitutes a final determination—

(A) A written determination that an overpayment exists and a written demand for payment; or

(B) A written determination of an underpayment.

(iii) Other examples of cases in which an NPR is not used are carrier reasonable charge determinations under subpart E of this part, interim cost settlements made for HMOs, CMPs, and HCPPs under §§ 417.574 and 417.810(e) of this chapter, and initial retroactive adjustment determinations under § 413.64(f)(2) of this chapter. In the case of interim cost settlements and initial retroactive adjustment determinations, if the debtor does not dispute the adjustment determination within the timeframe designated in the notice of the determination (generally at least 15 days), a final determination is deemed to have been made. If the provider or supplier does dispute portions of the determination, a final determination is deemed to have been made on those portions when the intermediary issues a new determination in response to the dispute.

(iv) The due date of a timely-filed cost report that indicates an amount is due CMS, and is not accompanied by payment in full. (If an additional overpayment or underpayment is determined by the carrier or intermediary, a final determination on the additional amount is made in accordance with paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii), of this section.)

(v) With respect to a cost report that is not filed on time, the day following the date the cost report was due (plus a single extension of time not to exceed 30 days if granted for good cause), until the time as a cost report is filed. (When the cost report is subsequently filed, there is an additional determination as specified in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section.)

(2) Except as required by any subsequent administrative or judicial reversal and specifically as provided in paragraphs (i) and (j) of this section, interest accrues from the date of final determination as specified in this section.

(d) *Rate of interest.* (1) The interest rate on overpayments and underpayments is the higher of—

(i) The rate as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of final determination as defined in paragraph (c) of this section (this rate is published quarterly in the FEDERAL REGISTER by the Department under 45 CFR 30.13(a)); or

(ii) The current value of funds rate (this rate is published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(2) [Reserved]

(e) *Accrual of interest.* (1) If a cost report is filed that does not indicate an amount is due CMS but the intermediary makes a final determination that an overpayment exists, or if a carrier makes a final determination that an overpayment to a physician or supplier exists, interest will accrue beginning with the date of such final determination. Interest will continue to accrue during periods of administrative and judicial appeal and until final disposition of the claim.

(2)(i) If a cost report is filed and indicates that an amount is due CMS, interest on the amount due will accrue from the due date of the cost report unless—

(A) Full payment on the amount due accompanies the cost report; or

(B) The provider and the intermediary agree in advance to liquidate the overpayment through a reduction in interim payments over the next 30-day period.

(ii) If the intermediary determines an additional overpayment during the cost settlement process, interest will accrue from the date of each determination.

(iii) The interest rate on each of the final determinations of an overpayment will be the rate of interest in effect on the date the determination is made.

(3) In the case of a cost report that is not filed on time, interest also will accrue on a determined overpayment from the day following the due date of the report (plus a single extension of time not to exceed 30 days if granted

for good cause, as specified in §413.24(f)) of this chapter, to the time the cost report is filed.

(4) If an intermediary or a carrier makes a final determination that an underpayment exists, interest to the provider or the supplier will accrue from the date of notification of the underpayment.

(f) *Waiver of interest charges.* (1) When an intermediary or a carrier makes a final determination that an overpayment or underpayment exists, as specified in paragraphs (e)(1), (e)(2)(ii), and (e)(4)—

(i) Interest charges will be waived if the overpayment or underpayment is completely liquidated within 30 days from the date of the final determination.

(ii) CMS may waive interest charges if it determines that the administrative cost of collecting them exceeds the interest charges.

(2) Interest will not be waived for that period of time during which the cost report was due but remained unfiled for more than 30 days, as specified in paragraph (e)(3) of this section.

(g) *Rules applicable to partial payments.* If an overpayment is repaid in installments or recouped by withholding from several payments due the provider or supplier of services—

(1) Each payment or recoupment will be applied first to accrued interest and then to the principal; and

(2) After each payment or recoupment, interest will accrue on the remaining unpaid balance.

(h) *Nonallowable cost.* As specified in §§412.113 and 413.153 of this chapter, interest accrued on overpayments and interest on funds borrowed specifically to repay overpayments are not considered allowable costs, up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(See §413.153(a)(2) of this chapter for exceptions based on administrative or judicial reversal.)

(i) *Exceptions to applicability.* (1) The provisions of this section do not apply to the time period for which interest is payable under §413.64(j) of this chapter because the provider seeks judicial review of a decision of the Provider Reimbursement Review Board, or a subsequent reversal, affirmance, or modification of that decision by the Administrator. Prior to that time, until the provider seeks judicial review, interest accrues at the rate specified in this section on outstanding unpaid balances resulting from final determinations as defined in paragraph (c) of this section.

(2) If an overpayment or an underpayment determination is reversed administratively or judicially, and the reversal is no longer subject to appeal, appropriate adjustments will be made with respect to the overpayment or underpayment and the amount of interest charged.

(j) *Special rule for provider or supplier overpayments subject to §405.379.* If an overpayment determination subject to the limitation on recoupment under §405.379 is reversed in whole or in part by an Administrative Law Judge (ALJ) or at subsequent administrative or judicial levels of appeal and if funds have been recouped and retained by the Medicare contractor, interest will be paid to the provider or supplier as follows:

(1) The applicable rate of interest is that provided in paragraph (d) of this section.

(2) The interest rate in effect on the date the ALJ, the Medicare Appeals Council, the Federal district court or subsequent appellate court issues a decision reversing the overpayment determination in whole or in part is the rate used to calculate the interest due the provider or supplier.

(3) Interest will be calculated as follows:

(i) Interest will be paid on the principal amount recouped only.

(ii) Interest will be calculated on a simple rather than a compound basis.

(iii) Interest will be calculated in full 30-day periods and will not be payable on amounts recouped for any periods of less than 30 days in which the Medicare contractor had possession of the funds.

(iv) In calculating the period in which the amount was recouped, days in which the ALJ's adjudication period to conduct a hearing are tolled under 42 CFR 405.1014 shall not be counted.

(v) In calculating the period in which the amount was recouped, days in which the Medicare Appeals Council's

adjudication period to conduct a review are tolled under 42 CFR 405.1106 shall not be counted.

(4) If the decision by the ALJ, Medicare Appeals Council, Federal district court or a subsequent Federal reviewing court, reverses the overpayment determination, as modified by prior levels of administrative or judicial review, in part, the Medicare contractor in effectuating the decision may allocate recouped monies to that part of the overpayment determination affirmed by the decision. Interest will be paid to the provider or supplier on recouped amounts that remain after this allocation in accordance with this paragraph (j) of this section.

[47 FR 54814, Dec. 6, 1982, as amended at 49 FR 36102, Sept. 14, 1984; 49 FR 44472, Nov. 7, 1984; 51 FR 34792, Sept. 30, 1986; 56 FR 31336, July 10, 1991. Redesignated at 61 FR 63745, Dec. 2, 1996; 69 FR 45607, July 30, 2004; 74 FR 47468, Sept. 16, 2009]

§ 405.379 Limitation on recoupment of provider and supplier overpayments.

(a) *Basis and purpose.* This section implements section 1893(f)(2)(A) of the Act which limits recoupment of Medicare overpayments if a provider of services or supplier seeks a reconsideration until a decision is rendered by a Qualified Independent Contractor (QIC). This section also limits recoupment of Medicare overpayments when a provider or supplier seeks a redetermination until a redetermination decision is rendered.

(b) *Overpayments subject to limitation.* (1) This section applies to overpayments that meet the following criteria:

(i) Is one of the following types of overpayments:

(A) Post-pay denial of claims for benefits under Medicare Part A which is determined and for which a written demand for payment has been made on or after November 24, 2003; or

(B) Post-pay denial of claims for benefits under Medicare Part B which is determined and for which a written demand for payment has been made on or after October 29, 2003; or

(C) Medicare Secondary Payer (MSP) recovery where the provider or supplier received a duplicate primary payment and for which a written demand for payment was issued on or after October 10, 2003; or

(D) Medicare Secondary Payer (MSP) recovery based on the provider's or supplier's failure to file a proper claim with the third party payer plan, program, or insurer for payment and, if Part A, demanded on or after November 24, 2003, or, if Part B, demanded on or after October 29, 2003; and

(ii) The provider or supplier can appeal the overpayment as a revised initial determination under the Medicare claims appeal process at 42 CFR parts 401 and 405 or as an initial determination for provider/supplier MSP duplicate primary payment recoveries.

(2) This section does not apply to all other overpayments including, but not limited to, the following:

(i) All Medicare Secondary Payer recoveries except those expressly identified in paragraphs (b)(1)(i)(C) and (D) of this section;

(ii) Beneficiary overpayments; and

(iii) Overpayments that arise from a cost report determination and are appealed under the provider reimbursement process of 42 CFR part 405 Subpart R—Provider Reimbursement Determinations and Appeals.

(c) *Rules of construction.* (1) For purposes of this section, what constitutes a valid and timely request for a redetermination is to be determined in accordance with § 405.940 through § 405.958.

(2) For purposes of this section, what constitutes a valid and timely request for a reconsideration is to be determined in accordance with § 405.960 through § 405.978.

(d) *General rules.* (1) Medicare contractors can begin recoupment no earlier than 41 days from the date of the initial overpayment demand but shall cease recoupment of the overpayment in question, upon receipt of a timely and valid request for a redetermination of an overpayment. If the recoupment has not yet gone into effect, the contractor shall not initiate recoupment.

(2) If the redetermination decision is an affirmation in whole or in part of the overpayment determination, recoupment may be initiated or resumed in accordance with paragraph (e) of this section.

(3) Upon receipt of a timely and valid request for a reconsideration of an

overpayment, the Medicare contractor shall cease recoupment of the overpayment in question. If the recoupment has not yet gone into effect, the contractor must not initiate recoupment.

(4) The contractor may initiate or resume recoupment following action by the QIC in accordance with paragraph (f) of this section.

(5) If the provider or supplier subsequently appeals the overpayment to the ALJ, the Medicare Appeals Council, or Federal court, recoupment remains in effect as provided in § 405.373(e).

(6) If an overpayment determination is appealed and recoupment stopped, the contractor may continue to recoup other overpayments owed by the provider or supplier in accordance with this section.

(7) Amounts recouped prior to a reconsideration decision may be retained by the Medicare contractor in accordance with paragraph (g) of this section.

(8) If either the redetermination or reconsideration decision is a full reversal of the overpayment determination or if the overpayment determination is reversed in whole or in part at subsequent levels of administrative or judicial appeal, adjustments shall be made with respect to the overpayment and the amount of interest charged.

(9) Interest accrues and is payable in accordance with the provisions of § 405.378.

(e) *Initiating or resuming recoupment after redetermination decision.* (1) Recoupment that has been deferred or stopped may be initiated or resumed if the debt (remaining unpaid principal balance and interest) has not been satisfied in full and the provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375. Recoupment may be resumed under any of the following circumstances:

(i) Immediately upon receipt by the Medicare contractor of the provider's or supplier's request for a withdrawal of a request for a redetermination in accordance with § 405.952(a).

(ii) On the 60th calendar day after the date of the notice of redetermination issued under § 405.956 if the redetermination decision is an affirmation in whole of the overpayment determination in question.

(iii) On the 60th calendar day after the date of the written notice to the provider or supplier of the revised overpayment amount, if the redetermination decision is an affirmation in part, which has the effect of reducing the amount of the overpayment.

(2) Notwithstanding paragraphs (e)(i), (ii) and (iii) of this section, recoupment must not be resumed, or if resumed, must cease upon receipt of a timely and valid request for a reconsideration by the QIC.

(f) *Initiating or resuming recoupment following action by the QIC on the reconsideration request.* (1) Recoupment may be initiated or resumed upon action by the QIC subject to the following limitations:

(i) The provider or supplier has been afforded the opportunity for rebuttal in accordance with the requirements of § 405.373 through § 405.375; and

(ii) The debt (remaining unpaid principal balance and interest) has not been satisfied in full; and

(iii) If the action by the QIC is the notice of the reconsideration, the reconsideration decision either affirms in whole or in part the overpayment determination, including the redetermination, in question.

(2) For purposes of this paragraph (f), the action by the QIC on the reconsideration request is the earliest to occur of the following:

(i) The QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request in its entirety in accordance with § 405.972; or

(ii) The QIC receives a timely and valid request to withdraw the request for the reconsideration in accordance with § 405.972; or

(iii) The QIC transmits written notice of the reconsideration in accordance with § 405.976; or

(iv) The QIC notifies the parties in writing that the reconsideration is being escalated to an ALJ in accordance with § 405.970.

(g) *Disposition of funds recouped.* (1) If the Medicare contractor recouped funds before a timely and valid request for a redetermination was received, the amount recouped may be retained and applied first to accrued interest and

then to reduce or eliminate the principal balance of the overpayment subject to the following:

(i) If the redetermination results in a reversal, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider.

(ii) If the redetermination results in a partial reversal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier before any excess is released to the provider or supplier.

(iii) If the redetermination results in an affirmation and the provider or supplier subsequently requests a reconsideration, the Medicare contractor may retain the amount recouped and apply the funds first to accrued interest and then to outstanding principal pending action by the QIC on the reconsideration request.

(2) If the Medicare contractor also recouped funds in accordance with paragraph (e) of this section, the amount recouped may be retained by the Medicare contractor and applied first to accrued interest and then to reduce or eliminate the outstanding principal balance pending action by the QIC on the reconsideration request.

(3) If the action by the QIC is a dismissal, receipt of a withdrawal, a notice that the reconsideration is being escalated to an ALJ, or a reconsideration which affirms in whole the overpayment determination, including the redetermination, in question, the amount recouped is applied to interest first, then to reduce the outstanding principal balance and recoupment may be resumed as provided under paragraph (f) of this section.

(4) If the action by the QIC is a reconsideration, which reverses in whole the overpayment determination, including the redetermination, in question, the amount recouped may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(5) If the action by the QIC is a reconsideration which results in a partial reversal and the decision reduces the overpayment plus assessed interest below the amount already recouped, the excess may be applied to any other debt, including interest, owed by the provider or supplier to CMS or to HHS before any excess is released to the provider or supplier.

(h) *Relationship to extended repayment schedules.* Notwithstanding § 401.607 (c)(2)(v) of this chapter regarding an extended repayment schedule (ERS), a provider or supplier will not be deemed in default if recoupment of an overpayment is not effectuated or stopped in accordance with this section, and the following conditions are met:

(1) The provider or supplier has been granted an ERS under § 401.607(c) of this chapter.

(2) The ERS has been granted for an overpayment that is listed in paragraph (b) of this section.

(3) The provider or supplier has submitted a valid and timely request to the Medicare contractor for a redetermination of the overpayment in accordance with §§ 405.940 through 405.958 or reconsideration of the overpayment in accordance with §§ 405.960 through 405.978.

[74 FR 47469, Sept. 16, 2009]

REPAYMENT OF SCHOLARSHIPS AND LOANS

§ 405.380 Collection of past-due amounts on scholarship and loan programs.

(a) *Basis and purpose.* This section implements section 1892 of the Act, which authorizes the Secretary to deduct from Medicare payments for services amounts considered as past-due obligations under the National Health Service Corps Scholarship program, the Physician Shortage Area Scholarship program, and the Health Education Assistance Loan program.

(b) *Offsetting against Medicare payment.* (1) Medicare carriers and intermediaries offset against Medicare payments in accordance with the signed repayment agreement between the Public Health Service and individuals who have breached their scholarship or loan obligations and who—

(i) Accept Medicare assignment for services;

(ii) Are employed by or affiliated with a provider, HMO, or Competitive Medical Plan (CMP) that receives Medicare payment for services; or

(iii) Are members of a group practice that receives Medicare payment for services.

(2) For purposes of this section, ''provider'' includes all entities eligible to receive Medicare payment in accordance with an agreement under section 1866 of the Act.

(c) *Beginning of offset.* (1) The Medicare carrier offsets Medicare payments beginning six months after it notifies the individual or the group practice of the amount to be deducted and the particular individual to whom the deductions are attributable.

(2) The Medicare intermediary offsets payments beginning six months after it notifies the provider, HMO, CMP or group practice of the amount to be deducted and the particular individuals to whom the deductions are attributable. Offset of payments is made in accordance with the terms of the repayment agreement. If the individual ceases to be employed by the provider, HMO, or CMP, or leaves the group practice, no deduction is made.

(d) *Refusal to offset against Medicare payment.* If the individual refuses to enter into a repayment agreement, or breaches any provision of the agreement, or if Medicare payment is insufficient to maintain the offset collection according to the agreed upon formula, then—

(1) The Department, within 30 days if feasible, informs the Attorney General; and

(2) The Department excludes the individual from Medicare until the entire past due obligation has been repaid, unless the individual is a sole community practitioner or the sole source of essential specialized services in a community and the State requests that the individual not be excluded.

[57 FR 19092, May 4, 1992]

Subpart D—Private Contracts

AUTHORITY: Secs. 1102, 1802, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395a, and 1395hh).

SOURCE: 63 FR 58901, Nov. 2, 1998, unless otherwise noted.

§ 405.400 Definitions.

For purposes of this subpart, the following definitions apply:

Beneficiary means an individual who is enrolled in Part B of Medicare.

Emergency care 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.

Legal representative means one or more individuals who, as determined by applicable State law, has the legal authority to enter into the contract with the physician or practitioner on behalf of the beneficiary.

Opt-out means the status of meeting the conditions specified in § 405.410.

Opt-out period means, with respect to an affidavit that meets the requirements of § 405.420, a 2-year period beginning on the date the affidavit is signed, as specified by § 405.410(c)(1) or (2) as applicable, and each successive 2-year period unless the physician or practitioner properly cancels opt-out in accordance with § 405.445.

Participating physician means a ''physician'' as defined in this section who has signed an agreement to participate in Part B of Medicare.

Physician means a doctor of medicine; doctor of osteopathy; doctor of dental surgery or of dental medicine; doctor of podiatric medicine; or doctor of optometry who is legally authorized to practice medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions.

Practitioner means a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, mental health counselor, registered dietitian or nutrition professional, who is currently legally authorized to practice in that capacity by each State in

which he or she furnishes services to patients or clients.

Private contract means a document that meets the criteria specified in § 405.415.

Properly opt-out means to complete, without defect, the requirements for opt-out as specified in § 405.410.

Properly terminate opt-out means to complete, without defect, the requirements for terminating opt-out as specified in § 405.445.

Urgent care services means services furnished to an individual who requires services to be furnished within 12 hours in order to avoid the likely onset of an emergency medical condition.

[63 FR 58901, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 71 FR 69782, Dec. 1, 2006; 79 FR 68001, Nov. 13, 2014; 80 FR 71370, Nov. 16, 2015; 88 FR 79523, Nov. 16, 2023]

§ 405.405 General rules.

(a) A physician or practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare, provided the conditions of this subpart are met.

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts out of Medicare for the opt-out period described in § 405.400 unless the opt-out is terminated early according to § 405.445.

(c) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void if the physician or practitioner fails to properly opt-out in accordance with the conditions of this subpart.

(d) Both the private contracts described in paragraph (a) of this section and the physician's or practitioner's opt-out described in paragraph (b) of this section are null and void for the remainder of the opt-out period if the physician or practitioner fails to remain in compliance with the conditions of this subpart during the opt-out period.

(e) Services furnished under private contracts meeting the requirements of this subpart are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly, except as permitted in accordance with § 405.435(c).

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.410 Conditions for properly opting-out of Medicare.

The following conditions must be met for a physician or practitioner to properly opt-out of Medicare:

(a) Each private contract between a physician or a practitioner and a Medicare beneficiary that is entered into prior to the submission of the affidavit described in paragraph (b) of this section must meet the specifications of § 405.415.

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare Administrative Contractor with which he or she would file claims absent the opt-out.

(c) A nonparticipating physician or a practitioner may opt-out of Medicare at any time in accordance with the following:

(1) The initial 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file the opt-out affidavit(s) as specified in the previous paragraph, the initial 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit, and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in

§ 405.420 is submitted to the participating physician's Medicare Administrative Contractors at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter, and the furnishing of any items or services to a Medicare beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.415 Requirements of the private contract.

A private contract under this subpart must:

(a) Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract.

(b) Clearly state whether the physician or practitioner is excluded from Medicare under sections 1128, 1156, or 1892 or any other section of the Social Security Act.

(c) State that the beneficiary or his or her legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician or practitioner.

(d) State that the beneficiary or his or her legal representative understands that Medicare limits do not apply to what the physician or practitioner may charge for items or services furnished by the physician or practitioner.

(e) State that the beneficiary or his or her legal representative agrees not to submit a claim to Medicare or to ask the physician or practitioner to submit a claim to Medicare.

(f) State that the beneficiary or his or her legal representative understands that Medicare payment will not be made for any items or services furnished by the physician or practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted.

(g) State that the beneficiary or his or her legal representative enters into this contract with the knowledge that he or she has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted-out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted-out.

(h) State the expected or known effective date and the expected or known expiration date of the current 2-year opt-out period.

(i) State that the beneficiary or his or her legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare.

(j) Be signed by the beneficiary or his or her legal representative and by the physician or practitioner.

(k) Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician or practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with § 405.440.)

(l) Be provided (a photocopy is permissible) to the beneficiary or to his or her legal representative before items or services are furnished to the beneficiary under the terms of the contract.

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the current 2-year opt-out period.

(n) Be made available to CMS upon request.

(o) Be entered into for each 2-year opt-out period.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71370, Nov. 16, 2015]

§ 405.420 Requirements of the opt-out affidavit.

An affidavit under this subpart must:

(a) Be in writing and be signed by the physician or practitioner.

(b) Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number, if one has been assigned, uniform provider identification number (UPIN) if one has been assigned, or, if neither an NPI nor a

UPIN has been assigned, the physician's or practitioner's tax identification number (TIN).

(c) State that, except for emergency or urgent care services (as specified in § 405.440), during the opt-out period the physician or practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of paragraph § 405.415 for services that, but for their provision under a private contract, would have been Medicare-covered services.

(d) State that the physician or practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician or practitioner permit any entity acting on his or her behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in § 405.440.

(e) State that, during the opt-out period, the physician or practitioner understands that he or she may receive no direct or indirect Medicare payment for services that he or she furnishes to Medicare beneficiaries with whom he or she has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan.

(f) State that a physician or practitioner who opts-out of Medicare acknowledges that, during the opt-out period, his or her services are not covered under Medicare and that no Medicare payment may be made to any entity for his or her services, directly or on a capitated basis.

(g) State a promise by the physician or practitioner to the effect that, during the opt-out period, the physician or practitioner agrees to be bound by the terms of both the affidavit and the private contracts that he or she has entered into.

(h) Acknowledge that the physician or practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician or practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom he or she has not previously privately contracted) without regard to any payment arrangements the physician or practitioner may make.

(i) With respect to a physician who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit.

(j) Acknowledge that the physician or practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of § 405.440 apply if the physician furnishes such services.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014]

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart, the following results obtain during the opt-out period:

(a) Except as provided in § 405.440, no payment may be made directly by Medicare or by any Medicare Advantage plan to the physician or practitioner or to any entity to which the physician or practitioner reassigns his right to receive payment for services.

(b) The physician or practitioner may not furnish any item or service that would otherwise be covered by Medicare (except for emergency or urgent care services) to any Medicare beneficiary except through a private contract that meets the requirements of this subpart.

(c) The physician or practitioner is not subject to the requirement to submit a claim for items or services furnished to a Medicare beneficiary, as specified in § 424.5(a)(6) of this chapter, except as provided in § 405.440.

(d) The physician or practitioner is prohibited from submitting a claim to Medicare for items or services furnished to a Medicare beneficiary except as provided in § 405.440.

(e) In the case of a physician, he or she is not subject to the limiting charge provisions of § 414.48 of this

chapter, except for services provided under § 405.440.

(f) The physician or practitioner is not subject to the prohibition-on-reassignment provisions of § 414.80 of this chapter, except for services provided under § 405.440.

(g) In the case of a practitioner, he or she is not prohibited from billing or collecting amounts from beneficiaries (as provided in 42 U.S.C. 1395u(b)(18)(B)).

(h) The death of a beneficiary who has entered into a private contract (or whose legal representative has done so) does not invoke § 424.62 or § 424.64 of this chapter with respect to the physician or practitioner with whom the beneficiary (or legal representative) has privately contracted.

(i) The physician or practitioner who has not been excluded under sections 1128, 1156 or 1892 of the Act and whose Medicare enrollment is not revoked under § 424.535 of this chapter may order, certify the need for, prescribe, or refer a beneficiary for Medicare-covered items, services, and drugs, provided the physician or practitioner is not paid, directly or indirectly, for such services (except as provided in § 405.440).

(j) The physician or practitioner who is excluded under sections 1128, 1156 or 1892 of the Act or whose Medicare enrollment is revoked under § 424.535 of this chapter may not order, prescribe or certify the need for Medicare-covered items, services, and drugs except, with respect to exclusions, as provided in § 1001.1901 of this title, and must otherwise comply with the terms of any exclusion in accordance with § 1001.1901 of this title effective with the date of the exclusion.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014; 80 FR 71370, Nov. 16, 2015; 84 FR 47852, Sept. 10, 2019]

§ 405.430 Failure to properly opt-out.

(a) A physician or practitioner fails to properly opt-out if—

(1) Any private contract between the physician or practitioner and a Medicare beneficiary, that was entered into before the affidavit described in § 405.420 was filed, does not meet the specifications of § 405.415; or

(2) He or she fails to submit the affidavit(s) in accordance with § 405.420.

(b) If a physician or practitioner fails to properly opt-out in accordance with paragraph (a) of this section, the following results obtain:

(1) The physician's or practitioner's attempt to opt-out of Medicare is nullified, and all of the private contracts between the physician or practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt-out are deemed null and void.

(2) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician is subject to the limiting charge provisions of § 414.48 of this chapter. A participating physician is subject to the limitations on charges of the participation agreement he or she signed.

(3) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(4) The practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts.

(5) The physician or practitioner may make another attempt to properly opt-out at any time.

§ 405.435 Failure to maintain opt-out.

(a) A physician or practitioner fails to maintain opt-out under this subpart if, during the opt-out period—

(1) He or she knowingly and willfully—

(i) Submits a claim for Medicare payment (except as provided in § 405.440); or

(ii) Receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in § 405.440).

(2) He or she fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into contracts that fail to meet the specifications of § 405.415; or

(3) He or she fails to comply with the provisions of § 405.440 regarding billing

for emergency care services or urgent care services; or

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the current 2-year period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) If a physician or practitioner fails to maintain opt-out in accordance with paragraph (a) of this section, then, for the remainder of the opt-out period, except as provided by paragraph (d) of this section—

(1) All of the private contracts between the physician or practitioner and Medicare beneficiaries are deemed null and void.

(2) The physician's or practitioner's opt-out of Medicare is nullified.

(3) The physician or practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries.

(4) The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as provided in paragraph (c) of this section.

(5) The physician is subject to the limiting charge provisions of § 414.48 of this chapter.

(6) The practitioner may not reassign any claim except as provided in § 424.80 of this chapter.

(7) The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the current 2-year period expires.

(c) Medicare payment may be made for the claims submitted by a beneficiary for the services of an opt-out physician or practitioner when the physician or practitioner did not privately contract with the beneficiary for services that were not emergency care services or urgent care services and that were furnished no later than 15 days after the date of a notice by the carrier that the physician or practitioner has opted-out of Medicare.

(d) If a physician or practitioner demonstrates that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract) within 45 days of a notice from the Medicare Administrative Contractor of a violation of paragraph (a) of this section, then the requirements of paragraphs (b)(1) through (8) of this section are not applicable. In situations where a violation of paragraph (a) of this section is not discovered by the Medicare Administrative Contractor during the current 2-year period when the violation actually occurred, then the requirements of paragraphs (b)(1) through (8) of this section are applicable from the date that the first violation of paragraph (a) of this section occurred until the end of the 2-year period during which the violation occurred unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the Medicare Administrative Contractor that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (a) of this section. Good faith efforts include, but are not limited to, refunding any amounts collected in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract.

[63 FR 58901, Nov. 2, 1998, as amended at 70 FR 70329, Nov. 21, 2005; 80 FR 71370, Nov. 16, 2015]

§ 405.440 Emergency and urgent care services.

(a) A physician or practitioner who has opted-out of Medicare under this subpart need not enter into a private contract to furnish emergency care services or urgent care services to a Medicare beneficiary. Accordingly, a physician or practitioner will not be determined to have failed to maintain opt-out if he or she furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, provided the physician or practitioner complies with the billing requirements specified in paragraph (b) of this section.

(b) When a physician or practitioner who has not been excluded under sections 1128, 1156, or 1892 of the Social Security Act furnishes emergency care services or urgent care services to a Medicare beneficiary with whom the physician or practitioner has not previously entered into a private contract, he or she:

(1) Must submit a claim to Medicare in accordance with both 42 CFR part 424 and Medicare instructions (including but not limited to complying with proper coding of emergency or urgent care services furnished by physicians and practitioners who have opted-out of Medicare).

(2) May collect no more than—

(i) The Medicare limiting charge, in the case of a physician; or

(ii) The deductible and coinsurance, in the case of a practitioner.

(c) Emergency care services or urgent care services furnished to a Medicare beneficiary with whom the physician or practitioner has previously entered into a private contract (that is, entered into before the onset of the emergency medical condition or urgent medical condition), are furnished under the terms of the private contract.

(d) Medicare may make payment for emergency care services or urgent care services furnished by a physician or practitioner who has properly opted-out when the services are furnished and the claim for services is made in accordance with this section. A physician or practitioner who has been excluded must comply with the regulations at §1001.1901 (Scope and effect of exclusion) of this title when he or she furnishes emergency services to beneficiaries and may not bill and be paid for urgent care services.

§ 405.445 Cancellation of opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written notice to each Medicare Administrative Contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

(b) To properly terminate opt-out a physician or practitioner must:

(1) Not have previously opted out of Medicare.

(2) Notify all Medicare Administrative Contractors, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the initial 2-year period.

(3) Refund to each beneficiary with whom he or she has privately contracted all payment collected in excess of:

(i) The Medicare limiting charge (in the case of physicians); or

(ii) The deductible and coinsurance (in the case of practitioners).

(4) Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt-out and of the beneficiaries' right to have claims filed on their behalf with Medicare for the services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

(c) When the physician or practitioner properly terminates opt-out in accordance with paragraph (b), he or she will be reinstated in Medicare as if there had been no opt-out, and the provision of §405.425 shall not apply unless the physician or practitioner subsequently properly opts out.

(d) A physician or practitioner who has completed opt-out on or before January 1, 1999 may terminate opt-out during the 90 days following January 1, 1999 if he or she notifies all carriers to whom he or she would otherwise submit claims of the intent to terminate opt-out and complies with paragraphs (b)(3) and (4) of this section. Paragraph (c) of this section applies in these cases.

[63 FR 58901, Nov. 2, 1998, as amended at 80 FR 71371, Nov. 16, 2015]

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, failed to properly terminate opt-out, or failed to

properly cancel opt-out is an initial determination for purposes of § 498.3(b) of this chapter.

(b) A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted-out is an initial determination for purposes of § 405.924.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014; 80 FR 71371, Nov. 16, 2015]

§ 405.455 Application to Medicare Advantage contracts.

An organization that has a contract with CMS to provide one or more Medicare Advantage (M + C) plans to beneficiaries (part 422 of this chapter):

(a) Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted-out of Medicare.

(b) Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted-out of Medicare.

(c) May make payment to a physician or practitioner who furnishes emergency or urgent care services to a beneficiary who has not previously entered into a private contract with the physician or practitioner in accordance with § 405.440.

[63 FR 58901, Nov. 2, 1998, as amended at 79 FR 68001, Nov. 13, 2014]

Subpart E—Criteria for Determining Reasonable Charges

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 32 FR 12599, Aug. 31, 1967, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§ 405.500 Basis.

Subpart E is based on the provisions of the following sections of the Act: Section 1814(b) provides for Part A payment on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1832 establishes the scope of benefits provided under the Part B supplementary medical insurance program. Section 1833(a) sets forth the amounts of payment for supplementary medical insurance services on the basis of the lesser of a provider's reasonable costs or customary charges. Section 1834(a) specifies how payments are made for the purchase or rental of new and used durable medical equipment for Medicare beneficiaries. Section 1834(b) provides for payment for radiologist services on a fee schedule basis. Section 1834(c) provides for payments and standards for screening mammography. Section 1842(b) sets forth the provisions for a carrier to enter into a contract with the Secretary and to make determinations with respect to Part B claims. Section 1842(h) sets forth the requirements for a physician or supplier to voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. Section 1842(i) sets forth the provisions for the payment of Part B claims. Section 1848 establishes a fee schedule for payment of physician services. Section 1861(b) sets forth the inpatient hospital services covered by the Medicare program. Section 1861(s) sets forth medical and other health services covered by the Medicare program. Section 1861(v) sets forth the general authority under which CMS may establish limits on provider costs recognized as reasonable in determining Medicare program payments. Section 1861(aa) sets forth the rural health clinic services and Federally qualified health center services covered by the Medicare program. Section 1861(jj) defines the term ''covered osteoporosis drug.'' Section 1862(a)(14) lists services that are excluded from coverage. Section 1866(a) specifies the terms for provider agreements. Section 1881 authorizes special rules for the coverage of and payment for services furnished to patients with end-stage renal disease. Section 1886 sets forth the requirements for payment to hospitals for inpatient hospital services. Section 1887 sets forth requirements for payment of provider-based physicians and payment under certain percentage arrangements. Section 1889 provides for Medicare and Medigap information by telephone.

[60 FR 63175, Dec. 8, 1995]

§ 405.501 Determination of reasonable charges.

(a) Except as specified in paragraphs (b), (c), and (d) of this section, Medicare pays no more for Part B medical and other health services than the ''reasonable charge'' for such service. The reasonable charge is determined by the carriers (subject to any deductible and coinsurance amounts as specified in §§ 410.152 and 410.160 of this chapter).

(b) Part B of Medicare pays on the basis of ''reasonable cost'' (see part 413 of this chapter) for certain institutional services, certain services furnished under arrangements with institutions, and services furnished by entities that elect to be paid on a cost basis (including health maintenance organizations, rural health clinics, FQHCs that are authorized to bill under a reasonable cost system, and end-stage renal disease facilities).

(c) Carriers will determine the reasonable charge on the basis of the criteria specified in § 405.502, and the customary and prevailing charge screens in effect when the service was furnished. (Also see §§ 415.55 through 415.70 and §§ 415.100 through 415.130 of this chapter, which pertain to the determination of reimbursement for services performed by hospital-based physicians.) However, when services are furnished more than 12 months before the beginning of the fee screen year (January 1 through December 30) in which a request for payment is made, payment is based on the customary and prevailing charge screens in effect for the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is made.

(d) Payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

[47 FR 63274, Dec. 31, 1981, as amended at 51 FR 34978, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986; 54 FR 9003, Mar. 2, 1989; 57 FR 24975, June 12, 1992; 57 FR 33896, July 31, 1992; 57 FR 57688, Dec. 7, 1992; 60 FR 63176, Dec. 8, 1995; 79 FR 25473, May 2, 2014]

§ 405.502 Criteria for determining reasonable charges.

(a) *Criteria.* The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:

(1) The customary charges for similar services generally made by the physician or other person furnishing such services.

(2) The prevailing charges in the locality for similar services.

(3) In the case of physicians' services, the prevailing charges adjusted to reflect economic changes as provided under § 405.504 of this subpart.

(4) In the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services), the inflation-indexed charge as determined under § 405.509.

(5) [Reserved]

(6) In the case of medical services, supplies, and equipment (including equipment servicing) that the Secretary judges do not generally vary significantly in quality from one supplier to another, the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality.

(7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in paragraphs (g) and (h) of this section.

(8) In the case of laboratory services billed by a physician but performed by an outside laboratory, the payment levels established in accordance with the criteria stated in § 405.515.

(9) Except as provided in paragraph (a)(10) of this section, in the case of services of assistants-at-surgery as defined in § 405.580 in teaching and non-

teaching settings, charges that are not more than 16 percent of the prevailing charge in the locality, adjusted by the economic index, for the surgical procedure performed by the primary surgeon. Payment is prohibited for the services of an assistant-at-surgery in surgical procedures for which CMS has determined that assistants-at-surgery on average are used in less than 5 percent of such procedures nationally.

(10) In the case of services of assistants at surgery that meet the exception under § 415.190(c)(2) or (c)(3) of this chapter because the physician is performing a unique, necessary, specialized medical service in the total care of a patient during surgery, reasonable charges consistent with prevailing practice in the carrier's service area rather than the special assistant at surgery rate.

(b) *Comparable services limitation.* The law also specifies that the reasonable charge cannot be higher than the charge applicable for a comparable service under comparable circumstances to the carriers' own policyholders and subscribers.

(c) *Application of criteria.* In applying these criteria, the carriers are to exercise judgment based on factual data on the charges made by physicians to patients generally and by other persons to the public in general and on special factors that may exist in individual cases so that determinations of reasonable charge are realistic and equitable.

(d) *Responsibility of Administration and carriers.* Determinations by carriers of reasonable charge are not reviewed on a case-by-case basis by the Centers for Medicare & Medicaid Services, although the general procedures and performance of functions by carriers are evaluated. In making determinations, carriers apply the provisions of the law under broad principles issued by the Centers for Medicare & Medicaid Services. These principles are intended to assure overall consistency among carriers in their determinations of reasonable charge. The principles in §§ 405.503 through 405.507 establish the criteria for making such determinations in accordance with the statutory provisions.

(e) *Determination of reasonable charges under the End-Stage Renal Disease (ESRD) Program*—(1) *General.* Reasonable charges for renal-related items and services (furnished in connection with transplantation or dialysis) must be related to costs and allowances that are reasonable when the treatments are furnished in an effective and economical manner.

(2) *Nonprovider (independent) dialysis facilities.* Reasonable charges for renal-related items and services furnished before August 1, 1983 must be determined related to costs and charges prior to July, 1973, in accordance with the regulations at § 405.541. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(3) *Provider services and (hospital-based) dialysis facilities.* Renal-related items and services furnished by providers, or by ESRD facilities based in hospitals, before August 1, 1983 are paid for under the provider reimbursement provisions found generally in part 413 of this chapter. Items and services related to outpatient maintenance dialysis that are furnished after that date are paid for in accordance with §§ 405.544 and 413.170 of this chapter.

(4) *Physicians' services.* Reasonable charges for renal-related physicians' services must be determined considering charges made for other services involving comparable physicians' time and skill requirements, in accordance with regulations at §§ 405.542 and 405.543.

(5) *Health maintenance organizations (HMOs).* For special rules concerning the reimbursement of ESRD services furnished by risk-basis HMOs, or by facilities owned or operated by or related to such HMOs by common ownership or control, see §§ 405.2042(b)(14) and 405.2050(c).

(f) *Determining payments for certain physician services furnished in outpatient hospital settings*—(1) *General rule.* If physician services of the type routinely furnished in physicians' offices are furnished in outpatient hospital settings before January 1, 1992, carriers determine the reasonable charge for those services by applying the limits described in paragraph (f)(5) of this section.

(2) *Definition.* As used in this paragraph (f), *outpatient settings* means—

(i) Hospital outpatient departments, including clinics and emergency rooms; and

(ii) Comprehensive outpatient rehabilitation facilities.

(3) *Services covered by limits.* The carrier establishes a list of services routinely furnished in physicians' offices in the area. The carrier has the discretion to determine which professional services are routinely furnished in physicians' offices, based on current medical practice in the area. Listed below are some examples of routine services furnished by office-based physicians.

Examples

Review of recent history, determination of blood pressure, ausculation of heart and lungs, and adjustment of medication.

Brief history and examination, and initiation of diagnostic and treatment programs.

Treatment of an acute respiratory infection.

(4) *Services excluded from limits.* The limits established under this paragraph do not apply to the following:

(i) Rural health clinic services.

(ii) Surgical services included on the ambulatory surgical center list of procedures published under § 416.65(c) of this chapter.

(iii) Services furnished in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the patient's health in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part.

(iv) Anesthesiology services and diagnostic and therapeutic radiology services.

(v) Federally qualified health center services paid under the rules in part 405 subpart X.

(5) *Methodology for developing limits*—(i) *Development of a charge base.* The carrier establishes a charge base for each service identified as a routine office-based physician service. The charge base consists of the prevailing charge in the locality for each such service adjusted by the economic index. The carrier uses the prevailing charges that apply to services by nonspecialists in office practices in the locality in which the outpatient setting is located.

(ii) *Calculation of the outpatient limits.* The carrier calculates the charge limit for each service by multiplying the charge base amount for each service by .60.

(6) *Application of limits.* The reasonable charge for physician services of the type described in paragraph (f)(3) of this section that are furnished in an outpatient setting is the lowest of the actual charges, the customary charges in accordance with § 405.503, the prevailing charges applicable to these services in accordance with § 405.504, or the charge limits calculated in paragraph (f)(5)(ii) of this section.

(g) *Determination of payment amounts in special circumstances*—(1) *General.* (i) For purposes of this paragraph (g), a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physicians' services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital services or home health services) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS-initiated adjustments, CMS will publish in the FEDERAL REGISTER an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, CMS or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors CMS or a carrier considers in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup.* Price markup is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier may consider the price markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* CMS or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* CMS or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Use.* CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities.* CMS or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits*—(i) *National limits.* CMS publishes in the FEDERAL REGISTER proposed and final notices announcing a special payment limit described in paragraph (g) of this section before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii) *Carrier-level limits.* (A) A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section and must solicit comments. The notice must also consider the following:

(*1*) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(*2*) What entities would be affected, such as classes of providers or suppliers and beneficiaries.

(*3*) How significantly would these entities be affected.

(*4*) How would the adjustment affect beneficiary access to items or services.

(B) Before publication of a final notice, the carrier must—

(*1*) Evaluate the comments it receives on the proposed notice.

(*2*) Notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification.

(*3*) After receipt of CMS' acknowledgement, inform the affected suppliers and State Medicaid agencies of any final limits it establishes.

(C) The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data.* In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, valid and reliable data are used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) *Review of market prices.* If CMS or a carrier makes a payment adjustment of more than 15 percent under this paragraph (g), CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(5) of this section, CMS applies the following rules in establishing a payment adjustment greater than 15 percent of the payment amount for a

category of items or services within a year:

(1) *Potential impact of special limit.* CMS considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the FEDERAL REGISTER the proposed and final notices of a special payment limit before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Proposed notice.* The proposed notice—

(A) Explains the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established for a category of items or services;

(C) Explains the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice—

(A) Explains the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(i) *Paramedic intercept ambulance services.* (1) CMS establishes its payment allowance on a carrier-wide basis by using the median allowance from all localities within an individual carrier's jurisdiction.

(2) CMS's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) CMS bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

(Secs. 1102, 1814(b), 1833(a), 1842(b), and (h), and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, as amended, 79 Stat. 296, 302, 310, 331; 86 Stat. 1395, 1454; 42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1).

[32 FR 12599, Aug. 31, 1967]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 405.502, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 405.503 Determining customary charges.

(a) *Customary charge defined.* The term ''customary charges'' will refer to the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service. In determining such uniform amount, token charges for charity patients and substandard charges for welfare and other low income patients are to be excluded. The reasonable charge cannot, except as provided in § 405.506, be higher than the individual physician's or other person's customary charge. The customary charge for different physicians or other persons may, of course, vary. Payment for covered services would be based on the actual charge for the service when, in a given instance, that charge is less than the amount which the carrier would otherwise have found to be within the limits of acceptable charges for the particular service. Moreover, the income of the individual beneficiary is not to be taken into account by the carrier in determining the amount which is considered to be a reasonable charge for a service rendered to him. There is no provision in the law for a carrier to evaluate the reasonableness of charges in light of an individual beneficiary's economic status.

(b) *Variation of charges.* If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a ''customary charge'' for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's ''customary'' charge. Use of relative value scales will help in arriving at a decision in such instances.

(c) *Use of relative value scales.* If, for a particular medical procedure or service, the carrier is unable to determine the customary charge on the basis of reliable statistical data (for example, because the carrier does not yet have sufficient data or because the performance of the particular medical procedure or service by the physician or other person is infrequent), the carrier may use appropriate relative value scales to determine the customary charge for such procedure or service in relation to customary charges of the same physician or person for other medical procedures and services.

(d) *Revision of customary charge.* A physician's or other person's customary charge is not necessarily a static amount. Where a physician or other person alters his charges, a revised pattern of charges for his services may develop. Where on the basis of adequate evidence, the carrier finds that the physician or other person furnishing services has changed his charge for a service to the public in general, the customary charge resulting from the revised charge for the service should be recognized as the customary charge in making determinations of reasonable charges for such service when rendered thereafter to supplementary insurance beneficiaries. If the new customary charge is not above the top of the range of prevailing charges (see § 405.504(a)), it should be deemed to be reasonable by the carrier, subject to the provisions of § 405.508.

§ 405.504 Determining prevailing charges.

(a) *Ranges of charges.* (1) In the case of physicians' services furnished beginning January 1, 1987, the prevailing charges for a nonparticipating physician as defined in this paragraph will be no higher than the same level that was set for services furnished during the previous calendar year for a physician who was a participating physician during that year. A nonparticipating physician is a physician who has not entered into an agreement with the Medicare program to accept payment on an assignment-related basis (in accordance with § 424.55 of this chapter) for all items and services furnished to

individuals enrolled under Part B of Medicare during a given calendar year.

(2) No charge for Part B medical or other health services may be considered to be reasonable if it exceeds the higher of:

(i) The prevailing charge for similar services in the same locality in effect on December 31, 1970, provided such prevailing charge had been found acceptable by CMS; or

(ii) The prevailing charge that, on the basis of statistical data and methodology acceptable to CMS, would cover:

(A) 75 percent of the customary charges made for similar services in the same locality during the 12-month period of July 1 through June 30 preceding the fee screen year (January 1 through December 31) in which the service was furnished; or

(B) In the case of services furnished more than 12 months before the beginning of the fee screen year (January 1 through December 31) in which the claim or request for payment is submitted, 75 percent of the customary charges made for similar services in the same locality during the 12 month period of July 1 through June 30 preceding the fee screen year that ends immediately preceding the fee screen year in which the claim or request for payment is submitted.

(3)(i) In the case of physicians' services, furnished before January 1, 1992, each prevailing charge in each locality may not exceed the prevailing charge determined for the FY ending June 30, 1973 (without reference to the adjustments made in accordance with the economic stabilization program then in effect), except on the basis of appropriate economic index data that demonstrate the higher prevailing charge level is justified by:

(A) Changes in general earnings levels of workers that are attributable to factors other than increases in their productivity; and

(B) changes in expenses of the kind incurred by physicians in office practice. The office-expense component and the earnings component of such index shall be given the relative weights shown in data on self-employed physicians' gross incomes.

Example. The available data indicate the office-expense and earnings components of the index should be given relative weights of 40 percent and 60 percent, respectively, and it is calculated that the aggregate increase in expenses of practice for a particular July through June period was 112 percent over the expenses of practice for calendar year 1971 and the increase in earnings (less increases in workers' productivity was 110 percent over the earnings for calendar year 1971. The allowable increase in any prevailing charge that could be recognized during the next fee screen year would be 110.8 percent ((.40 × 112) + (.60) × 110) = 110.8) above the prevailing charge recognized for fiscal year 1973.

(ii)(A) If the increase in the prevailing charge in a locality for a particular physician service resulting from an aggregate increase in customary charges for that service does not exceed the index determined under paragraph (a)(3)(i) of this section, the increase is permitted and any portion of the allowable increase not used is carried forward and is a basis for justifying increases in that prevailing charge in the future. However, if the increase in the prevailing charge exceeds the allowable increase, the increase will be reduced to the allowable amount. Further increases will be justified only to the degree that they do not exceed further rises in the economic index. The prevailing charge for physicians' services furnished during the 15-month period beginning July 1, 1984 may not exceed the prevailing charge for physicians' services in effect for the 12-month period beginning July 1, 1983. The increase in prevailing charges for physicians' services for subsequent fee screen years similarly may not reflect the rise in the economic index that would have otherwise been provided for the period beginning July 1, 1984, and must be treated as having fully provided for the rise in the economic index which would have been otherwise taken into account.

(B) Notwithstanding the provisions of paragraphs (a)(3)(i) and (ii)(A) of this section, the prevailing charge in the case of a physician service in a particular locality determined pursuant to paragraphs (a)(2) and (3)(i) of this section for the fiscal year beginning July 1, 1975, and for any subsequent fee

screen years, if lower than the prevailing charge for the fiscal year ending June 30, 1975, by reason of the application of economic index data, must be raised to such prevailing charge which was in effect for the fiscal year ending June 30, 1975. (If the amount paid on any claim processed by a carrier after the original reasonable charge update for the fiscal year beginning July 1, 1975, and prior to the adjustments required by the preceding sentence, was at least $1 less than the amount due pursuant to the preceding sentence, the difference between the amount previously paid and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously and the amount due shall be paid within 6 months after December 31, 1975; however, no payment shall be made on any claim where the difference between the amount previously paid and the amount due is less than $1.)

(iii) If, for any reason, a prevailing charge for a service in a locality has no precise counterpart in the carrier's charge data for calendar year 1971 (the data on which the prevailing charge calculations for fiscal year 1973 were based), the limit on the prevailing charge will be estimated, on the basis of data and methodology acceptable to CMS, to seek to produce the effect intended by the economic index criterion. The allowance or reduction of an increase in a prevailing charge for any individual medical item or service may affect the allowance or reduction of an increase in the prevailing charges for other items or services if, for example, the limit on the prevailing charge is estimated, or if the prevailing charges for more than one item or service are established through the use of a relative value schedule and dollar conversion factors.

(b) *Variation in range of prevailing charges.* The range of prevailing charges in a locality may be different for physicians or other persons who engage in a specialty practice or service than for others. Existing differentials in the level of charges between different kinds of practice or service could, in some localities, lead to the development of more than one range of prevailing charges for application by the carrier in its determinations of reasonable charges. Carrier decisions in this respect should be responsive to the existing patterns of charges by physicians and other persons who render covered services, and should establish differentials in the levels of charges between different kinds of practice or service only where in accord with such patterns.

(c) *Re-evaluation and adjustment of prevailing charges.* Determinations of prevailing charges by the carrier are to be re-evaluated and adjusted from time to time on the basis of factual information about the charges made by physicians and other persons to the public in general. This information should be obtained from all possible sources including a carrier's experience with its own programs as well as with the supplementary medical insurance program.

(d) *Computation and issuance of the MEI after CY 1992*—(1) For update years after CY 1992, the MEI is a physician input price index, in which the annual percent changes for the direct-labor price components are adjusted by an annual percent change in a 10-year moving average index of labor productivity in the nonfarm business sector.

(2) The MEI is constructed, using as a base year, CY 1989 weights and annual percent changes in the economic price proxies as shown on the following chart:

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES

Expense category	1989 weights [1] [2] (percent)	Price proxy [3]
Total	100.0	
1. Physician's Own Time (net income, general earnings).	54.2	
a. Wages and Salaries	45.3	Average hourly earnings, total private non-farm. [4]
b. Fringe Benefits	8.8	Employment Cost Index, fringe benefits, private non-farm. [4]

MEDICARE ECONOMIC INDEX EXPENDITURE CATEGORIES, WEIGHTS, AND PRICE PROXIES—Continued

Expense category	1989 weights [1] [2] (percent)	Price proxy [3]
2. Physician Practice Expense	45.8	
a. Non-physician Employee Compensation	16.3	
(1) Wages and Salaries	13.8	Employment Cost Index, wages and salaries weighted for occupational mix of non-physician employees. [4]
(2) Fringe Benefits	2.5	Employment Cost Index, fringe benefits, white collar. [4]
b. Office Expense	10.3	CPI-U, housing.
c. Medical Materials and Supplies	5.2	PPI, ethical drugs; PPI, surgical appliances and supplies; and CPI-U medical equipment and supplies (equally weighted).
d. Professional Liability Insurance	4.8	CMS survey of change in average liability premiums for $100,000/$300,000 liability coverage among 9 major insurers.
e. Medical Equipment	2.3	PPI, medical instruments and equipment.
f. Other Professional Expense	6.9	
(1) Professional Car	1.4	CPI-U, private transportation.
(2) Other	5.5	CPI-U, all items less food and energy.

[1] Sources: Martin L. Gonzalez, ed.: *Physician Marketplace Statistics, Fall, 1990.* Center for Health Policy Research, Chicago, American Medical Association, 1990; Mark Holoweiko, ''Practice Expenses Take the Leap of the Decade,'' *Medical Economics,* November 12, 1990; and CMS, OACT special study.
[2] Due to rounding, weights may not sum to 100.0%
[3] All price proxies are for *annual* percent changes for the 12 months ending June 30th.
[4] Annual percent change values for Physicians' Own Time and Non-physician Employee Compensation are net of the change in the 10-year moving average of output per man-hour to exclude changes in non-farm business sector labor productivity.

(3) If there is no methodological change, CMS publishes a notice in the FEDERAL REGISTER to announce the annual increase in the MEI before the beginning of the update year to which it applies. If there are changes in the base year weights or price proxies, or if there are any other MEI methodological changes, they are published in the FEDERAL REGISTER with an opportunity for public comment.

[32 FR 12600, Aug. 31, 1967, as amended at 40 FR 25447, June 16, 1975; 42 FR 18275, Apr. 6, 1977. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 4430, Feb. 2, 1978; 47 FR 63274, Dec. 31, 1982; 51 FR 34978, Oct. 1, 1986; 53 FR 6648, Mar. 2, 1988; 57 FR 55912, Nov. 25, 1992]

§ 405.505 Determination of locality.

''Locality'' is the geographical area for which the carrier is to derive the reasonable charges or fee schedule amounts for services or items. Usually, a locality may be a State (including the District of Columbia, a territory, or a Commonwealth), a political or economic subdivision of a State, or a group of States. It should include a cross section of the population with respect to economic and other characteristics. Where people tend to gravitate toward certain population centers to obtain medical care or service, localities may be recognized on a basis constituting medical services areas (interstate or otherwise), comparable in concept to ''trade areas.'' Localities may differ in population density, economic level, and other major factors affecting charges for services. Carriers therefore shall delineate localities on the basis of their knowledge of local conditions. However, distinctions between localities are not to be so finely made that a locality includes only a very limited geographic area whose population has distinctly similar income characteristics (e.g., a very rich or very poor neighborhood within a city).

[57 FR 27305, June 18, 1992]

§ 405.506 Charges higher than customary or prevailing charges or lowest charge levels.

A charge which exceeds the customary charge of the physician or other person who rendered the medical or other health service, or the prevailing charge in the locality, or an applicable lowest charge level may be found to be reasonable, but only where there are unusual circumstances, or medical complications requiring additional time, effort or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The

mere fact that the physician's or other person's customary charge is higher than prevailing would not justify a determination that it is reasonable.

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331; 86 Stat. 1395, 1454; (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978]

§ 405.507 Illustrations of the application of the criteria for determining reasonable charges.

The following examples illustrate how the general criteria on customary charges and prevailing charges might be applied in determining reasonable charges under the supplementary medical insurance program. Basically, these examples demonstrate that, except where the actual charge is less, reasonable charges will reflect current customary charges of the particular physician or other person within the ranges of the current prevailing charges in the locality for that type and level of service:

The prevailing charge for a specific medical procedure ranges from $80 to $100 in a certain locality.

Doctor A's bill is for $75 although he customarily charges $80 for the procedure.

Doctor B's bill is his customary charge of $85

Doctor C's bill is his customary charge of $125

Doctor D's bill is for $100, although he customarily charges $80, and there are no special circumstances in the case.

The reasonable charge for Doctor A would be limited to $75 since under the law the reasonable charge cannot exceed the actual charge, even if it is lower than his customary charge and below the prevailing charges for the locality.

The reasonable charge for Doctor B would be $85, because it is his customary charge and it falls within the range of prevailing charges for that locality.

The reasonable charge for Doctor C could not be more than $100, the top of the range of prevailing charges.

The reasonable charge for Doctor D would be $80, because that is his customary charge. Even though his actual charge of $100 falls within the range of prevailing charges, the reasonable charge cannot exceed his customary charge in the absence of special circumstances.

§ 405.508 Determination of comparable circumstances; limitation.

(a) *Application of limitation.* The carrier may not in any case make a determination of reasonable charge which would be higher than the charge upon which it would base payment to its own policyholders for a comparable service in comparable circumstances. The charge upon which it would base payment, however, does not necessarily mean the amount the carrier would be obligated to pay. Under certain circumstances, some carriers pay amounts on behalf of individuals who are their policyholders, which are below the customary charges of physicians or other persons to other individuals. Payment under the supplementary medical insurance program would not be limited to these lower amounts.

(b) *When comparability exists.* ''Comparable circumstances,'' as used in the Act and this subpart, refers to the circumstances under which services are rendered to individuals and the nature of the carrier's health insurance programs and the method it uses to determine the amounts of payments under these programs. Generally, comparability would exist where:

(1) The carrier bases payment under its program on the customary charges, as presently constituted, of physicians or other persons and on current prevailing charges in a locality, and

(2) The determination does not preclude recognition of factors such as speciality status and unusual circumstances which affect the amount charged for a service.

(c) *Responsibility for determining comparability.* Responsibility for determining whether or not a carrier's program has comparability will in the first instance fall upon the carrier in reporting pertinent information about its programs to the Centers for Medicare & Medicaid Services. When the pertinent information has been reported, the Centers for Medicare & Medicaid Services will advise the carrier whether any of its programs have comparability.

§ 405.509 Determining the inflation-indexed charge.

(a) *Definition.* For purposes of this section, *inflation-indexed charge* means the lowest of the fee screens used to determine reasonable charges (as determined in § 405.503 for the customary charge, § 405.504 for the prevailing charge, this section for the inflation-indexed charge, and § 405.511 for the lowest charge level) for services, supplies, and equipment reimbursed on a reasonable charge basis (excluding physicians' services), that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor, as described in paragraph (b) of this section.

(b) *Application of inflation adjustment factor to determine inflation-indexed charge.* (1) For fee screen years beginning on or after January 1, 1987, the inflation-indexed charge is determined by updating the fee screen used to determine the reasonable charges in effect on December 31 of the previous fee screen year by application of an inflation adjustment factor, that is, the annual change in the level of the consumer price index for all urban consumers, as compiled by the Bureau of Labor Statistics, for the 12-month period ending on June 30 of each year.

(2) For services, supplies, and equipment furnished from October 1, 1985 through December 31, 1986 the inflation adjustment factor is zero.

(c) The inflation-indexed charge does not apply to any services, supplies, or equipment furnished after December 31, 1991, that are covered under or limited by the fee schedule for physicians' services established under section 1848 of the Act and part 415 of this chapter. These services are subject to the Medicare Economic Index described in § 415.30 of this chapter.

[51 FR 34979, Oct. 1, 1986; 51 FR 37911, Oct. 27, 1986, as amended at 56 FR 59621, Nov. 25, 1991]

§ 405.511 Reasonable charges for medical services, supplies, and equipment.

(a) *General rule.* (1) A charge for any medical service, supply, or equipment (including equipment servicing) that in the judgment of CMS generally does not vary significantly in quality from one supplier to another (and that is identified by a notice published in the FEDERAL REGISTER) may not be considered reasonable if it exceeds:

(i) The customary charge of the supplier (see § 405.503);

(ii) The prevailing charge in the locality (see § 405.504);

(iii) The charge applicable for a comparable service and under comparable circumstances to the policyholders or subscribers of the carrier (see § 405.508);

(iv) The lowest charge level at which the item or service is widely and consistently available in the locality (see paragraph (c) of this section); or

(v) The inflation-indexed charge, as determined under § 405.509, in the case of medical services, supplies, and equipment that are reimbursed on a reasonable charge basis (excluding physicians' services).

(2) In the case of laboratory services, paragraph (a)(1) of this section is applicable to services furnished by physicians in their offices, by independent laboratories (see § 405.1310(a)) and to services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital. Allowance of additional charges exceeding the lowest charge level can be approved by the carrier on the basis of unusual circumstances or medical complications in accordance with § 405.506.

(b) *Public notice of items and services subject to the lowest charge level rule.* Before the Secretary determines that lowest charge levels should be established for an item or service, notice of the proposed determination will be published with an opportunity for public comment. The descriptions or specifications of items or services in the notice will be in sufficient detail to permit a determination that items or services conforming to the descriptions will not vary significantly in quality.

(c) *Calculating the lowest charge level.* The lowest charge level at which an item or service is widely and consistently available in a locality is calculated by the carrier in accordance with instructions from CMS as follows:

(1) *For items or services furnished on or before December 31, 1986.* (i) A lowest charge level is calculated for each identified item or service in January and July of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the second calendar quarter preceding the determination date. Accordingly, the January calculations will be based on charges for the July through September quarter of the previous calendar year, and the July calculations will be based on charges for the January through March quarter of the same calendar year.

(2) *For items or services furnished on or after January 1, 1987.* (i) A lowest charge level is calculated for each identified item or service in January of each year.

(ii) The lowest charge level for each identified item or service is set at the 25th percentile of the charges (incurred or submitted on claims processed by the carrier) for that item or service, in the locality designated by the carrier for this purpose, during the 3-month period of July 1 through September 30 preceding the fee screen year (January 1 through December 31) for which the item or service was furnished.

(3) *Lowest charge levels for laboratory services.* In setting lowest charge levels for laboratory services, the carrier will consider only charges made for laboratory services performed by physicians in their offices, by independent laboratories which meet coverage requirements, and for services furnished by a hospital laboratory for individuals who are neither inpatients nor outpatients of a hospital.

(d) *Locality.* Subject to the approval of the Secretary, the carrier may designate its entire service area as the locality for purposes of this section, or may otherwise modify the localities used for calculating prevailing charges. (The modified locality for an item or service will also be used for calculating the prevailing charge for that item or service.)

(Secs. 1102, 1842(b) and 1871, 1903(i)(1) of the Social Security Act; 49 Stat. 647, 79 Stat. 302, 310, 331, 86 Stat. 1395, 1454 (42 U.S.C. 1302, 1395u(b), 1395hh, 1396b(i)(1)))

[43 FR 32300, July 26, 1978, as amended at 50 FR 40174, Oct. 1, 1985; 51 FR 34979, Oct. 1, 1986]

§ 405.512 Carriers' procedural terminology and coding systems.

(a) *General.* Procedural terminology and coding systems are designed to provide physicians and third party payers with a common language that accurately describes the kinds and levels of services provided and that can serve as a basis for coverage and payment determinations.

(b) *Modification of terminology and/or coding systems.* A carrier that wishes to modify its system of procedural terminology and coding shall submit its request to the Centers for Medicare & Medicaid Services with all pertinent data and information for approval before the revision is implemented. The Centers for Medicare & Medicaid Services will evaluate the proposal in the light of the guidelines specified in paragraph (c) of this section and such other considerations as may be pertinent, and consult with the Assistant Secretary for Health. The Centers for Medicare & Medicaid Services will approve such a revision if it determines that the potential advantages of the proposed new system, outweigh the disadvantages.

(c) *Guidelines.* The following considerations and guidelines are taken into account in evaluating a carrier's proposal to change its system of procedural terminology and coding:

(1) The rationale for converting to the new terminology and coding;

(2) The estimated short-run and long-run impact on the cost of the health insurance program, other medical care costs, administrative expenses, and the reliability of the estimates;

(3) The degree to which the conversion to the proposed new terminology and coding can be accomplished in a way that permits full implementation of the reasonable charge criteria in accordance with the provisions of this subpart;

(4) The degree to which the proposed new terminology and coding are accepted by physicians in the carrier's area (physician acceptance is assumed only if a majority of the Medicare and non-Medicare bills and claims completed by physicians in the area and submitted to the carrier can reasonably be expected to utilize the proposed new terminology and coding);

(5) The extent to which the proposed new terminology and coding system is used by the carrier in its non-Medicare business;

(6) The clarity with which the proposed system defines its terminology and whether the system lends itself to:

(i) Accurate determinations of coverage;

(ii) Proper assessment of the appropriate level of payment; and

(iii) Meeting the carrier's or Professional Standards Review Organizations' review needs and such other review needs as may be appropriate;

(7) Compatibility of the new terminology and coding system with other systems that the carrier and other carriers may utilize in the administration of the Medicare program—e.g., its compatibility with systems and statistical requirements and with the historical data in the carrier's processing system; and

(8) Compatibility of the proposed system with the carriers methods for determining payment under the fee schedule for physicians' services for services which are identified by a single element of terminology but which may vary in content.

[40 FR 7639, Feb. 21, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 59 FR 10298, Mar. 4, 1994]

§ 405.515 Reimbursement for clinical laboratory services billed by physicians.

This section implements section 1842(h) of the Social Security Act, which places a limitation on reimbursement for markups on clinical laboratory services billed by physicians. If a physician's bill, or a request for payment for a physician's services, includes a charge for a laboratory test for which payment may be made under this part, the amount payable with respect to the test shall be determined as follows (subject to the coinsurance and deductible provisions at §§ 410.152 and 410.160 of this chapter):

(a) If the bill or request for payment indicates that the test was personally performed or supervised either by the physician who submitted the bill (or for whose services the request for payment was made), or by another physician with whom that physician shares his or her practice, the payment will be based on the physician's reasonable charge for the test (as determined in accordance with § 405.502).

(b) If the bill or request for payment indicates that the test was performed by an outside laboratory, and identifies both the laboratory and the amount the laboratory charged, payment for the test will be based on the lower of—

(1) The laboratory's reasonable charge for the service (as determined in accordance with § 405.502), or

(2) The amount that the laboratory charged the physician for the service.

(c) If the bill or request for payment does not indicate that the conditions specified in paragraph (a) of this section were met, and does not identify both the laboratory and the amount the laboratory charged, payment will be based on the lowest charge at which the carrier estimates the test could have been secured from a laboratory serving the physician's locality. The carrier will estimate this lowest amount twice a year by (i) obtaining lists of charges laboratories make to physicians from as many commercial laboratories serving the carrier's area as possible (including laboratories in other States from which tests may be obtained by physicians in the carrier's service area) and (ii) establishing a schedule of lowest prices based on this information. The carrier will take into consideration specific circumstances, such as a need for emergency services that may be costlier than routine services, in making the estimate in a particular case. However, in no case may this estimate be higher than the lowest customary charge for commercial laboratories, or when applicable to the laboratory service, the lowest charge level determined in accordance with § 405.511, in the carrier's service area.

(d) When a physician bills, in accordance with paragraph (b) or (c) of this section, for a laboratory test and indicates that it was performed by an independent laboratory, a nominal payment will also be made to the physician for collecting, handling, and shipping the specimen to the laboratory, if the physician bills for such a service.

[46 FR 42672, Aug. 24, 1981, as amended at 51 FR 41351, Nov. 14, 1986]

§ 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.

(a) *Applicability*—(1) *Payment for drugs and biologicals before January 1, 2004.* Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not included in the ESRD composite rate set forth in § 413.170(c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.

(2) *Payment for drugs and biologicals on or after January 1, 2004.* Effective January 1, 2004, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart I of this chapter.

(3) *Payment for drugs and biologicals on or after January 1, 2005.* Effective January 1, 2005, payment for drugs and biologicals that are not paid on a cost or prospective payment basis are paid in accordance with part 414, subpart K of this chapter.

(b) *Methodology.* Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological.

(c) *Multiple-source drugs.* For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

[63 FR 58905, Nov. 2, 1998, as amended at 69 FR 1116, Jan. 7, 2004; 69 FR 66420, Nov. 15, 2004]

§ 405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialists' services and services furnished incident to their professional services.

(a) *General rule.* A physician assistant's, nurse practitioner's, and clinical nurse specialists' services, and services and supplies furnished incident to their professional services, are paid in accordance with the physician fee schedule. The payment for a physician assistants' services may not exceed the limits at § 414.52 of this chapter. The payment for a nurse practitioners' and clinical nurse specialists' services may not exceed the limits at § 414.56 of this chapter.

(b) *Requirements.* Medicare payment is made only if all claims for payment are made on an assignment-related basis in accordance with § 424.55 of this chapter, that sets forth, respectively, the conditions for coverage of physician assistants' services, nurse practitioners' services and clinical nurse specialists' services, and services and supplies furnished incident to their professional services.

(c) *Civil money penalties.* Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§ 402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.

[63 FR 58905, Nov. 2, 1998, as amended at 66 FR 49547, Sept. 28, 2001]

§ 405.534 Limitation on payment for screening mammography services.

The provisions in paragraphs (a), (b), and (c) of this section apply for services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are paid under the physician fee schedule in accordance with § 414.2 of this chapter.

(a) *Basis and scope.* This section implements section 1834(c) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each are set forth

in paragraphs (b) through (d) of this section.

(b) *Global or complete service billing representing both the professional and technical components of the procedure.* If a fee is billed for a global service, the amount of payment subject to the deductible is equal to 80 percent of the least of the following:

(1) The actual charge for the service.

(2) The amount established for the global procedure for a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at part 414, subpart A.

(3) The payment limit for the procedure. For screening mammography services furnished in CY 1994, the payment limit is $59.63. On January 1 of each subsequent year, the payment limit is updated by the percentage increase in the Medicare Economic Index (MEI) and reflects the relationship between the relative value units for the professional and technical components of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(c) *Professional component billing representing only the physician's interpretation for the procedure.* If the professional component of screening mammography services is billed separately, the amount of payment for that professional component, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the professional component of the service.

(2) The amount established for the professional component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The professional component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

(d) *Technical component billing representing other resources involved in furnishing the procedure.* If the technical component of screening mammography services is billed separately, the amount of payment, subject to the deductible, is equal to 80 percent of the least of the following:

(1) The actual charge for the technical component of the service.

(2) The amount established for the technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services.

(3) The technical component of the payment limit for screening mammography services described in paragraph (b)(3) of this section.

[55 FR 53521, Dec. 31, 1990, as amended at 59 FR 49833, Sept. 30, 1994; 66 FR 55328, Nov. 1, 2001]

§ 405.535 Special rule for nonparticipating physicians and suppliers furnishing screening mammography services before January 1, 2002.

The provisions in this section apply for screening mammography services provided from January 1, 1991 until December 31, 2001. Screening mammography services provided after December 31, 2001 are physician services pursuant to § 414.2 of this chapter paid under the physician fee schedule. If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier that does not accept assignment, a limiting charge applies to the charges billed to the beneficiary. The limiting charge is the lesser of the following:

(a) 115 percent of the payment limit set forth in § 405.534(b)(3), (c)(3), and (d)(3) (limitations on the global service, professional component, and technical component of screening mammography services, respectively).

(b) The limiting charge for the global service, professional component, and technical component of a diagnostic bilateral mammogram under the fee schedule for physicians' services set forth at § 414.48(b) of this chapter.

[59 FR 49833, Sept. 30, 1994, as amended at 62 FR 59098, Oct. 31, 1997; 66 FR 55328, Nov. 1, 2001]

Subparts F– G [Reserved]

Subpart H—Appeals Under the Medicare Part B Program

AUTHORITY: Secs. 1102, 1866(j), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395cc(j), and 1395hh).

SOURCE: 77 FR 29028, May 16, 2012, unless otherwise noted.

§ 405.800 Appeals of CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

(a) *Denial of a provider or supplier enrollment application.* If CMS or a CMS contractor denies a provider's or supplier's enrollment application, CMS or the CMS contractor notifies the provider or supplier by certified mail. The notice includes the following:

(1) The reason for the denial in sufficient detail to allow the provider or supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) *Revocation of Medicare billing privileges*—(1) *Notice of revocation.* If CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor notifies the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, except if the revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational. When a revocation is based on a Federal exclusion or debarment, felony conviction, license suspension or revocation, or the practice location is determined by CMS or its contractor not to be operational, the revocation is effective with the date of exclusion or debarment, felony conviction, license suspension or revocation or the date that CMS or its contractor determined that the provider or supplier was no longer operational.

(3) *Payment after revocation.* Medicare does not pay, and the CMS contractor rejects, claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

(c) *Additional years applied to a reenrollment bar.* (1) If, under § 424.535(c)(2)(i) of this chapter, CMS or a CMS contractor applies additional years to a provider's or supplier's existing reenrollment bar, CMS or the CMS contractor notifies the provider or supplier by certified mail. The notice includes the following:

(i) The reason for the application of additional years in sufficient detail to allow the provider or supplier to understand the nature of the action.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) Paragraph (c)(1) of this section applies only to the years added to the existing reenrollment bar under § 424.535(c)(2)(i) of this chapter and not to the original length of the reenrollment bar, which is not subject to appeal.

(d) *Scope of supplier.* For purposes of this subpart, the term ''supplier'' includes all of the following:

(1) The individuals and entities that qualify as suppliers under § 400.202 of this chapter.

(2) Physical therapists in private practice.

(3) Occupational therapists in private practice.

(4) Speech-language pathologists.

[77 FR 29028, May 16, 2012, as amended at 84 FR 47852, Sept. 10, 2019; 88 FR 79523, Nov. 16, 2023]

§ 405.803 Appeals rights.

(a) A provider or supplier may appeal the initial determination to deny a provider or supplier's enrollment application, or if applicable, to revoke current billing privileges by following the procedures specified in part 498 of this chapter.

(b) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges is handled by a CMS Regional Office or

a contractor hearing officer not involved in the initial determination.

(c) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(d) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(e) If the provider or supplier fails to submit the evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

§ 405.806 Impact of reversal of contractor determinations on claims processing.

(a) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges were not effective are rejected.

(b) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for the recovery of overpayments.

(c) If a revocation of a supplier's billing privileges is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(d) If the denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges become effective.

§ 405.809 Reinstatement of provider or supplier billing privileges following corrective action.

(a) *General rule.* A provider or supplier—

(1) May only submit a corrective action plan for a revocation for noncompliance under § 424.535(a)(1) of this chapter; and

(2) Subject to paragraph (a)(1) of this section, has only one opportunity to correct all deficiencies that served as the basis of its revocation through a corrective action plan.

(b) *Review of a corrective action plan.* Subject to paragraph (a)(1) of this section, CMS or its contractor reviews a submitted corrective action plan and does either of the following:

(1) Reinstates the provider or supplier's billing privileges if the provider or supplier provides sufficient evidence to CMS or its contractor that it has complied fully with the Medicare requirements, in which case—

(i) The effective date of the reinstatement is based on the date the provider or supplier is in compliance with all Medicare requirements; and

(ii) CMS or its contractor may pay for services furnished on or after the effective date of the reinstatement.

(2) Refuses to reinstate a provider or supplier's billing privileges. The refusal of CMS or its contractor to reinstate a provider or supplier's billing privileges based on a corrective action plan is not an initial determination under part 498 of this chapter.

[79 FR 72530, Dec. 5, 2014]

§ 405.812 Effective date for DMEPOS supplier's billing privileges.

If a CMS contractor, contractor hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

§ 405.815 Submission of claims.

A provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are

considered filed timely upon resubmission. Previously denied claims for items or services furnished during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

§ 405.818 Deadline for processing provider enrollment initial determinations.

Contractors approve or deny complete provider or supplier enrollment applications to approval or denial within the following timeframes:

(a) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(b) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(c) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

Subpart I—Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Part A and Part B)

SOURCE: 70 FR 11472, Mar. 8, 2005, unless otherwise noted.

§ 405.900 Basis and scope.

(a) *Statutory basis.* This subpart is based on the following provisions of the Act:

(1) Section 1869(a) through (e) and (g) of the Act.

(2) Section 1862(b)(2)(B)(viii) of the Act.

(b) *Scope.* This subpart establishes the requirements for appeals of initial determinations for benefits under Part A or Part B of Medicare, including the following:

(1) The initial determination of whether an individual is entitled to benefits under Part A or Part B. (Regulations governing reconsiderations of these initial determinations are at 20 CFR, part 404, subpart J).

(2) The initial determination of the amount of benefits available to an individual under Part A or Part B.

(3) Any other initial determination relating to a claim for benefits under Part A or Part B, including an initial determination made by a quality improvement organization under section 1154(a)(2) of the Act or by an entity under contract with the Secretary (other than a contract under section 1852 of the Act) to administer provisions of titles XVIII or XI of the Act.

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.902 Definitions.

For the purposes of this subpart, the term—

Additional documentation means any information requested by a contractor when conducting a prepayment review or post-payment review.

Additional documentation request (ADR) means a contractor's initial documentation request in reviewing claims selected for prepayment review or post-payment review.

ALJ means an Administrative Law Judge of the Department of Health and Human Services.

Appellant means the beneficiary, assignee or other person or entity that has filed and pursued an appeal concerning a particular initial determination. Designation as an appellant does not in itself convey standing to appeal the determination in question.

Applicable plan means liability insurance (including self-insurance), no-fault insurance, or a workers' compensation law or plan.

Appointed representative means an individual appointed by a party to represent the party in a Medicare claim or claim appeal.

Assignee means:

(1) A supplier that furnishes items or services to a beneficiary and has accepted a valid assignment of a claim or

(2) A provider or supplier that furnishes items or services to a beneficiary, who is not already a party, and has accepted a valid assignment of the right to appeal a claim executed by the beneficiary.

Assignment of a claim means the transfer by a beneficiary of his or her claim for payment to the supplier in return for the latter's promise not to charge more for his or her services than what the carrier finds to be the

Medicare-approved amount, as provided in §§ 424.55 and 424.56 of this chapter.

Assignment of appeal rights means the transfer by a beneficiary of his or her right to appeal under this subpart to a provider or supplier who is not already a party, as provided in section 1869(b)(1)(C) of the Act.

Assignor means a beneficiary whose provider of services or supplier has taken assignment of a claim or an appeal of a claim.

Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

Authorized representative means an individual authorized under State or other applicable law to act on behalf of a beneficiary or other party involved in the appeal. The authorized representative will have all of the rights and responsibilities of a beneficiary or party, as applicable, throughout the appeals process.

Beneficiary means an individual who is enrolled to receive benefits under Medicare Part A or Part B.

Carrier means an organization that has entered into a contract with the Secretary in accordance to section 1842 of the Act and is authorized to make determinations for Part B of title XVIII of the Act.

Clean claim means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under title XVIII within the time periods specified in sections 1816(c) and 1842(c) of the Act.

Contractor means an entity that contracts with the Federal government to review and/or adjudicate claims, determinations and/or decisions.

Council stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

Family member means for purposes of the QIC reconsideration panel under § 405.968 the following persons as they relate to the physician or healthcare provider.

(1) The spouse (other than a spouse who is legally separated from the physician or health care professional under a decree of divorce or separate maintenance);

(2) Children (including stepchildren and legally adopted children);

(3) Grandchildren;

(4) Parents; and

(5) Grandparents.

Fiscal Intermediary means an organization that has entered into a contract with CMS in accordance with section 1816 of the Act and is authorized to make determinations and payments for Part A of title XVIII of the Act, and Part B provider services as specified in § 421.5(c) of this chapter.

OMHA stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

Party means an individual or entity listed in § 405.906 that has standing to appeal an initial determination and/or a subsequent administrative appeal determination.

Post-payment medical review (or post-payment review) means a review that occurs after payment is made on the selected claim to determine whether the initial determination for payment was appropriate.

Prepayment medical review (or prepayment review) means a review that occurs before an initial determination for payment is made on the selected claim to determine whether payment should be made.

Provider means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that has in effect an agreement to participate in Medicare, or clinic, rehabilitation agency, or public health agency that has in effect a similar agreement, but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Qualified Independent Contractor (QIC) means an entity which contracts with

the Secretary in accordance with section 1869 of the Act to perform reconsiderations under § 405.960 through § 405.978.

Quality Improvement Organization (QIO) means an entity that contracts with the Secretary in accordance with sections 1152 and 1153 of the Act and 42 CFR subchapter F, to perform the functions described in section 1154 of the Act and 42 CFR subchapter F, including expedited determinations as described in § 405.1200 through § 405.1208.

Reliable evidence means evidence that is relevant, credible, and material.

Remand means to vacate a lower level appeal decision, or a portion of the decision, and return the case, or a portion of the case, to that level for a new decision.

Similar fault means to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim as defined in part 411 of this chapter.

Supplier means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under Medicare.

Vacate means to set aside a previous action.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017; 86 FR 65659, Nov. 19, 2021]

§ 405.903 Prepayment review.

(a) A contractor may select a claim(s) for prepayment review.

(b) In conducting a prepayment review, a contractor may issue additional documentation requests to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45-calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after the 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) A contractor's prepayment review will result in an initial determination under § 405.920.

[86 FR 65660, Nov. 19, 2021]

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) *General overview*—(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Council to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the

initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

(b) *Non-beneficiary appellants.* In general, the procedures described in paragraph (a) of this section are also available to parties other than beneficiaries either directly or through a representative acting on a party's behalf, consistent with the requirements of this subpart I. A provider generally has the right to judicial review only as provided under section 1879(d) of the Act; that is, when a determination involves a finding that services are not covered because—

(1) They were custodial care (see § 411.15(g) of this chapter); they were not reasonable and necessary (see § 411.15(k) of this chapter); they did not qualify as covered home health services because the beneficiary was not confined to the home or did not need skilled nursing care on an intermittent basis (see § 409.42(a) and (c)(1) of this chapter); or they were hospice services provided to a non-terminally ill individual (see § 418.22 of this chapter); and

(2) Either the provider or the beneficiary, or both, knew or could reasonably be expected to know that those services were not covered under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5106, Jan. 17, 2017]

§ 405.906 Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews.

(a) *Parties to the initial determination.* The parties to the initial determination are the following individuals and entities:

(1) A beneficiary who files a claim for payment under Medicare Part A or Part B or has had a claim for payment filed on his or her behalf, or in the case of a deceased beneficiary, when there is no estate, any person obligated to make or entitled to receive payment in accordance with part 424, subpart E of this chapter. Payment by a third party payer does not entitle that entity to party status.

(2) A supplier who has accepted assignment for items or services furnished to a beneficiary that are at issue in the claim.

(3) A provider of services who files a claim for items or services furnished to a beneficiary.

(4) An applicable plan for an initial determination under § 405.924(b)(16) where Medicare is pursuing recovery directly from the applicable plan. The applicable plan is the sole party to an initial determination under § 405.924(b)(16) (that is, where Medicare is pursuing recovery directly from the applicable plan).

(b) *Parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review.* The parties to the redetermination, reconsideration, proceedings on a request for hearing, and Council review are—

(1) The parties to the initial determination in accordance with paragraph (a) of this section, except under paragraph (a)(1) of this section where a beneficiary has assigned appeal rights under § 405.912;

(2) A State agency in accordance with § 405.908;

(3) A provider or supplier that has accepted an assignment of appeal rights from the beneficiary according to § 405.912;

(4) A non-participating physician not billing on an assigned basis who, in accordance with section 1842(l) of the Act, may be liable to refund monies collected for services furnished to the beneficiary because those services were denied on the basis of section 1862(a)(1) of the Act; and

(5) A non-participating supplier not billing on an assigned basis who, in accordance with sections 1834(a)(18) and 1834(j)(4) of the Act, may be liable to refund monies collected for items furnished to the beneficiary.

(c) *Appeals by providers and suppliers when there is no other party available.* If a provider or supplier is not already a party to the proceeding in accordance with paragraphs (a) and (b) of this section, a provider of services or supplier may appeal an initial determination relating to services it rendered to a beneficiary who subsequently dies if there is no other party available to appeal the determination. This paragraph (c) does not apply to an initial determination with respect to an applicable plan under § 405.924(b)(16).

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017]

§ 405.908 Medicaid State agencies.

When a beneficiary is enrolled to receive benefits under both Medicare and Medicaid, the Medicaid State agency may file a request for an appeal with respect to a claim for items or services furnished to a dually eligible beneficiary only for services for which the Medicaid State agency has made payment, or for which it may be liable. A Medicaid State agency is considered a party only when it files a timely redetermination request with respect to a claim for items or services furnished to a beneficiary in accordance with 42 CFR parts 940 through 958. If a State agency files a request for redetermination, it may retain party status at the QIC, OMHA, Council, and judicial review levels.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5106, Jan. 17, 2017]

§ 405.910 Appointed representatives.

(a) *Scope of representation.* An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent.

(b) *Persons not qualified.* A party may not name as an appointed representative, an individual who is disqualified, suspended, or otherwise prohibited by law from acting as a representative in any proceedings before DHHS, or in entitlement appeals, before SSA.

(c) *Completing a valid appointment.* For purposes of this subpart, an appointment of representation must:

(1) Be in writing and signed and dated by both the party and individual agreeing to be the representative;

(2) Provide a statement appointing the representative to act on behalf of the party, and in the case of a beneficiary, authorizing the adjudicator to release identifiable health information to the appointed representative.

(3) Include a written explanation of the purpose and scope of the representation;

(4) Contain both the party's and appointed representative's name, phone number, and address;

(5) Identify the beneficiary's Medicare number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

(6) Include the appointed representative's professional status or relationship to the party;

(7) Be filed with the entity processing the party's initial determination or appeal.

(d) *Curing a defective appointment of representative.* (1) If any one of the seven elements named in paragraph (c) of this section is missing from the appointment, the adjudicator should contact the party and provide a description of the missing documentation or information.

(2) Unless the defect is cured, the prospective appointed representative lacks the authority to act on behalf of the party, and is not entitled to obtain or

receive any information related to the appeal, including the appeal decision.

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

(e) *Duration of appointment.* (1) Unless revoked, an appointment is considered valid for 1 year from the date that the Appointment of Representative (AOR) form or other conforming written instrument contains the signatures of both the party and the appointed representative.

(2) To initiate an appeal within the 1-year time frame, the representative must file a copy of the AOR form, or other conforming written instrument, with the appeal request. Unless revoked, the representation is valid for the duration of an individual's appeal of an initial determination.

(3) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed in connection with the party's efforts to make a claim for third party payment is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(4) For an initial determination of a Medicare Secondary Payer recovery claim, an appointment signed by an applicable plan which has party status in accordance with §405.906(a)(4) is valid from the date that appointment is signed for the duration of any subsequent appeal, unless the appointment is specifically revoked.

(f) *Appointed representative fees*—(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

(2) *No fees or costs against trust funds.* No award of attorney or any other representative's fees or any costs in connection with an appeal may be made against the Medicare trust funds.

(3) *Special rules for providers and suppliers.* A provider or supplier that furnished the items or services to a beneficiary that are the subject of the appeal may represent that beneficiary in an appeal under this subpart, but the provider or supplier may not charge the beneficiary any fee associated with the representation. If a provider or supplier furnishes services or items to a beneficiary, the provider or supplier may not represent the beneficiary on the issues described in section 1879(a)(2) of the Act, unless the provider or supplier waives the right to payment from the beneficiary for the services or items involved in the appeal.

(4) *Special rules for purposes of third party payment.* The Secretary does not review fee arrangements made by a beneficiary for purposes of making a claim for third party payment (as defined in 42 CFR 411.21) even though the representation may ultimately include representation for a Medicare Secondary Payer recovery claim.

(5) *Reasonableness of representative fees.* In determining the reasonableness of a representative's fee, the Secretary will not apply the test specified in sections 206(a)(2) and (a)(3) of the Act.

(g) *Responsibilities of an appointed representative.* (1) An appointed representative has an affirmative duty to—

(i) Inform the party of the scope and responsibilities of the representation;

(ii) Inform the party of the status of the appeal and the results of actions taken on behalf of the party, including, but not limited to, notification of appeal determinations, decisions, and further appeal rights;

(iii) Disclose to a beneficiary any financial risk and liability of a non-assigned claim that the beneficiary may have;

(iv) Not act contrary to the interest of the party; and

(v) Comply with all laws and CMS regulations, CMS Rulings, and instructions.

(2) An appeal request filed by a provider or supplier described in paragraph (f)(3) of this section must also include a statement signed by the provider or supplier stating that no financial liability is imposed on the beneficiary in connection with that representation. If applicable, the appeal request must also include a signed statement that the provider or supplier waives the right to payment from the beneficiary for services or items regarding issues described in section 1879(a)(2) of the Act.

(h) *Authority of an appointed representative.* An appointed representative may, on behalf of the party—

(1) Obtain appeals information about the claim to the same extent as the party;

(2) Submit evidence;

(3) Make statements about facts and law; and

(4) Make any request, or give, or receive, any notice about the appeal proceedings.

(i) *Notice or request to an appointed representative*—(1) *Initial determinations.* When a contractor takes an action or issues an initial determination, it sends the action or notice to the party.

(2) *Appeals.* When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

(4) For initial determinations and appeals involving Medicare Secondary Payer recovery claims where the beneficiary is a party, the adjudicator sends notices and requests to both the beneficiary and the beneficiary's representative, if the beneficiary has a representative.

(j) *Effect of notice or request to an appointed representative.* A notice or request sent to the appointed representative has the same force and effect as if was sent to the party.

(k) *Information available to the appointed representative.* An appointed representative may obtain any and all appeals information applicable to the claim at issue that is available to the party.

(l) *Delegation of appointment by appointed representative.* (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (l)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (l)(1)(ii) of this section, unless the appointed representative and designee are attorneys in the same law firm or organization, in which case the notice described in paragraph (l)(1)(i) of this section may be submitted even though the acceptance described in paragraph (l)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) *Revoking the appointment of representative.* (1) A party may revoke an appointment of representative without cause at any time.

(2) *Revocation.* Revocation is not effective until the adjudicator receives a signed, written statement from the party.

(3) *Death of the party.* (i) The death of a party terminates the authority of the

appointed representative, except as specified in paragraph (m)(3)(ii) of this section.

(ii) A party's death does not terminate an appeal that is in progress if another individual or entity may be entitled to receive or obligated to make payment for the items or services that are the subject of the appeal. The appointment of representative remains in effect for the duration of the appeal except for MSP recovery claims.

(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015; 82 FR 5106, Jan. 17, 2017; 84 FR 19869, May 7, 2019]

§ 405.912 Assignment of appeal rights.

(a) *Who may be an assignee.* Only a provider, or supplier that—

(1) Is not a party to the initial determination as defined in § 405.906; and

(2) Furnished an item or service to the beneficiary may seek assignment of appeal rights from the beneficiary for that item or service.

(b) *Who may not be an assignee.* An individual or entity who is not a provider or supplier may not be an assignee. A provider or supplier that furnishes an item or service to a beneficiary may not seek assignment for that item or service when considered a party to the initial determination as defined in § 405.906.

(c) *Requirements for a valid assignment of appeal right.* The assignment of appeal rights must—

(1) Be executed using a CMS standard form;

(2) Be in writing and signed by both the beneficiary assigning his or her appeal rights and by the assignee;

(3) Indicate the item or service for which the assignment of appeal rights is authorized;

(4) Contain a waiver of the assignee's right to collect payment from the assignor for the specific item or service that are the subject of the appeal except as set forth in paragraph (d)(2) of this section; and

(5) Be submitted at the same time the request for redetermination or other appeal is filed.

(d) *Waiver of right to collect payment.* (1) Except as specified in paragraph (d)(2) of this section, the assignee must waive the right to collect payment for the item or service for which the assignment of appeal rights is made. If the assignment is revoked under paragraph (g)(2) or (g)(3) of this section, the waiver of the right to collect payment nevertheless remains valid. A waiver of the right to collect payment remains in effect regardless of the outcome of the appeal decision.

(2) The assignee is not prohibited from recovering payment associated with coinsurance or deductibles or when an advance beneficiary notice is properly executed.

(e) *Duration of a valid assignment of appeal rights.* Unless revoked, the assignment of appeal rights is valid for all administrative and judicial review associated with the item or service as indicated on the standard CMS form, even in the event of the death of the assignor.

(f) *Rights of the assignee.* When a valid assignment of appeal rights is executed, the assignor transfers all appeal rights involving the particular item or service to the assignee. These include, but are not limited to—

(1) Obtaining information about the claim to the same extent as the assignor;

(2) Submitting evidence;

(3) Making statements about facts or law; and

(4) Making any request, or giving, or receiving any notice about appeal proceedings.

(g) *Revocation of assignment.* When an assignment of appeal rights is revoked, the rights to appeal revert to the assignor. An assignment of appeal rights may be revoked in any of the following ways:

(1) *In writing by the assignor.* The revocation of assignment must be delivered to the adjudicator and the assignee, and is effective on the date of receipt by the adjudicator.

(2) By abandonment if the assignee does not file an appeal of an unfavorable decision.

(3) By act or omission by the assignee that is determined by an adjudicator to be contrary to the financial interests of the assignor.

(h) *Responsibilities of the assignee.* Once the assignee files an appeal, the assignee becomes a party to the appeal. The assignee must meet all requirements for appeals that apply to any other party.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005]

INITIAL DETERMINATIONS

§ 405.920 Initial determinations.

After a claim is filed with the appropriate contractor in the manner and form described in subpart C of part 424 of this chapter, the contractor must—

(a) Determine if the items and services furnished are covered or otherwise reimbursable under title XVIII of the Act;

(b) Determine any amounts payable and make payment accordingly; and

(c) Notify the parties to the initial determination of the determination in accordance with § 405.921.

§ 405.921 Notice of initial determination.

(a) *Notice of initial determination sent to the beneficiary.* (1) The notice must be written in a manner calculated to be understood by the beneficiary, and sent to the last known address of the beneficiary.

(2) *Content of the notice.* The notice of initial determination must contain all of the following:

(i) The reasons for the determination, including whether a local medical review policy, a local coverage determination, or national coverage determination was applied.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the beneficiary is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(b) *Notice of initial determination sent to providers and suppliers.* (1) An electronic or paper remittance advice (RA) notice is the notice of initial determination sent to providers and suppliers that accept assignment.

(i) The electronic RA must comply with the format and content requirements of the standard adopted for national use by covered entities under the Health Insurance Portability and Accountability Act (HIPAA) and related CMS manual instructions.

(ii) When a paper RA is mailed, it must comply with CMS manual instructions that parallel the HIPAA data content and coding requirements.

(2) The notice of initial determination must contain all of the following:

(i) The basis for any full or partial denial determination of services or items on the claim.

(ii) Information on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination.

(iii) All applicable claim adjustment reason and remark codes to explain the determination.

(iv) The source of the RA and who may be contacted if the provider or supplier requires further information.

(v) All content requirements of the standard adopted for national use by covered entities under HIPAA.

(vi) Any other requirements specified by CMS.

(c) *Notice of initial determination sent to an applicable plan*—(1) *Content of the notice.* The notice of initial determination under § 405.924(b)(16) must contain all of the following:

(i) The reasons for the determination.

(ii) The procedures for obtaining additional information concerning the contractor's determination, such as a specific provision of the policy, manual, law or regulation used in making the determination.

(iii) Information on the right to a redetermination if the liability insurance (including self-insurance), no-fault insurance, or workers' compensation law or plan is dissatisfied with the outcome of the initial determination and instructions on how to request a redetermination.

(iv) Any other requirements specified by CMS.

(2) [Reserved]

[70 FR 11472, Mar. 8, 2005, as amended at 80 FR 10617, Feb. 27, 2015]

§ 405.922 Time frame for processing initial determinations.

The contractor issues initial determinations on clean claims within 30 calendar days of receipt if they are submitted by or on behalf of the beneficiary who received the items and/or services; otherwise, interest must be paid at the rate specified at 31 U.S.C. 3902(a) for the period beginning on the day after the required payment date and ending on the date payment is made.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.924 Actions that are initial determinations.

(a) *Applications and entitlement of individuals.* SSA makes initial determinations and processes reconsiderations with respect to an individual on the following:

(1) A determination with respect to entitlement to hospital insurance or supplementary medical insurance under Medicare.

(2) A disallowance of an individual's application for entitlement to hospital or supplementary medical insurance, if the individual fails to submit evidence requested by SSA to support the application. (SSA specifies in the initial determination the conditions of entitlement that the applicant failed to establish by not submitting the requested evidence).

(3) A denial of a request for withdrawal of an application for hospital or supplementary medical insurance, or a denial of a request for cancellation of a request for withdrawal.

(4) A determination as to whether an individual, previously determined as entitled to hospital or supplementary medical insurance, is no longer entitled to those benefits, including a determination based on nonpayment of premiums.

(5) An adjustment of premium for hospital or supplementary medical insurance as outlined in §§ 406.32(d), 408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301.

(b) *Claims made by or on behalf of beneficiaries.* The Medicare contractor makes initial determinations regarding claims for benefits under Medicare Part A and Part B. A finding that a request for payment or other submission does not meet the requirements for a Medicare claim as defined in § 424.32 of this chapter, is not considered an initial determination. An initial determination for purposes of this subpart includes, but is not limited to, determinations with respect to any of the following:

(1) If the items and/or services furnished are covered under title XVIII.

(2) In the case of determinations on the basis of section 1879(b) or (c) of the Act, if the beneficiary, or supplier who accepts assignment under § 424.55 of this chapter knew, or could reasonably have expected to know at the time the items or services were furnished, that the items or services were not covered.

(3) In the case of determinations on the basis of section 1842(l)(1) of the Act, if the beneficiary or physician knew, or could reasonably have expected to know at the time the services were furnished, that the services were not covered.

(4) Whether the deductible is met.

(5) The computation of the coinsurance amount.

(6) The number of days used for inpatient hospital, psychiatric hospital, or post-hospital extended care.

(7) Periods of hospice care used.

(8) Requirements for certification and plan of treatment for physician services, durable medical equipment, therapies, inpatient hospitalization, skilled nursing care, home health, hospice, and partial hospitalization services.

(9) The beginning and ending of a spell of illness, including a determination made under the presumptions established under § 409.60(c)(2) of this chapter, and as specified in § 409.60(c)(4) of this chapter.

(10) The medical necessity of services, or the reasonableness or appropriateness of placement of an individual at an acute level of patient care made by the Quality Improvement Organization (QIO) on behalf of the contractor in accordance with § 476.86(c)(1) of this chapter.

(11) Any other issues having a present or potential effect on the amount of benefits to be paid under Part A or Part B of Medicare, including a determination as to whether there

was an underpayment of benefits paid under Part A or Part B, and if so, the amount thereof.

(12) If a waiver of adjustment or recovery under sections 1870(b) and (c) of the Act is appropriate—

(i) When an overpayment of hospital insurance benefits or supplementary medical insurance benefits (including a payment under section 1814(e) of the Act) was made for an individual; or

(ii) For a Medicare Secondary Payer recovery claim against a beneficiary or against a provider or supplier.

(13) If a particular claim is not payable by Medicare based upon the application of the Medicare Secondary Payer provisions of section 1862(b) of the Act.

(14) Under the Medicare Secondary Payer provisions of sections 1862(b) of the Act that Medicare has a recovery claim against a provider, supplier, or beneficiary for services or items that were already paid by the Medicare program, except when the Medicare Secondary Payer recovery claim against the provider or supplier is based upon failure to file a proper claim as defined in part 411 of this chapter because this action is a reopening.

(15) A claim not payable to a beneficiary for the services of a physician who has opted-out.

(16) Under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery claim if Medicare is pursuing recovery directly from an applicable plan. That is, there is an initial determination with respect to the amount and existence of the recovery claim.

(c) *Determinations by QIOs.* An initial determination for purposes of this subpart also includes a determination made by a QIO that:

(1) A provider can terminate services provided to an individual when a physician certified that failure to continue the provision of those services is likely to place the individual's health at significant risk; or

(2) A provider can discharge an individual from the provider of services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 79 FR 68001, Nov. 13, 2014; 80 FR 10618, Feb. 27, 2015; 83 FR 16721, Apr. 16, 2018]

§ 405.925 Decisions of utilization review committees.

(a) *General rule.* A decision of a utilization review committee is a medical determination by a staff committee of the provider or a group similarly composed and does not constitute a determination by the Secretary within the meaning of section 1869 of the Act. The decision of a utilization review committee may be considered by CMS along with other pertinent medical evidence in determining whether or not an individual has the right to have payment made under Part A of title XVIII.

(b) *Applicability under the prospective payment system.* CMS may consider utilization review committee decisions related to inpatient hospital services paid for under the prospective payment system (see part 412 of this chapter) only as those decisions concern:

(1) The appropriateness of admissions resulting in payments under subparts D, E and G of part 412 of this chapter.

(2) The covered days of care involved in determinations of outlier payments under § 412.80(a)(1)(i) of this chapter; and

(3) The necessity of professional services furnished in high cost outliers under § 412.80(a)(1)(ii) of this chapter.

[48 FR 39831, Sept. 1, 1983. Redesignated at 77 FR 29028, May 16, 2012]

§ 405.926 Actions that are not initial determinations.

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to the following:

(a) Any determination for which CMS has sole responsibility, for example one of the following:

(1) If an entity meets the conditions for participation in the program.

(2) If an independent laboratory meets the conditions for coverage of services.

(3) Determination under the Medicare Secondary Payer provisions of section 1862(b) of the Act of the debtor for a particular recovery claim.

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system.

(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A.

(d) Whether an individual's appeal meets the qualifications for expedited access to judicial review provided in § 405.990.

(e) Any determination regarding whether a Medicare overpayment claim must be compromised, or collection action terminated or suspended under the Federal Claims Collection Act of 1966, as amended.

(f) Determinations regarding the transfer or discharge of residents of skilled nursing facilities in accordance with § 483.5 definition of 'transfer and discharge' and § 483.15 of this chapter.

(g) Determinations regarding the readmission screening and annual resident review processes required by subparts C and E of part 483 of this chapter.

(h) Determinations for a waiver of Medicare Secondary Payer recovery under section 1862(b) of the Act.

(i) Determinations for a waiver of interest.

(j) Determinations for a finding regarding the general applicability of the Medicare Secondary Payer provisions (as opposed to the application of these provisions to a particular claim or claims for Medicare payment for benefits).

(k) Except as specified in § 405.924(b)(16), determinations under the Medicare Secondary Payer provisions of section 1862(b) of the Act that Medicare has a recovery against an entity that was or is required or responsible (directly, as an insurer or self-insurer; as a third party administrator; as an employer that sponsors, contributes to or facilitates a group health plan or a large group health plan; or otherwise) to make payment for services or items that were already reimbursed by the Medicare program.

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

(n) Determinations that a provider or supplier failed to submit a claim timely or failed to submit a timely claim despite being requested to do so by the beneficiary or the beneficiary's subrogee.

(o) Determinations with respect to whether an entity qualifies for an exception to the electronic claims submission requirement under part 424 of this chapter.

(p) Determinations by the Secretary of sustained or high levels of payment errors in accordance with section 1893(f)(3)(A) of the Act.

(q) A contractor's prior determination related to coverage of physicians' services.

(r) Requests for anticipated payment under the home health prospective payment system under § 409.43(c)(ii)(2) of this chapter.

(s) Claim submissions on forms or formats that are incomplete, invalid, or do not meet the requirements for a Medicare claim and returned or rejected to the provider or supplier.

(t) A contractor's prior authorization determination with regard to—

(1) Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS)); and

(2) Hospital outpatient department (OPD) services.

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 80 FR 10618, Feb. 27, 2015; 80 FR 81706, Dec. 30, 2015; 81 FR 57267, Aug. 22, 2016; 81 FR 68847, Oct. 4, 2016; 82 FR 5107, Jan. 17, 2017; 84 FR 19869, May 7, 2019; 84 FR 61490, Nov. 12, 2019]

§ 405.927 Initial determinations subject to the reopenings process.

Minor errors or omissions in an initial determination must be corrected only through the contractor's reopenings process under § 405.980(a)(3).

§ 405.928 Effect of the initial determination.

(a) An initial determination described in § 405.924(a) is binding unless it is revised or reconsidered in accordance with 20 CFR 404.907, or revised as a result of a reopening in accordance with 20 CFR 404.988.

(b) An initial determination described in § 405.924(b) is binding upon all parties to the initial determination unless—

(1) A redetermination is completed in accordance with § 405.940 through § 405.958; or

(2) The initial determination is revised as a result of a reopening in accordance with § 405.980.

(c) An initial determination listed in § 405.924(b) where a party submits a timely, valid request for redetermination under § 405.942 through § 405.944 must be processed as a redetermination under § 405.948 through § 405.958 unless the initial determination involves a clerical error or other minor error or omission.

§ 405.929 Post-payment review.

(a) A contractor may select a claim(s) for post-payment review, which is conducted under the reopening authority in § 405.980.

(b) In conducting a post-payment review, a contractor may issue an additional documentation request to a provider or supplier.

(1) A provider or supplier will be provided 45 calendar days to submit additional documentation in response to a contractor's request, except as stated in paragraph (b)(2) and (c) of this section.

(2) A contractor may accept documentation received after 45 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the contractor deems good cause in accepting the documentation.

(c) A provider or supplier will be provided 30 calendar days to submit additional documentation in response to a UPIC's request for additional documentation. A UPIC may accept documentation received after 30 calendar days for good cause. Good cause means situations such as natural disasters, interruptions in business practices, or other extenuating circumstances that the UPIC deems good cause in accepting the documentation.

(d) The outcome of a contractor's review will result in either no change to the initial determination or a revised determination under § 405.984.

[86 FR 65660, Nov. 19, 2021]

§ 405.930 Failure to respond to additional documentation request.

If a contractor gives a provider or supplier notice and time to respond to an additional documentation request and the provider or supplier does not provide the additional documentation in a timely manner, the contractor has authority to deny the claim.

[86 FR 65660, Nov. 19, 2021]

REDETERMINATIONS

§ 405.940 Right to a redetermination.

A person or entity that may be a party to a redetermination in accordance with § 405.906(b) and that is dissatisfied with an initial determination may request a redetermination by a contractor in accordance with § 405.940 through § 405.958, regardless of the amount in controversy.

§ 405.942 Time frame for filing a request for a redetermination.

(a) *Time frame for filing a request.* Except as provided in paragraph (b) of this section, any request for redetermination must be filed within 120 calendar days from the date a party receives the notice of the initial determination.

(1) For purposes of this section, the date of receipt of the initial determination will be presumed to be 5 calendar days after the date of the notice of initial determination, unless there is evidence to the contrary.

(2) The request is considered as filed on the date it is received by the contractor.

(b) *Extending the time frame for filing a request. General rule.* If the 120 calendar day period in which to file a request for a redetermination has expired and a party shows good cause, the contractor may extend the time frame for filing a request for redetermination.

(1) *How to request an extension.* A party may file a request for an extension of time for filing a request for a redetermination with the contractor. The party should include any evidence supporting the request for extension. The request for redetermination extension must—

(i) Be in writing;

(ii) State why the request for redetermination was not filed within the required time frame; and

(iii) Meet the requirements of § 405.944.

(2) *How the contractor determines if good cause exists.* In determining if a party has good cause for missing a deadline to request a redetermination, the contractor considers—

(i) The circumstances that kept the party from making the request on time;

(ii) If the contractor's action(s) misled the party; and

(iii) If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

(3) *Examples of good cause.* Examples of circumstances when good cause may be found to exist include, but are not limited to, the following situations:

(i) The party was prevented by serious illness from contacting the contractor in person, in writing, or through a friend, relative, or other person; or

(ii) The party had a death or serious illness in his or her immediate family; or

(iii) Important records of the party were destroyed or damaged by fire or other accidental cause; or

(iv) The contractor gave the party incorrect or incomplete information about when and how to request a redetermination; or

(v) The party did not receive notice of the determination or decision; or

(vi) The party sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate contractor until after the time period to file a request expired.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

§ 405.944 Place and method of filing a request for a redetermination.

(a) *Filing location.* The request for redetermination must be filed with the contractor indicated on the notice of initial determination.

(b) *Content of redetermination request.* The request for redetermination must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements as follows:

(1) The beneficiary's name;

(2) The Medicare number;

(3) Specific service(s) and/or item(s) for which the redetermination is being requested and the specific date(s) of the service;

(4) The name of the party or the representative of the party.

(c) *Requests for redetermination by more than one party.* If more than one party timely files a request for redetermination on the same claim before a redetermination is made on the first timely filed request, the contractor must consolidate the separate requests into one proceeding and issue one redetermination.

[70 FR 11472, Mar. 8, 2005, as amended at 84 FR 19869, May 7, 2019]

§ 405.946 Evidence to be submitted with the redetermination request.

(a) *Evidence submitted with the request.* When filing the request for redetermination, a party must explain why it disagrees with the contractor's determination and should include any evidence that the party believes should be considered by the contractor in making its redetermination.

(b) *Evidence submitted after the request.* When a party submits additional evidence after filing the request for redetermination, the contractor's 60 calendar day decision-making time frame is automatically extended for up to 14 calendar days for each submission.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§ 405.947 Notice to the beneficiary of applicable plan's request for a redetermination.

(a) A CMS contractor must send notice of the applicable plan's appeal to the beneficiary.

(b) Issuance and content of the notice must comply with CMS instructions.

[80 FR 10618, Feb. 27, 2015]

§ 405.948 Conduct of a redetermination.

A redetermination consists of an independent review of an initial determination. In conducting a redetermination, the contractor reviews the evidence and findings upon which the initial determination was based, and any additional evidence the parties submit or the contractor obtains on its own. An individual who was not involved in making the initial determination must make a redetermination. The contractor may raise and develop new issues that are relevant to the claims in the particular case.

§ 405.950 Time frame for making a redetermination.

(a) *General rule.* The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses within 60 calendar days of the date the contractor receives a timely filed request for redetermination.

(b) *Exceptions.* (1) If a contractor grants an appellant's request for an extension of the 120 calendar day filing deadline made in accordance with § 405.942(b), the 60 calendar day decision-making time frame begins on the date the contractor receives the late-filed request for redetermination, or when the request for an extension is granted, whichever is later.

(2) If a contractor receives from multiple parties timely requests for redetermination of a claim determination, consistent with § 405.944(c), the contractor must issue a redetermination or dismissal within 60 calendar days of the latest filed request.

(3) If a party submits additional evidence after the request for redetermination is filed, the contractor's 60 calendar day decision-making time frame is extended for up to 14 calendar days for each submission, consistent with § 405.946(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65333, Dec. 9, 2009]

§ 405.952 Withdrawal or dismissal of a request for a redetermination.

(a) *Withdrawing a request.* A party that files a request for redetermination may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must contain a clear statement that the appellant is withdrawing the request for a redetermination and does not intend to proceed further with the appeal. The request must be received in the contractor's mailroom before a redetermination is issued. The appeal will proceed with respect to any other parties that have filed a timely request for redetermination.

(b) *Dismissing a request.* A contractor 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 § 405.906(b) or does not otherwise have a right to a redetermination under section 1869(a) of the Act;

(2) When the contractor determines the party failed to make out a valid request for redetermination that substantially complies with § 405.944;

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with § 405.942;

(4) When a beneficiary or the beneficiary's representative files a request

for redetermination, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the contractor considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party filed a valid and timely redetermination request under §§ 405.942 and 405.944;

(5) When a party filing the redetermination request submits a timely written request for withdrawal with the contractor; or

(6) When the contractor has not issued an initial determination on the claim or the matter for which a redetermination is sought.

(c) *Notice of dismissal.* A contractor mails or otherwise transmits a written notice of the dismissal of the redetermination request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a contractor may vacate its dismissal of a request for redetermination within 180 calendar days from the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless it is modified or reversed by a QIC under § 405.974(b) or vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009; 84 FR 19870, May 7, 2019]

§ 405.954 Redetermination.

Upon the basis of the evidence of record, the contractor adjudicates the claim(s), and renders a redetermination affirming or reversing, in whole or in part, the initial determination in question.

§ 405.956 Notice of a redetermination.

(a) *Notification to parties*—(1) *General rule.* Written notice of a redetermination affirming, in whole or in part, the initial determination must be mailed or otherwise transmitted to all parties at their last known addresses in accordance with the time frames established in § 405.950. Written notice of a redetermination fully reversing the initial determination must be mailed or otherwise transmitted to the appellant in accordance with the time frames established in § 405.950. If the redetermination results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.* In an overpayment case involving multiple beneficiaries who have no liability, the contractor may issue a written notice only to the appellant.

(b) *Content of the notice for affirmations, in whole or in part.* For decisions that are affirmations, in whole or in part, of the initial determination, the redetermination must be written in a manner calculated to be understood by a beneficiary, and contain—

(1) A clear statement indicating the extent to which the redetermination is favorable or unfavorable;

(2) A summary of the facts, including, as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies apply to the facts of the case;

(4) A summary of the rationale for the redetermination in clear, understandable language;

(5) Notification to the parties of their right to a reconsideration and a description of the procedures that a party must follow in order to request a reconsideration, including the time frame within which a reconsideration must be requested;

(6) A statement of any specific missing documentation that must be submitted with a request for a reconsideration, if applicable;

(7) A statement that all evidence the appellant wishes to introduce during the claim appeals process should be submitted with the request for a reconsideration;

(8) Notification that evidence not submitted to the QIC as indicated in paragraph (b)(6) of this section, is not considered at the OMHA level or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously; and

(9) The procedures for obtaining additional information concerning the redetermination, such as specific provisions of the policy, manual, or regulation used in making the redetermination.

(10) Any other requirements specified by CMS.

(c) *Content of the notice for a full reversal.* For decisions that are full reversals of the initial determination, the redetermination must be in writing and contain—

(1) A clear statement indicating that the redetermination is wholly favorable;

(2) Any other requirements specified by CMS.

(d) *Exception for beneficiary appeal requests.* (1) The notice must inform beneficiary appellants that the requirements of paragraph (b)(8) of this section are not applicable for purposes of beneficiary appeals.

(2) This exception does not apply for appeal requests from beneficiaries who are represented by providers or suppliers.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5107, Jan. 17, 2017]

§ 405.958 Effect of a redetermination.

In accordance with section 1869(a)(3)(D) of the Act, once a redetermination is issued, it becomes part of the initial determination. The redetermination is binding upon all parties unless—

(a) A reconsideration is completed in accordance with § 405.960 through § 405.978; or

(b) The redetermination is revised as a result of a reopening in accordance with § 405.980.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65333, Dec. 9, 2009]

RECONSIDERATION

§ 405.960 Right to a reconsideration.

A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy.

§ 405.962 Timeframe for filing a request for a reconsideration.

(a) *Timeframe for filing a request.* Except as provided in paragraph (b) of this section and in § 405.974(b)(1), regarding a request for QIC reconsideration of a contractor's dismissal of a redetermination request, any request for a reconsideration must be filed within 180 calendar days from the date the party receives the notice of the redetermination.

(1) For purposes of this section, the date of receipt of the redetermination will be presumed to be 5 calendar days after the date of the notice of redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 180 calendar day filing deadline, the request is considered as filed on the date it is received by the QIC.

(b) *Extending the time for filing a request*—(1) *General rule.* A QIC may extend the 180 calendar day timeframe for filing a request for reconsideration for good cause.

(2) *How to request an extension.* A party to the redetermination must file its request for an extension of the time for filing the reconsideration request with its request for reconsideration. A party should include evidence to support the request for extension. The request for reconsideration and request for extension must—

(i) Be in writing;

(ii) State why the request for reconsideration was not filed within the required timeframe; and

(iii) Meet the requirements of § 405.964.

(3) *How the QIC determines whether good cause exists.* In determining whether a party has good cause for missing a deadline to request reconsideration, the QIC applies the good cause provisions contained in § 405.942(b)(2) and (b)(3).

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.964 Place and method of filing a request for a reconsideration.

(a) *Filing location.* The request for reconsideration must be filed with the QIC indicated on the notice of redetermination.

(b) *Content of reconsideration request.* The request for reconsideration must be in writing and should be made on a standard CMS form. A written request that is not made on a standard CMS form is accepted if it contains the same required elements, as follows:

(1) The beneficiary's name;

(2) Medicare number;

(3) Specific service(s) and item(s) for which the reconsideration is requested and the specific date(s) of service;

(4) The name of the party or the representative of the party; and

(5) The name of the contractor that made the redetermination.

(c) *Requests for reconsideration by more than one party.* If more than one party timely files a request for reconsideration on the same claim before a reconsideration is made on the first timely filed request, the QIC must consolidate the separate requests into one proceeding and issue one reconsideration.

[70 FR 11472, Mar. 8, 2005, as amended at 84 FR 19870, May 7, 2019]

§ 405.966 Evidence to be submitted with the reconsideration request.

(a) *Evidence submitted with the request.* When filing a request for reconsideration, a party should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination, including the redetermination.

(1) This evidence must include any missing documentation identified in the notice of redetermination, consistent with § 405.956(b)(6).

(2) Absent good cause, failure to submit all evidence, including documentation requested in the notice of redetermination prior to the issuance of the notice of reconsideration precludes subsequent consideration of that evidence.

(b) *Evidence submitted after the request.* Each time a party submits additional evidence after filing the request for reconsideration, the QIC's 60 calendar day decisionmaking timeframe is automatically extended by up to 14 calendar days for each submission. This extension does not apply to timely submissions of documentation specifically requested by a QIC, unless the documentation was originally requested in the notice of redetermination.

(c) *Exception for beneficiaries and State Medicaid Agencies that file reconsideration requests.* (1) Beneficiaries and State Medicaid Agencies that file requests for reconsideration are not required to comply with the requirements of paragraph (a) of this section. However, the automatic 14 calendar day extension described in paragraph (b) of this section applies to each evidence submission made after the request for reconsideration is filed.

(2) Beneficiaries who are represented by providers or suppliers must comply with the requirements of paragraph (a) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009]

§ 405.968 Conduct of a reconsideration.

(a) *General rules.* (1) A reconsideration consists of an independent, on-the-record review of an initial determination, including the redetermination and all issues related to payment of the claim. In conducting a reconsideration, the QIC reviews the evidence and findings upon which the initial determination, including the redetermination, was based, and any additional evidence the parties submit or that the QIC obtains on its own. If the initial determination involves a finding on whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A) of the Act), a QIC's reconsideration must involve consideration by a panel of physicians

or other appropriate health care professionals, and be based on clinical experience, the patient's medical records, and medical, technical, and scientific evidence of record to the extent applicable.

(b) *Authority of the QIC.* (1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under § 401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.

(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.

(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.

(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims.

(c) *Qualifications of the QIC's panel members.* (1) Members of a QIC's panel who conduct reconsiderations must have sufficient medical, legal, and other expertise, including knowledge of the Medicare program.

(2) When a redetermination is made with respect to whether an item or service is reasonable and necessary (section 1862(a)(1)(A) of the Act), the QIC designates a panel of physicians or other appropriate health care professionals to consider the facts and circumstances of the redetermination.

(3) Where a claim pertains to the furnishing of treatment by a physician, or the provision of items or services by a physician, a reviewing professional must be a physician.

(d) *Disqualification of a QIC panel member.* No physician or health care professional employed by or otherwise working for a QIC may review determinations regarding—

(1) Health care services furnished to a patient if that physician or health care professional was directly responsible for furnishing those services; or

(2) Health care services provided in or by an institution, organization, or agency, if that physician or health care professional or any member of the physician's family or health care professional's family has, directly or indirectly, a significant financial interest in that institution, organization, or agency (see the term family member as defined in § 405.902).

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5107, Jan. 17, 2017]

§ 405.970 Timeframe for making a reconsideration following a contractor redetermination.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

(1) The reconsideration;

(2) Its inability to complete its review within 60 calendar days in accordance with paragraphs (c) through (e) of this section; or

(3) Dismissal.

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for

each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

(1) Notify all parties of its reconsideration, consistent with § 405.976.

(2) Notify the parties that it cannot complete the reconsideration by the deadline specified in paragraph (b) of this section and offer the appellant the opportunity to escalate the appeal to OMHA. The QIC continues to process the reconsideration unless it receives a written request from the appellant to escalate the case to OMHA after the adjudication period has expired.

(d) *Responsibilities of the appellant.* If an appellant wishes to exercise the option of escalating the case to OMHA, the appellant must notify the QIC in writing.

(e) *Actions following appellant's notice.* (1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) If the appellant notifies the QIC that the appellant wishes to escalate the case, the QIC must take one of the following actions within 5 calendar days of receipt of the notice or 5 calendar days from the end of the applicable adjudication period under paragraph (a) or (b) of this section:

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37702, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5107, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination.

(a) *Withdrawing a request.* An appellant that files a request for reconsideration may withdraw its request by filing a written and signed request for withdrawal. The request for withdrawal must—

(1) Contain a clear statement that the appellant is withdrawing the request for reconsideration and does not intend to proceed further with the appeal.

(2) Be received in the QIC's mailroom before the reconsideration is issued.

(b) *Dismissing a request.* A QIC 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 reconsideration is not a proper party under § 405.906(b) or does not otherwise have a right to a reconsideration under section 1869(b) of the Act;

(2) When the QIC determines that the party failed to make out a valid request for reconsideration that substantially complies with § 405.964(a) and (b);

(3) When the party fails to file the reconsideration request in accordance with the timeframes established in § 405.962, or fails to file the request for review of a contractor's dismissal of a redetermination request in accordance with the timeframes established in § 405.974(b)(1);

(4) When a beneficiary or the beneficiary's representative files a request for reconsideration, but the beneficiary dies while the request is pending, and all of the following criteria apply:

(i) The beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the QIC considers if the surviving spouse or estate remains liable for the services for which payment was denied or a Medicare contractor held

the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of payment for services at issue;

(ii) No other individual or entity with a financial interest in the case wishes to pursue the appeal; and

(iii) No other party to the redetermination filed a valid and timely request for reconsideration under §§ 405.962 and 405.964.

(5) When a party filing for the reconsideration submits a written request of withdrawal to the QIC and satisfies the criteria set forth in paragraph (a) of this section before the reconsideration has been issued; or

(6) When the contractor has not issued a redetermination on the initial determination for which a reconsideration is sought.

(c) *Notice of dismissal.* A QIC mails or otherwise transmits written notice of the dismissal of the reconsideration request to the parties at their last known addresses. The notice states that there is a right to request that the contractor vacate the dismissal action. The appeal will proceed with respect to any other parties that have filed a timely request for reconsideration.

(d) *Vacating a dismissal.* If good and sufficient cause is established, a QIC may vacate its dismissal of a request for reconsideration within 180 calendar days of the date of the notice of dismissal.

(e) *Effect of dismissal.* The dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under § 405.1004 or vacated under paragraph (d) of this section. The dismissal of a request for review of a contractor's dismissal of a redetermination request is binding and not subject to further review unless vacated under paragraph (d) of this section.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009; 82 FR 5107, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.974 Reconsideration and review of a contractor's dismissal of a request for redetermination.

(a) *Reconsideration of a contractor determination.* Except as provided in § 405.972, upon the basis of the evidence of record, the QIC must issue a reconsideration affirming or reversing, in whole or in part, the initial determination, including the redetermination, in question.

(b) *Review of a contractor's dismissal of a redetermination request.* (1) A party to a contractor's dismissal of a request for redetermination has a right to have the dismissal reviewed by a QIC, if the party files a written request for review of the dismissal with the QIC within 60 calendar days after receipt of the contractor's notice of dismissal.

(i) For purposes of this section, the date of receipt of the contractor's notice of dismissal is presumed to be 5 calendar days after the date of the notice of dismissal, 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 QIC indicated on the notice of dismissal.

(2) If the QIC determines that the contractor's dismissal was in error, it vacates the dismissal and remands the case to the contractor for a redetermination.

(3) A QIC's review of a contractor's dismissal of a redetermination request is binding and not subject to further review.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

§ 405.976 Notice of a reconsideration.

(a) *Notification to parties*—(1) *General rules.* (i) Written notice of the reconsideration must be mailed or otherwise transmitted to all parties at their last known addresses, in accordance with the timeframes established in § 405.970(a) or (b).

(ii) The notice must be written in a manner reasonably calculated to be understood by a beneficiary.

(iii) The QIC must promptly notify the entity responsible for payment of claims under Part A or Part B of its reconsideration. If the reconsideration results in issuance of supplemental payment to a provider or supplier, the Medicare contractor must also issue an electronic or paper RA notice to the provider or supplier.

(2) *Overpayment cases involving multiple beneficiaries who have no liability.*

In an overpayment case involving multiple beneficiaries who have no liability, the QIC may issue a written notice only to the appellant.

(b) *Content of the notice.* The reconsideration must be in writing and contain—

(1) A clear statement indicating whether the reconsideration is favorable or unfavorable;

(2) A summary of the facts, including as appropriate, a summary of the clinical or scientific evidence used in making the reconsideration;

(3) An explanation of how pertinent laws, regulations, coverage rules, and CMS policies, apply to the facts of the case, including, where applicable, the rationale for declining to follow an LCD, LMRP, or CMS program guidance;

(4) In the case of a determination on whether an item or service is reasonable or necessary under section 1862(a)(1)(A) of the Act, an explanation of the medical and scientific rationale for the decision;

(5) A summary of the rationale for the reconsideration.

(i) If the notice of redetermination indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration; and

(ii) The summary must also specify that, consistent with §§ 405.956(b)(8) and 405.966(b), all evidence, including evidence requested in the notice of redetermination, that is not submitted prior to the issuance of the reconsideration will not be considered at the OMHA level, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. This requirement does not apply to beneficiaries, unless the beneficiary is represented by a provider or supplier or to State Medicaid Agencies;

(6) Information concerning to the parties' right to an ALJ hearing, including the applicable amount in controversy requirement and aggregation provisions;

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

(8) A description of the procedures that a party must follow in order to obtain an ALJ hearing of an expedited reconsideration, including the time frame under which a request for an ALJ hearing must be filed;

(9) If appropriate, advice as to the requirements for use of the expedited access to judicial review process set forth in § 405.990;

(10) The procedures for obtaining additional information concerning the reconsideration, such as specific provisions of the policy, manual, or regulation used in making the reconsideration; and

(11) Any other requirements specified by CMS.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.978 Effect of a reconsideration.

A reconsideration is binding on all parties, unless—

(a) An ALJ or attorney adjudicator decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014;

(b) A review entity issues a decision in accordance to a request for expedited access to judicial review under § 405.990; or

(c) The reconsideration is revised as a result of a reopening in accordance with § 405.980.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

REOPENINGS

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) *General rules.* (1) A reopening is a remedial action taken to change a binding determination or decision that resulted in either an overpayment or

underpayment, even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by—

(i) A contractor to revise the initial determination or redetermination;

(ii) A QIC 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) If a contractor issues a denial of a claim because it did not receive requested documentation during medical review and the party subsequently requests a redetermination, the contractor must process the request as a reopening.

(3) Notwithstanding paragraph (a)(4) of this section, a contractor must process clerical errors (which includes minor errors and omissions) as reopenings, instead of as redeterminations as specified in § 405.940. If the contractor receives a request for reopening and disagrees that the issue is a clerical error, the contractor must dismiss the reopening request and advise the party of any appeal rights, provided the timeframe to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human or mechanical errors on the part of the party or the contractor such as—

(i) Mathematical or computational mistakes;

(ii) Inaccurate data entry; or

(iii) Denials of claims as duplicates.

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

(6) A determination under the Medicare secondary payer provisions of section 1862(b) of the Act that Medicare has an MSP recovery claim for services or items that were already reimbursed by the Medicare program is not a reopening, except where the recovery claim is based upon a provider's or supplier's failure to demonstrate that it filed a proper claim as defined in part 411 of this chapter.

(b) *Time frames and requirements for reopening initial determinations and redeterminations initiated by a contractor.* A contractor may reopen an initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in § 405.986.

(3) At any time if there exists reliable evidence as defined in § 405.902 that the initial determination was procured by fraud or similar fault as defined in § 405.902.

(4) At anytime if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

(5) At any time to effectuate a decision issued under the coverage appeals process.

(c) *Time frame and requirements for reopening initial determinations and redeterminations requested by a party.* (1) A party may request that a contractor reopen its initial determination or redetermination within 1 year from the date of the initial determination or redetermination for any reason.

(2) A party may request that a contractor reopen its initial determination or redetermination within 4 years from the date of the initial determination or redetermination for good cause in accordance with § 405.986.

(3) A party may request that a contractor reopen its initial determination at any time if the initial determination is unfavorable, in whole or in part, to the party thereto, but only for the purpose of correcting a clerical error on which that determination was based.

Third party payer error does not constitute clerical error. See § 405.986(c).

(4) A party may request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment under § 401.305 of this chapter.

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.* (1) A QIC may reopen its reconsideration on its own motion within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986. If the QIC's reconsideration was procured by fraud or similar fault, then the QIC 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 § 405.986. 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 § 405.986. 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 a party.* (1) A party to a reconsideration may request that a QIC reopen its reconsideration within 180 calendar days from the date of the reconsideration for good cause in accordance with § 405.986.

(2) A party to an ALJ or attorney adjudicator decision 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 § 405.986.

(3) A party to a Council review 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 § 405.986.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 81 FR 7684, Feb. 12, 2016; 82 FR 5108, Jan. 17, 2017]

§ 405.982 Notice of a revised determination or decision.

(a) *When adjudicators initiate reopenings.* When any determination or decision is reopened and revised as provided in § 405.980, the contractor, QIC, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. 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 a party.* The contractor, QIC, ALJ or attorney adjudicator, or the Council must mail its revised determination or decision to the parties to that determination or decision at their last known address. In the case of a full or partial reversal resulting in issuance of a payment to a provider or supplier, a revised electronic or paper remittance advice notice must be issued by the Medicare contractor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.984 Effect of a revised determination or decision.

(a) *Initial determinations.* The revision of an initial determination is binding upon all parties unless a party files a written request for a redetermination that is accepted and processed in accordance with § 405.940 through § 405.958.

(b) *Redeterminations.* The revision of a redetermination is binding upon all parties unless a party files a written request for a QIC reconsideration that

is accepted and processed in accordance with § 405.960 through § 405.978.

(c) *Reconsiderations.* The revision of a reconsideration is binding upon all parties unless a party files a written request for an ALJ hearing that is accepted and processed in accordance with § 405.1000 through § 405.1063.

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party 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 initial determination, redetermination, reconsideration, or hearing decision revised by the reopening may be subsequently appealed.

(g) *Effect of a revised determination or decision.* A revised determination or decision is binding unless it is appealed or otherwise reopened.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5108, Jan. 17, 2017]

§ 405.986 Good cause for reopening.

(a) *Establishing good cause for reopening.* 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.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, or a change in legal interpretation or policy by SSA in a regulation, SSA ruling, or SSA general instruction in entitlement appeals, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude contractors from conducting reopenings to effectuate coverage decisions issued under the authority granted by section 1869(f) of the Act.

(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.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 86 FR 65660, Nov. 19, 2021]

EXPEDITED ACCESS TO JUDICIAL REVIEW

§ 405.990 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 (DAB), 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) A party 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) A party may request EAJR in place of an ALJ hearing or Council review if the following conditions are met:

(i) A QIC has made a reconsideration determination and the party has filed a request for—

(A) An ALJ hearing in accordance with § 405.1002 and a decision, dismissal order, or remand order of the ALJ or attorney adjudicator has not been issued;

(B) Council review in accordance with § 405.1102 and a final decision, dismissal order, or remand order of the Council has not been issued; or

(ii) The appeal has been escalated from the QIC to OMHA for an ALJ hearing after the period described in § 405.970(a) and § 405.970(b) has expired, and the QIC does not issue a decision or dismissal order within the timeframe described in § 405.970(e).

(2) The requestor is a party, as defined in paragraph (e) of this section.

(3) The amount remaining in controversy meets the requirements of § 405.1006(b) or (c).

(4) If there is more than one party to the reconsideration, hearing, or Council review, each party 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 requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

(i) A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

(ii) A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC reconsideration and of any ALJ or attorney adjudicator decision that the requester has received;

(4) If any QIC reconsideration or ALJ or attorney adjudicator decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC reconsideration or ALJ or attorney adjudicator decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor 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 requestor 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 party may file a request for the EAJR—

(i) If the party 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 party has requested Council review, at any time before receipt of notice of the Council's decision.

(e) *Parties to the EAJR.* The parties to the EAJR are the persons or entities who were parties to the QIC's reconsideration determination and, if applicable, to the ALJ hearing.

(f) *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 to paragraph (g) 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 (g) 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 time frame specified in paragraph (f)(2) of this section, then the requestor may bring a civil action in Federal district court within 60 calendar days of the end of the time frame.

(g) *Certification by the review entity.* If a party meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(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, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party 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 requestor 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 requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under § 405.1136(a) and § 405.1136(c) through § 405.1136(f).

(i) *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 in writing all parties 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.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60 calendar day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

ALJ HEARINGS

§ 405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010, or join the hearing before an ALJ as a party under § 405.1012.

(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 all parties who are due a notice of hearing in accordance with § 405.1020(c) waive their 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 parties 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 non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide 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 for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

[82 FR 5109, Jan. 17, 2017]

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 calendar days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the reconsideration, 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 QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in § 405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal for a hearing before an ALJ after the period described in § 405.970(a) and (b) has expired and the party files the request in accordance with § 405.970(d);

(2) The QIC does not issue a decision or dismissal order within 5 calendar days of receiving the request for escalation in accordance with § 405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in § 405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1004 Right to a review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 calendar days after the date of the 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 QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates

the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with § 405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with § 405.1052(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) ''Common issues of law and fact'' means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) ''Delivery of similar or related services'' means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party 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 (b)(1) of this section is not a multiple of $10, then 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.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be $1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy*—(1) *In general.* The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Limitation on liability.* Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 of this chapter or if that liability was not limited under § 411.402 of this chapter, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

(3) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(4) *Overpayments.* Notwithstanding paragraph (d)(1) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter, or the amount of the revised overpayment if the amount originally demanded changes as a result of a subsequent determination or appeal, for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter, or as subsequently revised.

(5) *Coinsurance and deductible challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(6) *Fee schedule or contractor price challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) *Aggregating claims to meet the amount in controversy*—(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1008 Parties to the proceedings on a request for an ALJ hearing.

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

[82 FR 5110, Jan. 17, 2017]

§ 405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made*— (1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to—

(i) The assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator; and

(ii) The parties who were sent a copy of the notice of reconsideration or, for escalated requests for reconsideration, any party that filed a request for reconsideration or was found liable for the services at issue subsequent to the initial determination.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (3) of this section, 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 a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in paragraph (d)(3) of this section. However, the parties 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 or contractor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit the position paper or written testimony, a position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent within the same time frame specified in paragraph (c)(3)(i) of this section to—

(A) The parties that are required to be sent a copy of the notice of intent to participate in accordance with paragraph (b)(1) of this section, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has been made a party to a hearing in accordance with §405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with §405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with §405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under §405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with §405.1012.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election 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 election, and the written notice must be sent as soon as possible after the oral notice is provided.

[82 FR 5110, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§405.1012 When CMS or its contractors may be a party to a hearing.

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(2) Unless the request for hearing is filed by an unrepresented beneficiary, an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse

inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties who were sent a copy of the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent within the same time frame specified in paragraph (c)(2)(i) of this section to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3), unless the ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election 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 election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

[82 FR 5111, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1014 Request for an ALJ hearing or a review of a QIC dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare health number of the beneficiary whose

claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *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 appellant 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 appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant'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.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely, and any applicable time frame specified in §405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or ''cc'' line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant, other than an unrepresented beneficiary, again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant's request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an extension for good cause (See § 405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, 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 a QIC dismissal, or upon notice that the request may be dismissed because it was not timely filed, with the office specified in the notice of reconsideration or dismissal.

(3) 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 a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC 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 a QIC 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).

(4) If a request for hearing is not timely filed, any applicable adjudication period in § 405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

[82 FR 5112, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, 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 QIC's notice of reconsideration, unless

the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in §405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with §405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) 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 claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation*—(1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with §405.1102(a), and the appeal will be escalated to the Council for a review in accordance with §405.1108; and

(ii) Forward the case file to the Council.

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

[82 FR 5113, Jan. 17, 2017]

§ 405.1018 Submitting evidence.

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 405.1016 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.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.* (1) The requirements in paragraphs (a) and (b) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

(2) The requirements in paragraph (c) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an applicable plan, or a beneficiary represented by someone other than a provider or supplier.

[82 FR 5113, Jan. 17, 2017]

§ 405.1020 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 beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find 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 beneficiary.

(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) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary 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 VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC 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 all parties that filed

an appeal or participated in the reconsideration; any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record; the QIC that issued the reconsideration or from which the request for reconsideration was escalated, or another contractor designated to receive the notice of hearing by CMS; and CMS or a contractor that elected to participate in the proceedings in accordance with §405.1010(b) or that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing 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 party or 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 or a contractor that wishes 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) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with §405.1038(b). As provided in §405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

(5) If the party's objection to the place of the hearing includes a request for an in-person or VTC 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 party's contention that—

(1) The party 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 party's reason for requesting the change, the facts supporting the request, and the impact of the proposed 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 party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 calendar days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party'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 a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party 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) that he or she has.

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that 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 appellant 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 § 405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with § 405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication time frame 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 party may appear in person or by VTC before the ALJ. Good cause is not required for a request for VTC hearing made by an unrepresented beneficiary 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 all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5114, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties

and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(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 initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 405.1032.

(2) The notice will inform the parties that they may designate a person to represent them 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 appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party 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 party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with § 405.1020(e).

[82 FR 5115, Jan. 17, 2017]

§ 405.1024 Objections to the issues.

(a) If a party 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.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a prehearing conference, or at the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5115, Jan. 17, 2017]

§ 405.1026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, 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

considers the party'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 party 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 § 405.1100 through § 405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with § 405.1016 is extended by 14 calendar days.

[82 FR 5115, Jan. 17, 2017]

§ 405.1028 Review of evidence submitted by parties.

(a) *New evidence*—(1) *Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

[82 FR 5115, Jan. 17, 2017]

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues,

questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or 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 party 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 a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with §405.1042 and respond in writing to any statements made by other parties or 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. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with §405.1028 for not producing the evidence earlier.

(d) *Effect of new evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in §405.1016 is extended in accordance with §405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with §405.1022, 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 parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with §405.1016, 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 §405.1022, except that the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with §405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

[82 FR 5116, Jan. 17, 2017]

§ 405.1032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term ''party'' does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or 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 parties that were or will be sent the notice of hearing 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 parties will have at least 10 calendar days 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 claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were 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 those claims in accordance with § 405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations*—(1) *Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

[82 FR 5116, Jan. 17, 2017]

§ 405.1034 Requesting information from the QIC.

(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 or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims, and official copies of dismissals of a request for redetermination or reconsideration, can be provided only by CMS or its contractors. Prior to issuing a request for information to the QIC, OMHA will confirm whether an electronic copy of the 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 or its contractors'' means the information is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. 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 or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

[82 FR 5117, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) Any party to a hearing has the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under § 405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under § 405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear.* (1) A party may submit to OMHA a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* A party or a person designated to act as a party's representative may appear before the ALJ to state the party'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. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(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 allows the parties or their designated representatives 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.

(f) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party 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 its contractors, on his or her own initiative or at the request of a party, to compel an appearance, testimony, or the production of evidence.

(2) A party's written request for a subpoena must—

(i) Give the names of the witnesses or documents to be produced;

(ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;

(iii) State the important facts that the witness or document is expected to prove; and

(iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set forth in paragraph (f)(2) of this section with the ALJ no later than the end of the discovery period established by the ALJ under § 405.1037(c).

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted by the ALJ; and

(iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review specified in § 405.1016(e) and (f), § 405.1102, or § 405.1110, as applicable. *Exception.* 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 an ALJ, the Council may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a subpoena ruling, the Council must take review and the subpoena ruling at issue is automatically stayed pending the Council's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek Council review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(v) If the Council grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the Council issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) *Enforcement.* (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ 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).

(ii) 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 party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with § 405.1012.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 calendar days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings*—(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review specified in § 405.1016(e) and (f), § 405.1100, § 405.1102, or § 405.1110, as applicable.

(2) *Exception.* To the extent a ruling authorizes discovery or 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 ALJ, the Council may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the Council must take review and the discovery ruling at issue is automatically stayed pending the Council's order.

(ii) Upon notice to the ALJ that a party intends to seek Council review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(iv) Where CMS requests the Council to take review of a discovery ruling or where the Council grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the Council issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a discovery ruling, if the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1038 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 appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with § 405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with § 405.1020(c) and who wish to appear.

(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 or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, 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 appellant or other liable parties 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 5117, Jan. 17, 2017]

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing

in accordance with § 405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party 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 a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) 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 parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

[82 FR 5118, Jan. 17, 2017]

§ 405.1042 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 conferences, 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, claims, 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, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review 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 or the case is escalated to the Council, 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 a party 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, a party 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 party may be asked to pay the costs of providing these items.

(2) If a party 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 § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party 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 requesting party 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 requesting party obtains consent from the individual.

[82 FR 5118, Jan. 17, 2017]

§ 405.1044 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 appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an appellant 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 appellant 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 §§ 405.1020 and 405.1022.

(b) *Consolidated or separate 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 appellant 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 appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006 and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

[82 FR 5118, Jan. 17, 2017]

§ 405.1046 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. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary 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) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to

§ 405.1028, a discussion of the new evidence and the good cause determination that was made;

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) 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 an item or service 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 contractor 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 contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924.

(b) *Decisions on requests for review of a QIC dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary 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 all the parties at their last known address.

[82 FR 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1048 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 on all parties unless—

(1) A party 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 § 405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 405.980;

(3) The expedited access to judicial review process at § 405.990 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 § 405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in § 405.980.

[82 FR 5119, Jan. 17, 2017]

§ 405.1050 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 to it. If the Council holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the Council has assumed responsibility for the case.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5118, Jan. 17, 2017]

§ 405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party 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 party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing, or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(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), that the party may have.

(2) The person or entity requesting a hearing has no right to it under § 405.1002.

(3) The party 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 § 405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(5) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review

of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under § 405.1004.

(2) The party 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 § 405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to § 405.1014.

(4) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC 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 appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant 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 appellant, all parties who were sent a copy of the request for hearing or review at their last known address, and to CMS or a CMS contractor that is a party to the proceedings on a request for hearing. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(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 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 405.1108(b), or vacated by the ALJ or attorney adjudicator under § 405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e).

[82 FR 5120, Jan. 17, 2017]

§ 405.1056 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 claim in accordance with § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor 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 § 405.1016 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 QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may jointly request a remand of the appeal to the entity that conducted the reconsideration. 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 a QIC's dismissal of a request for reconsideration.* (1) Consistent with § 405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC'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 QIC, 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) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the appellant, all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. 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 a party or CMS or one of its contractors 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 are not

available for and do not apply to remands that are issued under paragraph (d)(1) of this section.

[82 FR 5121, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1058 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 § 405.1056(g).

[82 FR 5121, Jan. 17, 2017]

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs and attorney adjudicators, and the Council.

(b) *Review by an ALJ or attorney adjudicator.* (1) An ALJ or attorney adjudicator may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ or attorney adjudicator may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the Council.* (1) The Council may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The Council may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 82 FR 5121, Jan. 17, 2017]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or 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 such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5121, Jan. 17, 2017]

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, 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 Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security

Administration 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, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[82 FR 5121, Jan. 17, 2017]

MEDICARE APPEALS COUNCIL REVIEW

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to 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) Under circumstances set forth in §§ 405.1016 and 405.1108, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

[82 FR 5122, Jan. 17, 2017]

§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

(2) 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.

(3) 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) A party 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;

(2) It is filed with the Council; and

(3) It 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).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140), unless specifically excepted, the term ''party'', includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

[82 FR 5122, Jan. 17, 2017]

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or

attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in §405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. 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 appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period under §405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in §405.1100 until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

[82 FR 5122, Jan. 17, 2017]

§405.1108 Council actions when request for review or escalation is filed.

(a) Except as specified in paragraphs (c) and (d) of this section, when a party 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 party requesting review does not have a right to a hearing before the Council. The Council will consider all of the evidence in 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 an ALJ or attorney adjudicator for further proceedings.

(b) When a party 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) The Council will dismiss a request for review when the party requesting review does not have a right to a review by the Council, 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) When an appellant requests escalation of a case from the OMHA level to the Council, the Council may take any of the following actions:

(1) Issue a decision based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) Conduct any additional proceedings, including a hearing, that the Council determines are necessary to issue a decision.

(3) Remand the case to OMHA for further proceedings, including a hearing.

(4) Dismiss the request for Council review because the appellant does not have the right to escalate the appeal.

(5) Dismiss the request for a hearing for any reason that the ALJ or attorney adjudicator could have dismissed the request.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5122, Jan. 17, 2017]

§405.1110 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 any of its contractors may refer a case to the Council for it to consider reviewing

under this authority anytime within 60 calendar days of receipt of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' 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' 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 decision or dismissal is received. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated 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.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* 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.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. 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. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, 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. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

(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 5122, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party 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. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

[82 FR 5123, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1114 Dismissal of request for review.

The Council dismisses a request for review if the party 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 party asks to withdraw the request for review;

(b) The party does not have a right to request Council review; or

(c) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(1) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the Council considers whether the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue;

(2) No other individual or entity with a financial interest in the case wishes to pursue an appeal under § 405.1102;

(3) No other party to the ALJ's or attorney adjudicator's action filed a valid and timely review request under §§ 405.1102 and 405.1112.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017; 84 FR 19871, May 7, 2019]

§ 405.1116 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.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§ 405.1118 Obtaining evidence from the Council.

A party 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 party

may be asked to pay the costs of providing these items. If a party 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 party's response will not be counted toward the 90 calendar day adjudication deadline.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§ 405.1120 Filing briefs with the Council.

Upon request, the Council will give the party requesting review, as well as all other parties, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. Any party who submits a brief or statement must send a copy to all of the other parties. Unless the party 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 § 405.1100. The Council may also request, but not require, CMS or its contractor to file a brief or position paper if the Council determines that it is necessary to resolve the issues in the case. The Council will not draw any adverse inference if CMS or a contractor either participates, or decides not to participate in Council review.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5123, Jan. 17, 2017]

§ 405.1122 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 limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ or attorney adjudicator. However, if the ALJ's or attorney adjudicator's decision decides a new issue that the parties were 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.

(b) *Appeal before Council as a result of appellant's request for escalation.* (1) If the Council is reviewing a case that is escalated from the OMHA level to the Council, the Council will decide the case based on the record constructed at the QIC and any additional evidence, including oral testimony, entered in the record by the ALJ or attorney adjudicator before the case was escalated.

(2) If the Council receives additional evidence with the request for escalation that is material to the question to be decided, or determines that additional evidence is needed to resolve the issues in the case, and the record provided to the Council indicates that the previous decision-makers did not attempt to obtain the evidence before escalation, the Council may remand the case to an ALJ or attorney adjudicator to consider or obtain the evidence and issue a new decision.

(c) *Evidence related to issues previously considered by the QIC.* (1) If new evidence related to issues previously considered by the QIC is submitted to the Council by a provider, supplier, or a beneficiary represented by a provider or supplier, the Council must determine if the provider, supplier, or the beneficiary represented by a provider or supplier had good cause for submitting it for the first time at the Council level.

(2) If the Council determines that good cause does not exist, the Council must exclude the evidence from the proceeding, may not consider it in reaching a decision, and may not remand the issue to an ALJ or attorney adjudicator.

(3) The Council must notify all parties if it excludes the evidence. The Council may remand to an ALJ or attorney adjudicator if—

(i) The ALJ or attorney adjudicator did not consider the new evidence submitted by the provider, supplier, or beneficiary represented by a provider or supplier because good cause did not exist; and

(ii) The Council finds that good cause existed under §405.1028 and the ALJ or attorney adjudicator should have reviewed the evidence.

(iii) The new evidence is submitted by a party that is not a provider, supplier, or a beneficiary represented by a provider or supplier.

(d) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, the Council may, on its own initiative or at the request of a party, issue subpoenas requiring a party 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 its contractors, on its own initiative or at the request of a party, to compel the production of evidence.

(2) A party's request for a subpoena must—

(i) Give a sufficient description of the documents to be produced;

(ii) State the important facts that the documents are expected to prove; and

(iii) Indicate why these facts could not be proven without issuing a subpoena.

(3) A party to the Council review on escalation that wishes to subpoena documents must file a written request that complies with the requirements set out in paragraph (d)(2) of this section within 10 calendar days of the request for escalation.

(4) A subpoena will issue only where a party—

(i) Has sought discovery;

(ii) Has filed a motion to compel;

(iii) Has had that motion granted; and

(iv) Nevertheless, has still not received the requested discovery.

(e) Reviewability of subpoena rulings—

(1) *General rule.* A Council ruling on a subpoena request is not subject to immediate review by the Secretary.

(2) *Exception.* 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 portion of the subpoena.

(3) Upon notice to the Council that a party or non-party, as applicable, intends to seek Secretary review of the subpoena, the Council must stay all proceedings affected by the subpoena.

(4) The Council determines the length of the stay under the circumstances of a given case, but in no event is less than 15 calendar days after the day on which the Council received notice of the party or non-party's intent to seek Secretary review.

(5) If the Secretary grants a request for review, the subpoena or portion of the subpoena, as applicable, is stayed until the Secretary issues a written decision that affirms, reverses, modifies, or remands the Council's action for the subpoena.

(6) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Council's action stands.

(f) *Enforcement.* (1) If the Council determines, whether on its own motion or at the request of a party, that a party or non-party 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) 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 party or nonparty subject to the subpoena.

(3) The Council must promptly mail a copy of the notice and related documents to the party or non-party subject to the subpoena, and to any other party and affected non-party to the appeal.

(4) If the Secretary does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the subpoena stands.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65337, Dec. 9, 2009; 82 FR 5123, Jan. 17, 2017]

§ 405.1124 Oral argument.

A party 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 tells the parties of the time and place of the oral argument at least 10 calendar days before the scheduled date.

(c) In case of a previously unrepresented beneficiary, 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 or its contractor to appear before it if the Council determines that it may be helpful in resolving the issues in the case.

(e) The Council will not draw any inference if CMS or a contractor decides not to participate in the oral argument.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1126 Case remanded by the Council.

(a) *When the Council may remand a case.* Except as specified in § 405.1122(c), 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.

(b) *Action by ALJ 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.

(c) *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 parties at their last known address. The notice tells them 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.

(d) *Filing briefs with the Council when ALJ or attorney adjudicator issues recommended decision.* (1) Any party to the recommended decision 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. Any party may ask the Council for additional time to file briefs or statements. The Council will extend this period, as appropriate, if the party shows that it has good cause for requesting the extension.

(2) All other rules for filing briefs with and obtaining evidence from the Council follow the procedures explained in this subpart.

(e) *Procedures before the Council.* (1) The Council, after receiving a recommended decision, will conduct proceedings and issue its decision or dismissal according to the procedures explained in this subpart.

(2) 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.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1128 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

§ 405.1122, 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's or attorney adjudicator's decisionor recommended decision.

(c) The Council mails a copy of its decision to all the parties at their last known addresses. For overpayment cases involving multiple beneficiaries where there is no beneficiary liability the Council may choose to send written notice only to the appellant. In the event the decision will result in a payment to a provider or supplier, the Medicare contractor must issue any electronic or paper remittance advice notice to that provider or supplier.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1130 Effect of the Council's decision.

The Council's decision is final and binding on all parties 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 § 405.980. A party may file an action in a Federal district court within 60 calendar days after the date it receives notice of the Council's decision.

[74 FR 65338, Dec. 9, 2009, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1132 Request for escalation to Federal court.

(a) If the Council does not issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ or attorney adjudicator dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the Council may—

(1) Issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or

(2) If the Council is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to issue a decision, dismissal or remand order within the statutory time frame.

(b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the Council's notice that the Council is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ or attorney adjudicator dismissal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1134 Extension of time to file action in Federal district court.

(a) Any party to the Council's decision or to a request for EAJR that has been certified by the review entity other than CMS 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 party 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).

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1136 Judicial review.

(a) *General rules.* (1) To the extent authorized by sections 1869, 1876(c)(5)(B), and 1879(d) of the Act, a party to a Council decision, or an appellant who requests escalation to Federal district court if the Council does not complete its review of the ALJ's or attorney adjudicator's decision within the applicable adjudication period, may obtain a court review if the amount remaining in controversy satisfies the requirements of § 405.1006(c).

(2) If the Council's adjudication period set forth in § 405.1100 expires and

the appellant does not request escalation to Federal district court, the case remains with the Council until a final decision, dismissal order, or remand order is issued.

(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 party resides or where such individual, institution, or agency has its principal place of business.

(2) If the party does not reside within any judicial district, or if the individual, institution, or agency does not have its principal place of business within any such 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 § 405.1130, § 405.1132, or § 405.1134, as applicable.

(2) For purposes of this section, the date of receipt of the notice of the Council's decision or the Council's notice that it is not able to issue a decision within the statutory timeframe 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 § 405.990, 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 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) *Prohibition against judicial review of certain Part B regulations or instructions.* Under section 1869(e)(1) of the Act, a court may not review a regulation or instruction that relates to a method of payment under Medicare Part B if the regulation was published, or the instructions issued, before January 1, 1991.

(f) *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 a party due to a party's failure to submit proof in conformity with a regulation prescribed under section 205(a) of the Act pertaining to the type of proof a party 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.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37705, June 30, 2005; 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

§ 405.1138 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 § 405.1140 will be followed.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1140 Council review of ALJ decision in a case remanded by a Federal district court.

(a) *General rules.* (1) In accordance with § 405.1138, 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 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 a party 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) *A party files exceptions disagreeing with the decision of the ALJ or attorney adjudicator.* (1) If a party 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. 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. The party must file exceptions within 30 calendar days of the date the party receives the decision of the ALJ or attorney adjudicator or submit a written request for an extension within the 30 calendar day period. 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 party 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).

(2) If written exceptions are timely filed, the Council considers the party'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.

(3) When a party 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 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 all parties at their last known address.

(3) The parties will be provided with the opportunity to file briefs or other written statements with the Council about the facts and law relevant to the case.

(4) After the briefs or other written statements are 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 of the cases within 60 calendar days after the date of the ALJ's or attorney adjudicator's decision, the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65338, Dec. 9, 2009; 82 FR 5124, Jan. 17, 2017]

Subpart J—Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for Inpatient Hospital Discharges

SOURCE: 69 FR 69264, Nov. 26, 2004, unless otherwise noted.

§ 405.1200 Notifying beneficiaries of provider service terminations.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1200 through 405.1204, the term, provider, is defined as a home health agency (HHA), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), or hospice.

(2) For purposes of §§ 405.1200 through 405.1204, a termination of Medicare-covered service is a discharge of a beneficiary from a residential provider of services, or a complete cessation of coverage at the end of a course of treatment prescribed in a discrete increment, regardless of whether the beneficiary agrees that the services should end. A termination does not include a reduction in services. A termination also does not include the termination of one type of service by the provider if the beneficiary continues to receive other Medicare-covered services from the provider.

(b) *Advance written notice of service terminations.* Before any termination of services, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services. The provider must use a standardized notice, as specified by CMS, in accordance with the following procedures:

(1) *Timing of notice.* A provider must notify the beneficiary of the decision to terminate covered services no later than 2 days before the proposed end of the services. If the beneficiary's services are expected to be fewer than 2 days in duration, the provider must notify the beneficiary at the time of admission to the provider. If, in a nonresidential setting, the span of time between services exceeds 2 days, the notice must 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 beneficiary's financial liability for continued services begins;

(iii) A description of the beneficiary's right to an expedited determination under § 405.1202, including information about how to request an expedited determination and about a beneficiary's right to submit evidence showing that services must continue;

(iv) A beneficiary's right to receive the detailed information specified under § 405.1202(f); and

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the termination notice is valid if—

(i) The beneficiary (or the beneficiary's authorized representative) has signed and dated the notice to indicate that he or she has received the notice and can comprehend its contents; 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 a beneficiary refuses to sign the notice.* The provider may annotate its notice to indicate the refusal, and the date of refusal is considered the date of receipt of the notice.

(5) *Financial liability for failure to deliver valid notice.* A provider is financially liable for continued services until 2 days after the beneficiary receives valid notice as specified under paragraph (b)(3) of this section, or until the service termination date specified on the notice, whichever is later. A beneficiary may waive continuation of services if he or she agrees with being discharged sooner than the planned service termination date.

§ 405.1202 Expedited determination procedures.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to an expedited determination by a QIO under the following circumstances:

(1) For services furnished by a nonresidential provider, the beneficiary disagrees with the provider of those services that services should be terminated, and a physician certifies that failure to continue the provision of the service(s) may place the beneficiary's health at significant risk.

(2) For services furnished by a residential provider or a hospice, the beneficiary disagrees with the provider's decision to discharge the beneficiary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination must submit a request for a determination to the QIO in the State in which the beneficiary is receiving those provider services, in writing or by telephone, by no later than noon of the calendar day following receipt of the provider's notice of termination. If the QIO is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIO is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or to supply information that the QIO may request to conduct its review.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIO in making its decision.

(4) If a beneficiary makes an untimely request for an expedited determination by a QIO, the QIO will accept the request and make a determination as soon as possible, but the 72-hour time frame under paragraph (e)(6) and the financial liability protection under paragraph (g) of this section do not apply.

(c) *Coverage of provider services.* Coverage of provider services continues until the date and time designated on the termination notice, unless the QIO reverses the provider's service termination decision. If the QIO's decision is delayed because the provider did not timely supply necessary information or records, the provider may be liable for the costs of any additional coverage, as determined by the QIO in accordance with paragraph (e)(7) of this section. If the QIO finds that the beneficiary did not receive valid notice, coverage of provider services continues until at least 2 days after valid notice has been received. Continuation of coverage is not required if the QIO determines that coverage could pose a threat to the beneficiary's health or safety.

(d) *Burden of proof.* When a beneficiary requests an expedited determination by a QIO, the burden of proof rests with the provider 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) In order for the QIO to determine whether the provider has met the burden of proof, the provider should supply any and all information that a QIO requires to sustain the provider's termination decision, consistent with paragraph (f) of this section.

(2) The beneficiary may submit evidence to be considered by a QIO in making its decision.

(e) *Procedures the QIO must follow.* (1) On the day the QIO receives the request for an expedited determination under paragraph (b) of this section, it must immediately notify the provider of those services that a request for an expedited determination has been made.

(2) The QIO determines whether the provider delivered valid notice of the termination decision consistent with § 405.1200(b) and paragraph (f) of this section.

(3) The QIO examines the medical and other records that pertain to the services in dispute. If applicable, the QIO determines whether a physician has certified that failure to continue the provision of services may place the beneficiary's health at significant risk.

(4) The QIO must solicit the views of the beneficiary who requested the expedited determination.

(5) The QIO must provide an opportunity for the provider/practitioner to explain why the termination or discharge is appropriate.

(6) No later than 72 hours after receipt of the request for an expedited determination, the QIO must notify the beneficiary, beneficiary's physician, and the provider of services of its determination whether termination of

Medicare coverage is the correct decision, either on the basis of medical necessity or based on other Medicare coverage policies.

(7) If the QIO does not receive the information needed to sustain a provider's decision to terminate services, 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 provider services, the provider may be held financially liable for these services, as determined by the QIO.

(8) The QIO's initial notification may be by telephone, followed by a written notice including the following information:

(i) The rationale for the determination;

(ii) An explanation of the Medicare payment consequences of the determination and the date a beneficiary becomes fully liable for the services; and

(iii) Information about the beneficiary's right to a reconsideration of the QIO's determination, including how to request a reconsideration and the time period for doing so.

(f) *Responsibilities of providers.* (1) When a QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed notice to the beneficiary by close of business of the day of the QIO'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 information about how the beneficiary may obtain a copy of the Medicare policy;

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case; and

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the provider must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required under § 405.1200(b) and under paragraph (f)(1) of this section. The provider must furnish this information as soon as possible, but no later than by close of business of the day the QIO notifies the provider of the request for an expedited determination. At the discretion of the QIO, the provider may make the information available by phone or in writing (with a written record of any information not transmitted initially in writing).

(3) At a beneficiary's request, the provider must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO including records of any information provided by telephone. The provider may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The provider must accommodate such a request by no later than close of business of the first day after the material is requested.

(g) *Coverage during QIO review.* When a beneficiary requests an expedited determination in accordance with the procedures required by this section, the provider may not bill the beneficiary for any disputed services until the expedited determination process (and reconsideration process, if applicable) has been completed.

§ 405.1204 Expedited reconsiderations.

(a) *Beneficiary's right to an expedited reconsideration.* A beneficiary who is dissatisfied with a QIO's expedited determination may request an expedited reconsideration by the appropriate QIC.

(b) *Requesting an expedited reconsideration.* (1) A beneficiary who wishes to obtain an expedited reconsideration must submit a request for the reconsideration to the appropriate QIC, in writing or by telephone, by no later than noon of the calendar day following initial notification (whether by telephone

or in writing) receipt of the QIO's determination. If the QIC is unable to accept the beneficiary's request, the beneficiary must submit the request by noon of the next day the QIC is available to accept a request.

(2) The beneficiary, or his or her representative, must be available to answer questions or supply information that the QIC may request to conduct its reconsideration.

(3) The beneficiary may, but is not required to, submit evidence to be considered by a QIC in making its decision.

(4) A beneficiary who does not file a timely request for an expedited QIC reconsideration subsequently may request a reconsideration under the standard claims appeal process, but the coverage protections described in paragraph (f) of this section would not extend through this reconsideration, nor would the timeframes or the escalation process described in paragraphs (c)(3) and (c)(5) of this section, respectively.

(c) *Procedures the QIC must follow.* (1) On the day the QIC receives the request for an expedited determination under paragraph (b) of this section, the QIC must immediately notify the QIO that made the expedited determination and the provider of services of the request for an expedited reconsideration.

(2) The QIC must offer the beneficiary and the provider an opportunity to provide further information.

(3) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, no later than 72 hours after receipt of the request for an expedited reconsideration, and any medical or other records needed for such reconsideration, the QIC must notify the QIO, the beneficiary, the beneficiary's physician, and the provider of services, of its decision on the reconsideration request.

(4) The QIC's initial notification may be done by telephone, followed by a written notice including:

(i) The rationale for the reconsideration decision;

(ii) An explanation of the Medicare payment consequences of the determination and the beneficiary's date of liability; and

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006.

(6) A beneficiary requesting an expedited reconsideration under this section may request (either in writing or orally) that the QIC grant such additional time as the beneficiary specifies (not to exceed 14 days) for the reconsideration. If an extension is granted, the deadlines in paragraph (c)(3) of this section do not apply.

(d) *Responsibilities of the QIO.* (1) When a QIC notifies a QIO that a beneficiary has requested an expedited reconsideration, the QIO must supply all information that the QIC needs to make its expedited reconsideration as soon as possible, but no later than by close of business of the day that the QIC notifies the QIO of the request for an expedited reconsideration.

(2) At a beneficiary's request, the QIO must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIC. The QIO may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The QIO must accommodate the request by no later than close of business of the first day after the material is requested.

(e) *Responsibilities of the provider.* A provider may, but is not required to, submit evidence to be considered by a QIC in making its decision. If a provider fails to comply with a QIC's request for additional information beyond that furnished to the QIO for purposes of the expedited determination, the QIC makes its reconsideration decision based on the information available.

(f) *Coverage during QIC reconsideration process.* When a beneficiary requests an expedited reconsideration in accordance with the deadline specified in (b)(1) of this section, the provider may not bill the beneficiary for any disputed services until the QIC makes its determination.

[69 FR 69624, Nov. 26, 2004, as amended at 82 FR 5124, Jan. 17, 2017]

§ 405.1205 Notifying beneficiaries of hospital discharge appeal rights.

(a) *Applicability and scope.* (1) For purposes of §§ 405.1204, 405.1205, 405.1206, and 405.1208, 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 includes critical access hospitals.

(2) For purposes of §§ 405.1204, 405.1205, 405.1206, and 405.1208, a discharge is a formal release of a beneficiary from an inpatient hospital.

(b) *Advance written notice of hospital discharge rights.* For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary'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 beneficiary's admission to the hospital.

(2) *Content of the notice.* The notice must include the following information:

(i) The beneficiary'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 beneficiary's right to request an expedited determination of the discharge decision including a description of the process under § 405.1206, and the availability of other appeals processes if the beneficiary fails to meet the deadline for an expedited determination.

(iii) The circumstances under which a beneficiary 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) A beneficiary's right to receive additional detailed information in accordance with § 405.1206(e).

(v) Any other information required by CMS.

(3) *When delivery of the notice is valid.* Delivery of the written notice of rights described in this section is valid if—

(i) The beneficiary (or the beneficiary'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 a beneficiary 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 beneficiary (or beneficiary'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 § 405.1205(b) is delivered within 2 calendar days of discharge.

[71 FR 68720, Nov. 27, 2006]

§ 405.1206 Expedited determination procedures for inpatient hospital care.

(a) *Beneficiary's right to an expedited determination by the QIO.* A beneficiary has a right to request an expedited determination by the QIO when a hospital (acting directly or through its utilization review committee), with physician concurrence, determines that inpatient care is no longer necessary.

(b) *Requesting an expedited determination.* (1) A beneficiary who wishes to exercise the right to an expedited determination 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 beneficiary, or his or her representative, upon request by the QIO, must be available to discuss the case.

(3) The beneficiary may, but is not required to, submit written evidence to be considered by a QIO in making its decision.

(4) A beneficiary who makes a timely request for an expedited QIO review in accordance with paragraph (b)(1) of this section is subject to the financial liability protections under paragraphs (f)(1) and (f)(2) of this section, as applicable.

(5) A beneficiary who fails to make a timely request for an expedited determination by a QIO, as described in paragraph (b)(1) of this section, and remains in the hospital without coverage, still may request an expedited QIO determination at any time during the hospitalization. The QIO will issue a decision in accordance with paragraph (d)(6)(ii) of this section, however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(6) A beneficiary who fails to make a timely request for an expedited determination in accordance with paragraph (b)(1) of this section, and who is no longer an inpatient in the hospital, may request QIO review within 30 calendar days after the date of discharge, or at any time for good cause. The QIO will issue a decision in accordance with paragraph (d)(6)(iii) of this section; however, the financial liability protection under paragraphs (f)(1) and (f)(2) of this section does not apply.

(c) *Burden of proof.* When a beneficiary (or his or her representative, if applicable) requests an expedited determination by a QIO, the burden of proof rests with the hospital 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 hospital should supply any and all information that a QIO requires to sustain the hospital's discharge determination.

(d) *Procedures the QIO must follow.* (1) When the QIO receives the request for an expedited determination under paragraph (b)(1) of this section, it must immediately notify the hospital that a request for an expedited determination has been made.

(2) The QIO determines whether the hospital delivered valid notice consistent with § 405.1205(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 beneficiary (or the beneficiary's representative) who requested the expedited determination.

(5) The QIO must provide an opportunity for the hospital to explain why the discharge is appropriate.

(6)(i) When the beneficiary requests an expedited determination in accordance with paragraph (b)(1) of this section, the QIO must make a determination and notify the beneficiary, the hospital, and physician of its determination within one calendar day after it receives all requested pertinent information.

(ii) When the beneficiary makes an untimely request for an expedited determination, and remains in the hospital, consistent with paragraph (b)(5) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and the physician of its determination within 2 calendar days following receipt of the request and pertinent information.

(iii) When the beneficiary makes an untimely request for an expedited determination, and is no longer an inpatient in the hospital, consistent with paragraph (b)(6) of this section, the QIO will make a determination and notify the beneficiary, the hospital, and physician of its determination within 30 calendar days after receipt of the request and pertinent information.

(7) If the QIO does not receive the information needed to sustain a hospital'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 hospital may be held financially liable for these services, as determined by the QIO.

(8) When the QIO issues an expedited determination, the QIO must notify the beneficiary, 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 a beneficiary becomes fully liable for the services.

(iv) Information about the beneficiary's right to a reconsideration of the QIO's determination as set forth in § 405.1204, including how to request a reconsideration and the time period for doing so.

(e) *Responsibilities of hospitals.* (1) When a QIO notifies a hospital that a beneficiary has requested an expedited determination, the hospital must deliver a detailed notice to the beneficiary 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 why services are either no longer reasonable and necessary or are otherwise no longer covered.

(ii) A description of any applicable Medicare coverage rule, instruction, or other Medicare policy, including information about how the beneficiary may obtain a copy of the Medicare policy.

(iii) Facts specific to the beneficiary and relevant to the coverage determination that are sufficient to advise the beneficiary of the applicability of the coverage rule or policy to the beneficiary's case.

(iv) Any other information required by CMS.

(2) Upon notification by the QIO of the request for an expedited determination, the hospital must supply all information that the QIO needs to make its expedited determination, including a copy of the notices required as specified in § 405.1205 (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 noon of the day after the QIO notifies the hospital of the request for an expedited determination. 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).

(3) At a beneficiary's (or representative's) request, the hospital must furnish the beneficiary with a copy of, or access to, any documentation that it sends to the QIO, including written records of any information provided by telephone. The hospital may charge the beneficiary a reasonable amount to cover the costs of duplicating the documentation and/or delivering it to the beneficiary. The hospital must accommodate such a request by no later than close of business of the first day after the material is requested.

(f) *Coverage during QIO expedited review*—(1) *General rule and liability while QIO review is pending.* If the beneficiary remains in the hospital past midnight of the discharge date ordered by the physician, and the hospital, the physician who concurred with the discharge determination, or the QIO subsequently finds that the beneficiary requires inpatient hospital care, the beneficiary is not financially responsible for continued care (other than applicable coinsurance and deductible) until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence from the physician responsible for the beneficiary's care or the QIO, and notifies the beneficiary with a notice consistent with 405.1205 (c).

(2) *Timely filing and limitation on liability.* If a beneficiary files a request for an expedited determination by the QIO in accordance with paragraph (b)(1) of this section, the beneficiary is not financially responsible for inpatient hospital services (other than applicable coinsurance and deductible) furnished before noon of the calendar day after the date the beneficiary (or his or her representative) receives notification (either orally or in writing) of the expedited determination by the QIO.

(3) *Untimely request and liability.* When a beneficiary does not file a request for

an expedited determination by the QIO in accordance with paragraph (b) of this section, but remains in the hospital past the discharge date, that beneficiary may be held responsible for charges incurred after the date of discharge or as otherwise stated by the QIO.

(4) *Hospital requests an expedited review.* When the hospital requests a review in accordance with § 405.1208, and the QIO concurs with the hospital's discharge determination, a hospital may not charge the beneficiary until the date specified by the QIO.

(g) *Effect of an expedited QIO determination.* The QIO determination is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *Right to request a reconsideration.* If the beneficiary 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 § 405.1204.

(2) *Right to pursue the general claims appeal process.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, the determination is subject to the general claims appeal process.

[71 FR 68721, Nov. 27, 2006]

§ 405.1208 Hospital requests expedited QIO review.

(a) *General rule.* (1) If the hospital (acting directly or through its utilization review committee) believes that the beneficiary does not require further inpatient hospital care but is unable to obtain the agreement of the physician, it may request an expedited determination by the QIO.

(2) When the hospital requests review, and the QIO concurs with the hospital's discharge determination, a hospital may not charge a beneficiary until the date specified by the QIO in accordance with 405.1206(f)(4).

(b) *Procedures hospital must follow.* (1) The hospital must (acting directly or through its utilization review committee) notify the beneficiary (or his or her representative) that it has requested that review.

(2) The hospital must supply any pertinent information the QIO requires to conduct its review and must make it available by phone or in writing, by close of business of the first full working day immediately following the day the hospital submits the request for review.

(c) *Procedures the QIO must follow.* (1) The QIO must notify the hospital that it has received the request for review and must notify the hospital if it has not received all pertinent records.

(2) The QIO must examine the pertinent records pertaining to the services.

(3) The QIO must solicit the views of the beneficiary in question.

(4) The QIO must make a determination and notify the beneficiary, the hospital, and physician within 2 working days of the hospital's request and receipt of any pertinent information submitted by the hospital.

(d) *Notice of an expedited determination.* (1) When a QIO issues an expedited determination as stated in paragraph (c)(4) of this section, it must notify the beneficiary, physician, and hospital of its decision, by telephone and subsequently in writing.

(2) A written notice of the expedited initial determination must contain the following:

(i) The basis for the determination;.

(ii) A detailed rationale for the determination;

(iii) A statement explaining the Medicare payment consequences of the expedited determination and date of liability, if any; and

(iv) A statement informing the beneficiary of his or her appeal rights and the timeframe for requesting an appeal.

(e) *Effect of an expedited determination.* The expedited determination under this section is binding upon the beneficiary, physician, and hospital, except in the following circumstances:

(1) *When a beneficiary remains in the hospital.* If the beneficiary is still an inpatient in the hospital and is dissatisfied with this determination, he or she may request a reconsideration according to the procedures described in § 405.1204. The procedures described in § 405.1204 will apply to reconsiderations requested under this section. If the beneficiary does not make a request in accordance with § 405.1204(b)(1), the timeframes described in § 405.1204(c)(3), the escalation procedures described in

§ 405.1204(c)(5), and the coverage rule described in § 405.1204(f) will not apply.

(2) *When a beneficiary is no longer an inpatient in the hospital.* If the beneficiary is no longer an inpatient in the hospital and is dissatisfied with this determination, this determination is subject to the general claims appeal process.

[69 FR 69624, Nov. 26, 2004, as amended at 71 FR 68722, Nov. 27, 2006]

Subparts K–Q [Reserved]

Subpart R—Provider Reimbursement Determinations and Appeals

AUTHORITY: Secs. 205, 1102, 1814(b), 1815(a), 1833, 1861(v), 1871, 1872, 1878, and 1886 of the Social Security Act (42 U.S.C. 405, 1302, 1395f(b), 1395g(a), 1395l, 1395x(v), 1395hh, 1395ii, 1395oo, and 1395ww).

SOURCE: 39 FR 34515, Sept. 26, 1974, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

EDITORIAL NOTE: Nomenclature changes to subpart R of part 405 appear at 79 FR 55031, Aug. 22, 2014.

§ 405.1801 Introduction.

(a) *Definitions.* As used in this subpart:

Administrator means the Administrator or Deputy Administrator of CMS.

Administrator review means that review provided for in section 1878(f) of the Act (42 U.S.C. 1395oo(f)) and § 405.1875.

Board means the Provider Reimbursement Review Board established in accordance with section 1878 of the Act (42 U.S.C. 1395oo) and § 405.1845.

Board hearing means that hearing provided for in section 1878(a) of the Act (42 U.S.C. 1395oo(a)), and § 405.1835.

CMS reviewing official means the reviewing official provided for in § 405.1834.

CMS reviewing official procedure means the review provided for in § 405.1834.

Contractor determination means the following:

(1) With respect to a provider of services that has filed a cost report under §§ 413.20 and 413.24 of this chapter, the term means a final determination of the amount of total reimbursement due the provider, pursuant to § 405.1803 following the close of the provider's cost reporting period, for items and services furnished to beneficiaries for which reimbursement may be made on a reasonable cost basis under Medicare for the period covered by the cost report.

(2) With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (part 412 of this chapter), the term means a final determination of the total amount of payment due the hospital, pursuant to § 405.1803 following the close of the hospital's cost reporting period, under that system for the period covered by the final determination.

(3) For purposes of appeal to the Provider Reimbursement Review Board, the term is synonymous with the phrases ''intermediary's final determination,'' ''final determination of the organization serving as its fiscal intermediary,'' ''Secretary's final determination'' and ''final determination of the Secretary,'' as those phrases are used in section 1878(a) of the Act, and with the phrases ''final contractor determination'' and ''final Secretary determination'' as those phrases are used in this subpart.

(4) For purposes of § 405.376 concerning claims collection activities, the term does not include an action by CMS with respect to a compromise of a Medicare overpayment claim, or termination or suspension of collection action on an overpayment claim, against a provider or physician or other supplier.

Contractor hearing means that hearing provided for in § 405.1809.

Contractor hearing officer(s) means the hearing officer or panel of hearing officers provided for in § 405.1817.

Date of receipt means the date a document or other material is received by either of the following:

(1) *A party or an affected nonparty.* A party or an affected nonparty, such as CMS, involved in proceedings before a reviewing entity.

(i) As applied to a party or an affected nonparty, the phrase ''date of receipt'' in this definition is synonymous with the term ''notice,'' as that term is

used in section 1878 of the Act and in this subpart.

(ii) For purposes of a contractor hearing, if no contractor hearing officer is appointed (or none is currently presiding), the date of receipt of materials sent to the contractor hearing officer (as permitted under paragraph (d) of this section) is presumed to be, as applicable, the date that the contractor stamps ''Received'' on the materials, or the date of electronic delivery.

(iii) The date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity is presumed to be 5 days after the date of issuance of a contractor notice or a reviewing entity document. This presumption, which is otherwise conclusive, may be overcome if it is established by a preponderance of the evidence that such materials were actually received on a later date.

(2) *A reviewing entity*. For purposes of this definition, a reviewing entity is deemed to include the Office of the Attorney Advisor. The determination as to the date of receipt by the reviewing entity to which the document or other material was submitted (as permitted under paragraph (d) of this section) is final and binding as to all parties to the appeal. The date of receipt of documents by a reviewing entity is presumed to be, as applicable, one of the following dates:

(i) Of delivery where the document or material is transmitted by a nationally-recognized next-day courier (such as the United States Postal Service's Express Mail, Federal Express, UPS, DHL, etc.).

(ii) Stamped ''Received'' by the reviewing entity on the document or other submitted material (where a nationally-recognized next-day courier is not employed). This presumption, which is otherwise conclusive, may be overcome if it is established by clear and convincing evidence that the document or other material was actually received on a different date.

(iii) Of electronic delivery. *In writing* or *written* means a hard copy or electronic submission (subject to the restrictions in paragraph (d) of this section), as applicable throughout this subpart.

Reviewing entity means the contractor hearing officer(s), a CMS reviewing official, the Board, or the Administrator.

(b) *General rules*—(1) *Providers*. In order to be paid for covered services furnished to Medicare beneficiaries, a provider must file a cost report with its contractor as specified in §413.24 of this chapter. For purposes of this subpart, the term ''provider'' includes a hospital (as described in part 482 of this chapter), hospice program (as described in §418.3 of this chapter), critical access hospital (CAH), comprehensive outpatient rehabilitation facility (CORF), renal dialysis facility, Federally qualified health center (FQHC), home health agency (HHA), rural health clinic (RHC), skilled nursing facility (SNF), and any other entity included under the Act. (FQHCs and RHCs are providers, for purposes of this subpart, effective with cost reporting periods beginning on or after October 1, 1991).

(2) *Other nonprovider entities participating in Medicare Part A*. (i) Providers of services, as well as, other entities (including, but not limited to health maintenance organizations (HMOs) and competitive medical plans (CMPs) (as described in §400.200 of this chapter)) may participate in the Medicare program, but do not qualify as providers under the Act or this subpart.

(ii) Some of these nonprovider entities are required to file periodic cost reports and are paid on the basis of information furnished in these reports. Except as provided at §413.420(g) of this chapter, these nonprovider entities may not obtain a contractor hearing or a Board hearing under section 1878 of the Act or this subpart.

(iii) Some other hearing will be available to these nonprovider entities, if the amount in controversy is at least $1,000.

(iv) For any nonprovider hearing, the procedural rules for a Board hearing set forth in this subpart are applicable to the maximum extent possible.

(c) *Effective dates*. (1) Except as provided in paragraphs (c)(2) and (c)(3) of this section or in §405.1885(e), this subpart applies to all cost reporting periods ending on or after December 31,

1971, for which reimbursement may be made on a reasonable cost basis.

(2) Sections 405.1835 to 405.1877 apply only to cost reporting periods ending on or after June 30, 1973, for which reimbursement may be made on a reasonable cost basis.

(3) With respect to hospitals under the prospective payment system (see part 412 of this chapter), the appeals procedures in §§ 405.1811 to 405.1877 that apply become applicable with the hospital's first cost reporting period beginning on or after October 1, 1983.

(d) *Method for submissions and calculating time periods and deadlines.* Except for subpoena requests being sent to a nonparty under § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Such methods or instructions apply to any period of time or deadline prescribed or allowed under this subpart (for example, requests for appeal under §§ 405.1811(b), 405.1835(b), and 405.1837(c) and (e)) or authorized by a reviewing entity. In computing any period of time or deadline prescribed or allowed under this subpart or authorized by a reviewing entity the following principles are applicable:

(1) The day of the act, event, or default from which the designated time period begins to run is not included.

(2) Each succeeding calendar day, including the last day, is included in the designated time period, except that, in calculating a designated period of time for an act by a reviewing entity, a day is not included where the reviewing entity is unable to conduct business in the usual manner due to extraordinary circumstances beyond its control such as natural or other catastrophe, weather conditions, fire, or furlough. In that case, the designated time period resumes when the reviewing entity is again able to conduct business in the usual manner.

(3) If the last day of the designated time period is a Saturday, a Sunday, a Federal legal holiday (as enumerated in Rule 6(a) of the Federal Rules of Civil Procedure), or a day on which the reviewing entity is unable to conduct business in the usual manner, the deadline becomes the next day that is not one of the aforementioned days.

(4) For purposes of paragraph (d) of this section, the reviewing entity is deemed to also include—

(i) The contractor, if the contractor hearing officer(s) is not yet appointed (or none is currently presiding); and

(ii) The Office of the Attorney Advisor.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 48 FR 39834, Sept. 1, 1983; 48 FR 45773, Oct. 7, 1983; 49 FR 322, Jan. 3, 1984; 49 FR 23013, June 1, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63749, Dec. 2, 1996; 73 FR 30243, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 80 FR 70597, Nov. 13, 2015; 85 FR 59018, Sept. 18, 2020; 87 FR 72284, Nov. 23, 2022]

§ 405.1803 Contractor determination and notice of amount of program reimbursement.

(a) *General requirement.* Upon receipt of a provider's cost report, or amended cost report where permitted or required, the contractor must within a reasonable period of time (as specified in § 405.1835(c)(1)), furnish the provider and other parties as appropriate (see § 405.1805) a written notice reflecting the contractor's final determination of the total amount of reimbursement due the provider. The contractor must include the following information in the notice, as appropriate:

(1) *Reasonable cost.* The notice must—

(i) Explain the contractor's determination of total program reimbursement due the provider on the basis of reasonable cost for the reporting period covered by the cost report or amended cost report; and

(ii) Relate this determination to the provider's claimed total program reimbursement due the provider for this period.

(2) *Prospective payment.* With respect to a hospital that receives payments for inpatient hospital services under the prospective payment system (see part 412 of this chapter), the contractor must include in the notice its determination of the total amount of the payments due the hospital under that system for the cost reporting period covered by the notice. The notice must explain (with appropriate use of the applicable money amounts) any difference in the amount determined to be

due, and the amounts received by the hospital during the cost reporting period covered by the notice.

(3) *Hospice caps.* With respect to a hospice, the reporting period for the cap calculation is the cap year; and the contractors' determination of program reimbursement letter, which provides the results of the inpatient and aggregate cap calculations, shall serve as a notice of program reimbursement. The time period for filing cap appeals begins with receipt of the determination of program reimbursement letter.

(b) *Requirements for contractor notices.* The contractor must include in each notice appropriate references to law, regulations, CMS Rulings, or program instructions to explain why the contractor's determination of the amount of program reimbursement for the period differs from the amount the provider claimed. The notice must also inform the provider of its right to contractor or Board hearing (see §§ 405.1809, 405.1811, 405.1815, 405.1835, and 405.1843) and that the provider must request the hearing within 180 days after the date of receipt of the notice.

(c) *Use of notice as basis for recoupment of overpayments.* The contractor's determination contained in its notice is the basis for making the retroactive adjustment (required by § 413.64(f) of this chapter) to any program payments made to the provider during the period to which the determination applies, including recoupment under § 405.373 from ongoing payments to the provider of any overpayments to the provider identified in the determination. Recoupment is made notwithstanding any request for hearing on the determination the provider may make under § 405.1811 or § 405.1835.

(d) *Effect of certain final agency decisions and final court judgments; audits of self-disallowed and other items.* (1) This paragraph applies to the following administrative decisions and court judgments:

(i) A final hearing decision by the contractor (as described in § 405.1833 of this subpart) or the Board (as described in § 405.1871(b) of this subpart).

(ii) A final decision by a CMS reviewing official (as described in § 405.1834(f)(1) of this subpart) or the Administrator (as described in § 405.1875(e)(4) of this subpart) following review of a hearing decision by the contractor or the Board, respectively.

(iii) A final, non-appealable judgment by a court on a Medicare reimbursement issue that the court rendered in accordance with jurisdiction under section 1878 of the Act (as described in §§ 405.1842 and 405.1877 of this subpart).

(2) For any final agency decision or final court judgment specified in paragraph (d)(1) of this section, the contractor must promptly, upon notification from CMS—

(i) Determine the effect of the final decision or judgment on the contractor determination for the cost reporting period at issue in the decision or judgment; and

(ii) Issue any revised contractor determination, and make any additional program payment, or recoup or offset any program payment (as described in § 405.371 of this subpart), for the period that may be necessary to implement the final decision or judgment on the specific matters at issue in the decision or judgment.

(3) CMS may require the contractor to audit any item, including any self-disallowed item, at issue in an appeal or a civil action, before any revised contractor determination or additional Medicare payment, recoupment, or offset may be determined for an item under paragraph (d)(2) of this section.

(4) For any final settlement agreement, whether for an appeal to the contractor hearing officer(s) or the Board or for a civil action before a court, the contractor must implement the settlement agreement in accordance with paragraphs (d)(2) and (d)(3) of this section, unless a particular administrative or judicial settlement agreement provides otherwise.

[48 FR 39834, Sept. 1, 1983, as amended at 49 FR 322, Jan. 3, 1984; 51 FR 34793, Sept. 30, 1986; 61 FR 63748, Dec. 2, 1996; 73 FR 30244, May 23, 2008; 74 FR 39412, Aug. 6, 2009; 80 FR 70597, Nov. 13, 2015]

§ 405.1804 Matters not subject to administrative and judicial review under prospective payment.

Neither administrative nor judicial review is available for controversies about the following matters:

(a) The determination of the requirement, or the proportional amount, of the budget neutrality adjustment in the prospective payment rates required under section 1886(e)(1) of the Social Security Act.

(b) The establishment of—

(1) Diagnosis related groups (DRGs);

(2) The methodology for the classification of inpatient discharges within the DRGs; or

(3) Appropriate weighting factors that reflect the relative hospital resources used with respect to discharge within each DRG.

[49 FR 322, Jan. 1, 1984, as amended at 78 FR 75195, Dec. 10, 2013]

§ 405.1805 Parties to contractor determination.

The parties to the contractor's determination are the provider and any other entity found by the contractor to be a related organization of the provider under § 413.17 of this chapter.

[48 FR 39835, Sept. 1, 1983, as amended at 51 FR 34793, Sept. 30, 1986]

§ 405.1807 Effect of contractor determination.

The determination shall be final and binding on the party or parties to such determination unless:

(a) A contractor hearing is requested in accordance with § 405.1811 and a contractor hearing decision rendered in accordance with § 405.1831; or

(b) The contractor determination is revised in accordance with § 405.1885; or

(c) A Board hearing is requested in accordance with § 405.1835 and a hearing decision rendered pursuant thereto.

§ 405.1809 Contractor hearing procedures.

(a) *Hearings.* Each contractor must establish and maintain written procedures for contractor hearings, in accordance with the regulations in this subpart, for resolving issues that may arise between the contractor and a provider concerning the amount of reasonable cost reimbursement, or prospective payment due the provider (except as provided in § 405.1804) under the Medicare program. The procedures must provide for a hearing on the contractor determination contained in the notice of program reimbursement (§ 405.1803), if the provider files a timely request for a hearing.

(b) *Amount in controversy.* In order for a contractor to grant a hearing, the following dates and amounts in controversy apply:

(1) For cost reporting periods ending prior to June 30, 1973, the amount of program reimbursement in controversy must be at least $1000.

(2) For cost reporting periods ending on or after June 30, 1973, the amount of program reimbursement in controversy must be at least $1000 but less than $10,000.

[48 FR 39835, Sept. 1, 1983, as amended at 49 FR 323, Jan. 1, 1984]

§ 405.1811 Right to contractor hearing; contents of, and adding issues to, hearing request.

(a) *Right to hearing on final contractor determination.* A provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice pursuant to § 405.1803. Exception: If a final contractor determination is reopened under § 405.1885, any review by the contractor hearing officer must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d), 405.1889(b), and the ''Exception'' in § 405.1832(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with § 405.1839) must be at least $1,000 but less than $10,000.

(3) Unless the provider qualifies for a good cause extension under § 405.1813, the date of receipt by the contractor of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) *Contents of request for a contractor hearing on final contractor determination.* The provider's request for a contractor hearing under paragraph (a) of this section must be submitted in writing to

the contractor, and the request must include the elements described in paragraphs (b)(1) through (b)(3) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (b)(1), (b)(2), or (b)(3) of this section, the contractor hearing officer may dismiss with prejudice the appeal or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it allegedly does not have access to underlying information concerning the calculation of its payment); and

(ii) How and why the provider believes Medicare payment should be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item (as specified in §413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (b)(1) and (b)(2) of this section.

(c) *Right to hearing based on untimely contractor determination.* Notwithstanding the provisions of paragraph (a) of this section, a provider (but no other individual, entity, or party) has a right to a contractor hearing, as a single provider appeal, for specific items for a cost reporting period if—

(1) A final contractor determination for the provider's cost reporting period is not issued (through no fault of the provider) within 12 months after the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in §413.24(f) of this chapter). The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date of electronic delivery, or the date the contractor stamped ''Received'' on such cost report unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(2) Unless the provider qualifies for a good cause extension under §405.1813, the date of receipt by the contractor of the provider's hearing request is no later than 180 days after the expiration of the 12 month period for issuance of the final contractor determination (as determined in accordance with paragraph (c)(1) of this section); and

(3) The amount in controversy (as determined in accordance with §405.1839) is at least $1,000 but less than $10,000.

(d) *Contents of request for a contractor hearing based on untimely contractor determination.* The provider's request for a contractor hearing under paragraph (c) of this section must be submitted in writing to the contractor, and the request must include the elements described in paragraphs (d)(1) through (d)(3) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (d)(1), (d)(2), or (d)(3) of this section, the contractor hearing officer may dismiss with prejudice the appeal or take any other remedial action he or she considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a contractor hearing as specified in paragraph (c) of this section.

(2) An explanation (for each specific item at issue) of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct

because it does not have access to underlying information concerning the calculation of Medicare payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement or payment sought for the item.

(3) A copy of any documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (d)(1) and (d)(2) of this section.

(e) *Adding issues to the hearing request.* After filing a hearing request in accordance with paragraphs (a) and (b), or paragraphs (c) and (d), of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the contractor hearing officer, only if—

(1) The request to add issues complies with the requirements of paragraphs (a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

(3) The contractor hearing officer receives the provider's request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) or paragraph (c)(2) of this section.

[73 FR 30244, May 23, 2008, as amended at 79 FR 50349, Aug. 22, 2014; 79 FR 59680, Oct. 3, 2014; 80 FR 70597, Nov. 13, 2015; 85 FR 59018, Sept. 18, 2020]

§ 405.1813 Good cause extension of time limit for requesting a contractor hearing.

(a) A request for a contractor hearing that is received by the contractor after the applicable 180-day time limit prescribed in § 405.1811(a)(3) or § 405.1811(c)(2) must be dismissed by the contractor hearing officer(s), except that the hearing officer(s) may extend the time limit upon a good cause showing by the provider.

(b) The contractor hearing officer(s) may find good cause to extend the time limit only if the provider demonstrates in writing it could not reasonably have been expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the contractor hearing officer(s) within a reasonable time (as determined by the contractor hearing officer(s) under the circumstances) after the expiration of the applicable 180-day limit prescribed in § 405.1811(a)(3) or § 405.1811(c)(2).

(c) The contractor hearing officer(s) may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the contractor of the provider's extension request is later than 3 years after the date of the contractor or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the contractor hearing officer(s) must send prompt written notice to the provider, and send a copy to each party to the appeal. The notice must include an explanation of the reasons for the decision by the hearing officer(s) and the facts underlying the decision.

(e)(1) A decision denying an extension request under this section and dismissing the appeal is final and binding on the provider, unless the dismissal decision is reviewed by a CMS reviewing official in accordance with § 405.1834(b)(2)(i) of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart. The contractor hearing officer(s) promptly sends the decision to the appropriate component of CMS (currently the Center for Medicare Management) (as specified in § 405.1834(b)(4) of this subpart).

(2) A decision granting an extension request under this section is not subject to immediate review by a CMS reviewing official (as described in § 405.1834(b)(3) of this subpart). Any decision may be examined during the course of CMS review of a final jurisdictional dismissal decision or a final hearing decision by the contractor hearing officer(s) (as described in §§ 405.1834(b)(2)(i) and 405.1834(b)(2)(ii) of this subpart).

[73 FR 30245, May 23, 2008, as amended at 80 FR 70598, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1814 Contractor hearing officer jurisdiction.

(a) *General rules.* (1) After a request for a contractor hearing is filed under § 405.1811 of this subpart, the contractor hearing officer(s) must do the following:

(i) Determine in accordance with paragraph (b) of this section whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(ii) Make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(A) Determining its authority to decide a legal question relevant to a matter at issue (as described in § 405.1829 of this subpart);

(B) Permitting discovery (as specified in § 405.1821 of this subpart); or

(C) Conducting a hearing (as specified in § 405.1819 of this subpart);

(2) The hearing officer(s) may revise a preliminary jurisdictional determination at any subsequent stage of the proceedings in an appeal, and it must promptly notify the parties of any revised determination.

(3) Under paragraph (c)(1) of this section, each contractor hearing decision (as described in § 405.1831 of this subpart) must include a final jurisdictional finding for each specific matter at issue in the appeal.

(4) If the hearing officer(s) finally determines it lacks jurisdiction over every specific matter at issue in the appeal, it issues a jurisdictional dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and jurisdictional dismissal decisions by the hearing officer(s) are subject to the CMS reviewing official procedure in accordance with paragraph (d) of this section and § 405.1834(b)(2)(i) and (b)(2)(ii) of this subpart.

(b) *Criteria.* Except for the amount in controversy requirement, the jurisdiction of the contractor hearing officer(s) to grant a hearing is determined separately for each specific matter at issue in the contractor or Secretary determination for the cost reporting period under appeal. The hearing officer(s) has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to a contractor hearing under § 405.1811. Certain matters at issue are removed from the jurisdiction of the contractor hearing officer(s); these matters include, but are not limited to, the following:

(1) A finding in a contractor determination that expenses incurred for certain items or services furnished by a provider to an individual are not payable under title XVIII of the Act because those items and services are excluded from coverage under section 1862 of the Act and part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of subpart I of part 405 and subpart B of part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and § 405.1804 of this subpart.

(c) *Final jurisdictional findings, and jurisdictional dismissal decisions by contractor hearing officer(s).* (1) In issuing a hearing decision under § 405.1831 of this subpart, the contractor hearing officer(s) must make a final determination of its jurisdiction, or lack thereof, for each specific matter at issue in the hearing decision. Each contractor hearing decision must include specific findings of fact and conclusions of law as

to the jurisdiction of the hearing officer(s), or lack thereof, to grant a hearing on each matter at issue in the appeal.

(2) If the hearing officer(s) finally determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a jurisdictional dismissal decision. Each jurisdictional dismissal decision by the hearing officer(s) must include specific findings of fact and conclusions of law explaining the determination that there is no jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the jurisdictional dismissal decision must be sent promptly to each party to the appeal.

(3) A jurisdictional dismissal decision by the contractor hearing officer(s) under paragraph (c)(2) of this section is final and binding on the parties, unless the decision is reviewed by a CMS reviewing official in accordance with § 405.1834 of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with § 405.1885 through § 405.1889 of this subpart.

(d) *CMS reviewing official review.* Any finding by the contractor hearing officer as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative review, except as provided in this paragraph. The contractor hearing officer's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of CMS reviewing official review of one of the contractor hearing officer decisions specified in § 405.1834(b)(2) of this subpart.

[73 FR 30245, May 23, 2008, as amended at 80 FR 70598, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1815 Parties to proceedings before the contractor hearing officer(s).

When a provider files a request for a contractor hearing in accordance with § 405.1811 of this subpart, the parties to all proceedings before the contractor hearing officer(s) are the provider and, if applicable, any other entity found by the contractor hearing officer(s) to be a related organization of the provider under the principles enunciated in § 413.17 of this chapter. The parties must be given reasonable notice of the time, date, and place of any contractor hearing. Neither the contractor nor CMS may be made a party to proceedings before the contractor hearing officer(s).

[73 FR 30246, May 23, 2008]

§ 405.1817 Hearing officer or panel of hearing officers authorized to conduct contractor hearing; disqualification of officers.

The contractor hearing provided for in § 405.1809 shall be conducted by a hearing officer or panel of hearing officers designated by the contractor. Such hearing officer or officers shall be persons knowledgeable in the field of health care reimbursement. The hearing officer or officers shall not have had any direct responsibility for the program reimbursement determination with respect to which a request for hearing is filed; no hearing officer (or officers) shall conduct a hearing in a case in which he is prejudiced or partial with respect to any party, or where he has any interest in the matter pending for determination before him. Notice of any objection which a party may have with respect to a hearing officer shall be presented in writing to such officer by the objecting party at the party's earliest opportunity. The hearing officer shall consider the objection and shall, at his discretion, either proceed in the conduct of the hearing or withdraw. If the hearing officer does not withdraw, the objecting party may, after the hearing, present his objections to an executive official of the contractor, who shall rule promptly on the objection.

§ 405.1819 Conduct of contractor hearing.

The hearing shall be open to all parties thereto (see § 405.1815) and to representatives of the contractor and of the Centers for Medicare & Medicaid Services (see § 405.1815). The hearing officer(s) shall inquire fully into all of the matters at issue and shall receive into evidence the testimony and any documents which are relevant and material to such matters. If the hearing officer(s) believes that there is relevant and material evidence available which has not been presented at the hearing,

he (they) may, at any time prior to the sending of notice of the decision, reopen the hearing record for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the hearing officer(s).

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1821 Prehearing discovery and other proceedings prior to the contractor hearing.

(a) *Discovery rule: Time limits.* (1) Limited prehearing discovery may be permitted by the contractor hearing officer(s) upon request of a party, provided the request is timely and the hearing officer(s) makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1814(a) of this subpart.

(2) A prehearing discovery request is timely if the request by a party is served no later than 120 days before the initially scheduled starting date of the contractor hearing, unless the contractor hearing officer(s) extends the time for requesting discovery.

(3) In the absence of a specific schedule for responses set by the contractor hearing officer(s), responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed. Responses by a party to interrogatories or requests for production of documents must be served no later than 45 days before the initially scheduled start of the contractor hearing, unless the contractor hearing officer(s) orders otherwise. Responses by a nonparty to requests for production of documents must be served no later than 75 days after the date the requests were served on the nonparty, unless the party requesting the documents and the nonparty to which the requests are directed agree on a different time for responding, or unless the contractor hearing officer(s) extends the time for responding.

(4) Before ruling on a request to extend the time for requesting discovery or for responding to discovery, the hearing officer(s) must give the other parties to the appeal and any nonparty subject to a discovery request a reasonable period to respond to the extension request.

(5) If the extension request is granted, the hearing officer(s) sets a new deadline and has the discretion to reschedule the hearing date.

(b) *Discovery criteria*—(1) *General rule.* The contractor hearing officer(s) may permit discovery of a matter that is relevant to the specific subject matter of the contractor hearing, provided the matter is not privileged or otherwise protected from disclosure and the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate. In determining whether to permit discovery, and in fixing the scope and limits of any discovery, the hearing officer(s) uses the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(2) *Limitations on discovery.* Any discovery before the contractor hearing officer(s) is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, HHS or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may request another party to respond to a reasonable number of written interrogatories.

(iii) A party may not request admissions, take oral or written depositions, or take any other form of discovery not permitted under this section.

(c) *Discovery procedures. Rights of nonparties: Motions to compel or for protective order.* (1) A party may request discovery of another party to the proceedings before the contractor hearing officer(s) or of a nonparty other than CMS, HHS or other Federal agency. Any discovery request filed with the contractor hearing officer(s) must be sent promptly to the party or nonparty from which the discovery is requested, and to any other party to the contractor hearing (as described in § 405.1815 of this subpart).

(2) If a discovery request is made of a nonparty to the contractor hearing, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right

to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the hearing officer(s).

(3) Each party and nonparty is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

(i) A party may submit to the contractor hearing officer(s) a motion to compel discovery that is permitted under this section, and a motion for a protective order regarding any discovery request may be submitted to the hearing officer(s) by a party or nonparty.

(ii) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. A self-sworn declaration describing efforts to resolve or narrow a discovery dispute also must be included with any response to a motion to compel or for a protective order.

(iii) The hearing officer(s) must—

(A) Decide the motion in accordance with this section and any prior discovery ruling; and

(B) Issue and send to each party and any affected nonparty a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the hearing officer(s) finds necessary and appropriate. Nothing in this section authorizes the contractor hearing officer to compel any action from the Secretary or CMS.

(d) *Reviewability of discovery or disclosure rulings*—(1) *General rule.* A discovery ruling issued in accordance with paragraph (c)(3) of this section, or a disclosure ruling (such as one issued at a hearing), is not subject to immediate review by a CMS official (as described in § 405.1834(b)(3) of this subpart). A discovery ruling may be examined solely during the course of CMS review under § 405.1834 of this subpart of a jurisdictional dismissal decision (as described in § 405.1814(c)(2) of this subpart) or a hearing decision (as described in § 405.1831 of this subpart) by the contractor hearing officer(s).

(2) *Exception.* To the extent a ruling authorizes discovery or 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 contractor hearing officer(s), that portion of the discovery or disclosure ruling may immediately be reviewed by a CMS reviewing official in accordance with § 405.1834(b)(3).

(i) Upon notice to the contractor hearing officer that the provider intends to seek immediate review of a ruling, or that the contractor or other affected nonparty intends to suggest that the Administrator through the CMS reviewing official, take own motion review of the ruling, the contractor hearing officer stays all proceedings affected by the ruling.

(ii) The contractor hearing officer must determine, under the circumstances of a given case, the length of any stay, but in no event may the stay be less than 15 days.

(iii) If the Administrator through the CMS reviewing official—

(A) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until such time as the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the contractor hearing officer's ruling.

(B) Does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling is not subject to immediate review.

(e) *Prehearing conference.* The contractor hearing officer(s) has discretion to schedule a prehearing conference. A prehearing conference may be conducted in person or telephonically, at the discretion of the contractor hearing officer(s). When a panel of contractor hearing officers is designated, the panel may appoint one or more hearing officers to act for the panel for any prehearing conference or any matter addressed at the conference.

[73 FR 30246, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1823 Evidence at contractor hearing.

Evidence may be received at the contractor hearing even though inadmissible under the rules of evidence applicable to court procedure. The hearing officer(s) shall give the parties opportunity for submission and consideration of facts and arguments, and during the course of the hearing, should in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The hearing officer(s) shall render a final ruling on the admissibility of evidence.

§ 405.1825 Witnesses at contractor hearing.

The hearing officer(s) may examine the witnesses and shall allow the parties and their representatives to do so. Parties to the proceedings may also cross-examine witnesses.

§ 405.1827 Record of proceedings before the contractor hearing officer(s).

(a) The contractor hearing officer(s) must maintain a complete record of all proceedings in an appeal.

(b) The record consists of all documents and any other tangible materials timely submitted to the hearing officer(s) by the parties to the appeal and by any nonparty (as described in § 405.1821(c) of this subpart), along with all correspondence, rulings, orders, and decisions (including the final decision) issued by the hearing officer(s).

(c) The record must include a complete transcription of the proceedings at any contractor hearing.

(d) A copy of the transcription must be made available to any party upon request.

[73 FR 30247, May 23, 2008]

§ 405.1829 Scope of authority of contractor hearing officer(s).

(a) The hearing officer(s) in exercising his authority must comply with all the provisions of title XVIII of the Act and regulations issued thereunder, as well as with CMS Rulings issued under the authority of the Administrator of the Centers for Medicare & Medicaid Services (as described in § 401.108 of this chapter), and with the general instructions issued by the Centers for Medicare & Medicaid Services in accordance with the Secretary's agreement with the contractor.

(b)(1) If the contractor hearing officer(s) has jurisdiction to conduct a hearing on the specific matters at issue under § 405.1811, and the legal authority to fully resolve the matters in a hearing decision (as described in § 405.1831 of this subpart), the hearing officer(s) must affirm, modify, or reverse the contractor's findings on each specific matter at issue in the contractor or Secretary determination for the cost year under appeal.

(2) The contractor hearing officer(s) also may make additional revisions on specific matters regardless of whether the contractor considered the matters in issuing the contractor determination for the cost year, provided the hearing officer(s) does not consider or decide any specific matter for which it lacks jurisdiction (as described in § 405.1814(b) of this subpart) or which was not timely raised in the provider's hearing request.

(3) The authority of the contractor hearing officer(s) under this paragraph to make the additional revisions is limited to those revisions necessary to fully resolve a specific matter at issue if—

(i) The hearing officer(s) has jurisdiction to grant a hearing on the specific matter under §§ 405.1811 and 405.1814 of this subpart; and

(ii) The specific matter was timely raised in an initial request for a contractor hearing filed in accordance with § 405.1811(b) of this subpart or in a timely request to add issues to an appeal submitted in accordance with § 405.1811(c) of this subpart.

[39 FR 34515, Sept. 26, 1974. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 73 FR 30247, May 23, 2008]

§ 405.1831 Contractor hearing decision.

(a) If the contractor hearing officer(s) finds jurisdiction (as described in § 405.1814(a) of this subpart) and conducts a hearing, the contractor hearing officer(s) must promptly issue a written hearing decision.

(b) The contractor hearing decision must be based on the evidence from the contractor hearing (as described in

§ 405.1823 of this subpart) and other evidence as may be included in the record (as described in § 405.1827 of this subpart).

(c) The decision must include findings of fact and conclusions of law on jurisdictional issues (as described in § 405.1814(c)(1) of this subpart) and on the merits of the provider's reimbursement claims, and include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(d) A copy of the decision must be sent promptly to the contractor, to each party and to the appropriate component of CMS (which currently is the Center for Medicare Management).

(e) When the contractor's denial of the relief that the provider seeks before the contractor hearing officer(s) was based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit), or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the contractor hearing officer(s) rule(s) that the basis of the contractor's denial is invalid, the contractor hearing officer(s) remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30248, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1832 Contractor hearing officer review of compliance with the substantive reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially qualify for reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If the provider files an appeal to the contractor seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the contractor hearing officer(s) must address such questions in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The contractor hearing officer(s) must give each party to the appeal an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence and legal argument (if any), the contractor hearing officer(s) must review such evidence and argument, and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in § 413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the contractor hearing officer(s) must follow the procedures set forth in § 413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The contractor hearing officer(s) must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in § 405.1827).

(2) *Limits on contractor hearing officer(s) actions.* The contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) must not be invoked or relied on by the contractor hearing officer(s) as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the contractor hearing officer(s)'s written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the contractor hearing officer(s) must proceed to issue one of the two types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the contractor

hearing officer(s) issues an overall contractor hearing decision (as specified in paragraph (d) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must be included in such overall contractor hearing decision regarding the specific item, along with the other matters that are required by the regulations for an overall contractor hearing decision. However, if the contractor hearing officer(s) issues an overall jurisdictional dismissal decision (as specified in paragraph (e) of this section) regarding the specific item under appeal, the contractor hearing officer(s)'s written specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) must not be included in the overall jurisdictional dismissal decision regarding the specific item. The contractor hearing officer(s) may permit reimbursement for the specific item under appeal, as part of an overall contractor hearing decision, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section).

(2) Regardless of whether the contractor hearing officer(s) determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to §405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the contractor must deny jurisdiction over the specific item under appeal (as prescribed in §§405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Impose any sanction or take any other action against the interests of any party to the appeal except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Contractor hearing decision must include any factual findings and legal conclusions under paragraph (b)(1) of this*

section. If the contractor hearing officer(s) issues a hearing decision regarding the specific item under appeal (pursuant to §405.1831), any specific findings of fact and conclusions of law by the contractor hearing officer(s) (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by §405.1831. The contractor hearing officer(s)'s factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of §405.1833 just as those provisions apply to the other parts of the contractor hearing decision. If the contractor hearing officer(s) determines that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the contractor hearing decision also must address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate claim for the specific item under appeal, the contractor hearing officer(s) has discretion whether or not to address in the contractor hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(e) *Contractor jurisdictional dismissal decision must not include factual findings and legal conclusions under paragraph (b)(1) of this section*. If the contractor hearing officer(s) issues a jurisdictional dismissal decision regarding the specific item under appeal (in accordance with §405.1814(c)), the contractor hearing officer(s)'s specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate claim for the specific item must not be included in such jurisdictional dismissal decision.

(f) Effects of the contractor hearing officer(s)'s factual findings and legal conclusions under paragraph (b)(1) of this section when part of a final contractor hearing decision. If the contractor hearing officer(s) determines, as part of a final and binding contractor hearing decision (pursuant to §405.1833 and paragraphs (b)(1) and (d) of this section), that the provider's cost report—

(1) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the contractor hearing officer(s) further determines in such final contractor hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(2) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the contractor hearing officer(s) further determines in such final contractor hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

[80 FR 70598, Nov. 13, 2015]

§ 405.1833 Effect of contractor hearing decision.

A contractor hearing decision issued in accordance with §405.1831 of this subpart is final and binding on all parties to the contractor hearing and on the contractor, unless the hearing decision is reviewed by a CMS reviewing official in accordance with §405.1834 of this subpart or reopened and revised by the contractor hearing officer(s) in accordance with §405.1885 through §405.1889 of this subpart. Final contractor hearing decisions are subject to the provisions of §405.1803(d) of this subpart.

[73 FR 30248, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1834 CMS reviewing official procedure.

(a) *Scope*. A provider that is a party to, and dissatisfied with, a final decision by the contractor hearing officer(s), upon submitting a request that meets the requirements of paragraph (c) of this section, is entitled to further administrative review of the decision,

or the decision may be reviewed at the discretion of the Administrator. No other individual, entity, or party has the right to the review. The review is conducted on behalf of the Administrator by a designated CMS reviewing official who considers whether the decision of the contractor hearing officer(s) is consistent with the controlling legal authority (as described in § 405.1834(e)(1) of this subpart) and the evidence in the record. Based on the review, the CMS reviewing official issues a decision on behalf of the Administrator.

(b) *General rules.* (1) A CMS reviewing official may immediately review any final decision of the contractor hearing officer(s) as specified in paragraph (b)(2) of this section.

(i) Nonfinal decisions and other nonfinal actions by the contractor hearing officer(s) are not immediately reviewable, except as provided in paragraph (b)(3) of this section.

(ii) The CMS reviewing official exercises this review authority in response to a request from a provider party to the appeal that meets the requirements of paragraph (c) of this section or may exercise his or her discretion to take own motion review.

(2) A CMS reviewing official may immediately review the following:

(i) Any final jurisdictional dismissal decision by the contractor hearing officer(s), including any finding that the provider failed to demonstrate good cause for extending the time in which to request a hearing (as described in §§ 405.1813(e)(1) and 405.1814(c)(3) of this subpart).

(ii) Any final contractor hearing decision (as described in § 405.1831 of this subpart).

(iii) If the CMS reviewing official reviews a contractor hearing decision regarding a specific item, then the CMS reviewing official's review of such a contractor hearing decision will include, and any decision issued by the CMS reviewing official (under paragraph (e) of this section) will address, the contractor hearing officer(s)'s specific findings of fact and conclusions of law in such contractor hearing decision (as specified in § 405.1832(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in § 413.24(j) of this chapter).

(3) Nonfinal decisions and other nonfinal actions by the contractor hearing officer(s) are not subject to the CMS reviewing official procedure until the contractor hearing officer(s) issues a final decision as specified in paragraph (b)(2) of this section (as described in §§ 405.1813(e)(2), 405.1814(c) and (d), and 405.1821(d)(1) of this subpart), except that the CMS reviewing official may immediately review a ruling, authorizing discovery or disclosure of a matter, where there is a claim of privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden.

(4) In order to facilitate the Administrator's exercise of this review authority, the contractor hearing officer(s) must promptly send copies of any decision specified in paragraph (b)(2) of this section or in § 405.1821(d)(2) of this subpart to the appropriate component of CMS (currently the Center for Medicare Management).

(i) All requests for review by a CMS reviewing official and all written submissions to a CMS reviewing official under paragraphs (c) and (d) of this section also must be sent to the appropriate component of CMS.

(ii) The appropriate CMS component examines each contractor hearing officer decision that is reviewable under paragraph (b)(2) of this section or § 405.1821(d)(2) of this subpart, along with any review requests and any other submissions made by a party in accordance with the provisions of this section, in order to assist the Administrator's exercise of this review authority.

(c) *Request for review.* (1) A provider's request for review by a CMS reviewing official is granted if—

(i) The date of receipt by the appropriate CMS component of the review request is no later than 60 days after the date of receipt by the provider of the contractor hearing officer decision; or

(ii) The request seeks review of a decision listed in paragraph (b)(2) of this section, and the provider complies with the requirements of paragraph (c)(2) of this section.

(2) The provider must submit its request for review in writing, attach a copy of the contractor decision for which it seeks review and include a brief description of all of the following:

(i) Those aspects of the contractor hearing officer decision with which the provider is dissatisfied.

(ii) The reasons for the provider's dissatisfaction.

(iii) Any argument or record evidence the provider believes supports its position.

(iv) Any additional, extra-record evidence relied on by the provider, along with a demonstration that such evidence was improperly excluded from the contractor hearing (as described in § 405.1823 of this subpart).

(3) A provider request for immediate review of a contractor hearing officer ruling authorizing discovery or disclosure in accordance with paragraph (b)(3) of this section must—

(i) Be made as soon as practicable after the ruling is made, but in no event later than 5 business days after the date it received notice of the ruling; and

(ii) State the reason(s) why the ruling is in error and the potential harm that may be caused if immediate review is not granted.

(d) *Own motion review.* (1) The Administrator has discretion to take own motion review of a contractor hearing officer decision (regardless of whether the decision was favorable or unfavorable to the provider) or other reviewable action.

(2) In order to exercise this authority, the CMS reviewing official must, no later than 60 days after the date of the contractor hearing officer's decision, notify the parties and the contractor that he or she intends to review the contractor hearing officer decision or other reviewable action.

(3) In the notice, the CMS reviewing official identifies with particularity the issues that are to be reviewed, and gives each party (as described in § 405.1815 of this subpart) and affected nonparty a reasonable period to comment on the issues through a written submission complying with paragraph (c)(2) of this section.

(e) *Review procedure.* (1) In reviewing a contractor hearing officer decision specified in paragraph (b)(2) of this section, the CMS reviewing official must—

(i) Comply with all applicable law, regulations, and CMS Rulings (as described in § 401.108 of this chapter), and afford great weight to other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS;

(ii) Subject to paragraph (e)(1)(iii) of this section, limit the review to the record of the proceedings before the contractor hearing officer(s) (as described in § 405.1827 of this subpart) and any written submissions by the parties under paragraphs (c)(2) or (d) of this section; and

(iii) Consider additional, extra-record evidence only if he or she determines that the evidence was improperly excluded from the contractor hearing (as described in § 405.1823 of this subpart).

(2) Review of a contractor decision specified in paragraph (b)(2) of this section is limited to a hearing on the written record in accordance with paragraph (e)(1)(ii) of this section, unless the CMS reviewing official determines that—

(i) Additional, extra-record evidence may be considered in accordance with paragraph (e)(1)(iii) of this section;

(ii) An oral hearing is necessary for consideration of the extra-record evidence; and

(iii) It is not necessary or appropriate to remand the matter to the contractor hearing officer(s).

(3) Upon completion of the review of a contractor hearing decision specified in paragraph (b)(2) of this section, the CMS reviewing official issues a written decision that affirms, reverses, modifies, or remands the contractor hearing decision. A copy of the decision must be sent promptly to each party, to the contractor, and to the appropriate component of CMS (currently the Center for Medicare Management).

(f) *Effect of a decision: Remand.* (1) A decision of affirmation, reversal, or modification by the CMS reviewing official is final and binding on each party and the contractor. No further review or appeal of a decision is available, but the decision may be reopened and revised by a CMS reviewing official in accordance with § 405.1885 through

§ 405.1889 of this subpart. Decisions of a CMS reviewing official are subject to the provisions of § 405.1803(d) of this subpart. A decision by a CMS reviewing official remanding an appeal to the contractor hearing officer(s) for further proceedings under paragraph (f)(2) of this section is not a final decision.

(2) A remand to the contractor hearing officer(s) by the CMS reviewing official must—

(i) Vacate the contractor hearing officer decision;

(ii) Be governed by the same criteria that apply to remands by the Administrator to the Board under § 405.1875(f)(2) of this subpart, and require the contractor hearing officer(s) to take specific actions on remand; and

(iii) Result in the contractor hearing officer(s) taking the actions required on remand and issuing a new contractor hearing decision in accordance with §§ 405.1831 and 405.1833 of this subpart.

[73 FR 30248, May 23, 2008; 73 FR 49356 Aug. 21, 2008, as amended at 80 FR 70599, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1835 Right to Board hearing; contents of, and adding issues to, hearing request.

(a) Right to hearing on final contractor determination. A provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, with respect to a final contractor or Secretary determination for the provider's cost reporting period, if—

(1) The provider is dissatisfied with the contractor's final determination of the total amount of reimbursement due the provider, as set forth in the contractor's written notice specified under § 405.1803. *Exception:* If a final contractor determination is reopened under § 405.1885, any review by the Board must be limited solely to those matters that are specifically revised in the contractor's revised final determination (§§ 405.1887(d), 405.1889(b), and the ''Exception'' in § 405.1873(c)(2)(i)).

(2) The amount in controversy (as determined in accordance with § 405.1839) must be $10,000 or more.

(3) Unless the provider qualifies for a good cause extension under § 405.1836, the date of receipt by the Board of the provider's hearing request must be no later than 180 days after the date of receipt by the provider of the final contractor or Secretary determination.

(b) *Contents of request for a Board hearing on final contractor determination.* The provider's request for a Board hearing under paragraph (a) of this section must be submitted in writing in the manner prescribed by the Board, and the request must include the elements described in paragraphs (b)(1) through (4) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (b)(1), (2), or (3) of this section, the Board may dismiss with prejudice the appeal or take any other remedial action it considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (a) of this section, including a specific identification of the final contractor or Secretary determination under appeal.

(2) For each specific item under appeal, a separate explanation of why, and a description of how, the provider is dissatisfied with the specific aspects of the final contractor or Secretary determination under appeal, including an account of all of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of its payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of the final contractor or Secretary determination under appeal and any other documentary evidence the provider considers necessary to satisfy the hearing request requirements

of paragraphs (b)(1) and (b)(2) of this section.

(4) With respect to a provider under common ownership or control, the name and address of its parent corporation, and a statement that—

(i) To the best of the provider's knowledge, no other provider to which it is related by common ownership or control, has pending a request for a Board hearing pursuant to this section or pursuant to § 405.1837(b)(1) on any of the same issues contained in the provider's hearing request for a cost reporting period that ends within the same calendar year as the calendar year covered by the provider's hearing request; or

(ii) Such a pending appeal(s) exist(s), and the provider name(s), provider number(s), and the case number(s) (if assigned), for such appeal(s).

(c) *Right to hearing based on untimely contractor determination.* Notwithstanding the provisions of paragraph (a) of this section, a provider (but no other individual, entity, or party) has a right to a Board hearing, as a single provider appeal, for specific items for a cost reporting period if—

(1) A final contractor determination for the provider's cost reporting period is not issued (through no fault of the provider) within 12 months after the date of receipt by the contractor of the provider's perfected cost report or amended cost report (as specified in § 413.24(f) of this chapter). The date of receipt by the contractor of the provider's perfected cost report or amended cost report is presumed to be the date the contractor stamped ''Received'' on such cost report unless it is shown by a preponderance of the evidence that the contractor received the cost report on an earlier date.

(2) Unless the provider qualifies for a good cause extension under § 405.1836, the date of receipt by the Board of the provider's hearing request is no later than 180 days after the expiration of the 12 month period for issuance of the final contractor determination (as determined in accordance with paragraph (c)(1) of this section); and

(3) The amount in controversy (as determined in accordance with § 405.1839) is $10,000 or more.

(d) *Contents of request for a Board hearing based on untimely contractor determination.* The provider's request for a Board hearing under paragraph (c) of this section must be submitted in writing in the manner prescribed by the Board, and the request must include the elements described in paragraphs (d)(1) through (4) of this section. If the provider submits a hearing request that does not meet the requirements of paragraph (d)(1), (2), or (3) of this section, the Board may dismiss with prejudice the appeal or take any other remedial action it considers appropriate.

(1) A demonstration that the provider satisfies the requirements for a Board hearing as specified in paragraph (c) of this section.

(2) An explanation (for each specific item at issue) of the following:

(i) Why the provider believes Medicare payment is incorrect for each disputed item (or, where applicable, why the provider is unable to determine whether Medicare payment is correct because it does not have access to underlying information concerning the calculation of Medicare payment).

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item.

(iii) If the provider self-disallows a specific item, a description of the nature and amount of each self-disallowed item and the reimbursement or payment sought for the item.

(3) A copy of any documentary evidence the provider considers necessary to satisfy the hearing request requirements of paragraphs (d)(1) and (d)(2) of this section.

(4) With respect to a provider under common ownership or control, the name and address of its parent corporation, and a statement that meets all of the requirements of paragraphs (b)(4)(i) and (b)(4)(ii) of this section.

(e) *Adding issues to the hearing request.* After filing a hearing request in accordance with paragraphs (a) and (b), or paragraphs (c) and (d), of this section, a provider may add specific Medicare payment issues to the original hearing request by submitting a written request to the Board only if—

(1) The request to add issues complies with the requirements of paragraphs

(a) and (b), or paragraphs (c) and (d), of this section as to each new specific item at issue.

(2) The specific items raised in the initial hearing request and the specific items identified in subsequent requests to add issues, when combined, satisfy the amount in controversy requirements of paragraph (a)(2) or paragraph (c)(3) of this section.

(3) The Board receives the provider's request to add issues no later than 60 days after the expiration of the applicable 180-day period prescribed in paragraph (a)(3) or paragraph (c)(2), of this section.

[73 FR 30249, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 79 FR 50350, Aug. 22, 2014; 79 FR 59680, Oct. 3, 2014; 80 FR 70599, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1836 Good cause extension of time limit for requesting a Board hearing.

(a) A request for a Board hearing that the Board receives after the applicable 180-day time limit prescribed in § 405.1835(a)(3) or § 405.1835(c)(2) must be dismissed by the Board, except that the Board may extend the time limit upon a good cause showing by the provider.

(b) The Board may find good cause to extend the time limit only if the provider demonstrates in writing it could not reasonably be expected to file timely due to extraordinary circumstances beyond its control (such as a natural or other catastrophe, fire, or strike), and the provider's written request for an extension is received by the Board within a reasonable time (as determined by the Board under the circumstances) after the expiration of the applicable 180-day limit specified in § 405.1835(a)(3) or § 405.1835(c)(2).

(c) The Board may not grant a request for an extension under this section if—

(1) The provider relies on a change in the law, regulations, CMS Rulings, or general CMS instructions (whether based on a court decision or otherwise) or a CMS administrative ruling or policy as the basis for the extension request; or

(2) The date of receipt by the Board of the provider's extension request is later than 3 years after the date of the contractor or other determination that the provider seeks to appeal.

(d) If an extension request is granted or denied under this section, the Board must give prompt written notice to the provider, and send a copy of the notice to each party to the appeal. The notice must include a detailed explanation of the reasons for the decision by the Board and the facts underlying the decision.

(e)(1) If the Board denies an extension request and determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a Board dismissal decision dismissing the appeal for lack of Board jurisdiction. This decision by the Board must be in writing and include the explanation of the extension request denial required under paragraph (d) of this section, in addition to specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal (as described in § 405.1840(c)). A copy of the Board's dismissal decision must be sent promptly to each party to the appeal (as described in § 405.1843).

(2) A Board dismissal decision under paragraph (e)(1) of this section is final and binding on the parties, unless the decision is reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(a)(2)(ii) and 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) This Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision, within the period.

(ii) A Board decision under paragraph (e)(1) of this section that is otherwise final and binding may be reopened and revised by the Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(3) The Administrator may review a Board decision granting an extension request solely during the course of an Administrator review of one of the Board decisions specified as final, or deemed final by the Administrator, under § 405.1875(a)(2) of this subpart.

(4) A finding by the Board or the Administrator that the provider did or did not demonstrate good cause for extending the time for requesting a Board hearing is not subject to judicial review.

[73 FR 30250, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 80 FR 70600, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1837 Group appeals.

(a) *Right to Board hearing as part of a group appeal: Criteria.* A provider (but no other individual, entity, or party) has a right to a Board hearing, as part of a group appeal with other providers, with respect to a final contractor or Secretary determination for the provider's cost reporting period, only if—

(1) The provider satisfies individually the requirements for a Board hearing under § 405.1835(a) or § 405.1835(c), except for the $10,000 amount in controversy requirement in § 405.1835(a)(2) or § 405.1835(c)(3).

(2) The matter at issue in the group appeal involves a single question of fact or interpretation of law, regulations, or CMS Rulings that is common to each provider in the group; and

(3) The amount in controversy is, in the aggregate, $50,000 or more, as determined in accordance with § 405.1839 of this subpart.

(b) *Usage and filing of group appeals*—(1) *Mandatory use of group appeals.* (i) Two or more providers under common ownership or control that wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations, or CMS Rulings that is common to the providers, and that arises in cost reporting periods that end in the same calendar year, and for which the amount in controversy is $50,000 or more in the aggregate, must bring the appeal as a group appeal.

(ii) One or more of the providers under common ownership or control may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the $50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(iii) A group appeal involving two or more providers under common ownership or control must consist entirely of providers under common (to all) ownership or control.

(iv)(A) Example 1: A, B, C and D are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY 2004 cost reports, and on D's CY 2005 cost report. The amount in controversy is more than $50,000 in the aggregate for providers A, B and C, and more than $10,000 for provider D. Providers A, B and C must appeal issue X as a group appeal. Provider D may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart, or if the Board agrees, Provider D may join the group appeal. (If Provider D joins the group appeal, the calendar years in the group appeal would then be 2004 and 2005, and any provider related to Providers A through D by common ownership or control would be required to appeal issue X for its cost reporting period ending in 2004 or 2005 through the group appeal.)

(B) Example 2: A, B and C are commonly owned providers that wish to appeal issue X. This issue was adjusted on A, B and C's CY 2004 cost reports. The amount in controversy is less than $50,000 in the aggregate for providers A, B and C ($10,000 for A, $10,000 for B and $7,000 for C). Providers A, B and C cannot appeal issue X as a group appeal. Provider A, if it wishes, and provider B, if it wishes, may pursue an individual appeal to the Board under the procedures set forth in § 405.1835 of this subpart. Provider C may not pursue an individual appeal to the Board, because the amount in controversy is less than $10,000; however, it may pursue an appeal to the contractor under the procedures set forth in § 405.1811 of this subpart.

(2) *Optional group appeals.* (i) Two or more providers not under common ownership or control may bring a group appeal before the Board under this section, if the providers wish to appeal to the Board a specific matter at issue that involves a question of fact or interpretation of law, regulations,

or CMS Rulings that is common to the providers. Alternatively, any provider may appeal to the Board any issues in a single provider appeal brought under § 405.1835 of this subpart.

(ii) One or more of the providers bringing a group appeal under this paragraph may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for purposes of meeting the $50,000 amount in controversy requirement, and, subject to the Board's discretion, may appeal more than one cost reporting period with respect to the issue that is the subject of the group appeal for other purposes, such as convenience.

(3) *Initiating a group appeal.* With respect to group appeals brought under paragraph (b)(1) of this section, one or more commonly owned or operated providers must make a written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section. Any group appeal filed by a single provider must be joined by related providers on common issues in accordance with paragraphs (b)(1) and (e) of this section. With respect to group appeals brought under paragraph (b)(2) of this section, two or more providers may submit—

(i) A written request for a Board hearing as a group appeal in accordance with paragraph (c) of this section; or

(ii) A request to the Board in accordance with paragraph (e)(4) of this section that a specific matter at issue in a single provider appeal, filed previously under § 405.1835 of this subpart, be transferred from the single appeal to a group appeal.

(c) *Contents of request for a group appeal.* The request for a Board hearing as a group appeal must be submitted in writing to the Board, and the request must include all of the following:

(1) A demonstration that the request satisfies the requirements for a Board hearing as a group appeal, as specified in paragraph (a) of this section.

(2) An explanation (for each specific item at issue) of each provider's dissatisfaction with the final contractor or Secretary determination under appeal, including an account of—

(i) Why the provider believes Medicare payment is incorrect for each disputed item;

(ii) How and why the provider believes Medicare payment must be determined differently for each disputed item; and

(iii) If the provider self-disallows a specific item (as specified in § 413.24(j) of this chapter), an explanation of the nature and amount of each self-disallowed item, the reimbursement sought for the item, and why the provider self-disallowed the item instead of claiming reimbursement for the item.

(3) A copy of each final contractor or Secretary determination under appeal, and any other documentary evidence the providers consider to satisfy the hearing request requirements of paragraphs (c)(1) and (c)(2) of this section, and a precise description of the one question of fact or interpretation of law, regulations, or CMS Rulings that is common to the particular matter at issue in the group appeal.

(4) A statement that—

(i) The providers believe they have satisfied all of the requirements for a group appeal hearing request under paragraph (a) of this section and requesting the Board to proceed to make jurisdictional findings in accordance with § 405.1840; or

(ii) The Board is requested to defer making jurisdictional findings until the providers request the findings in accordance with paragraph (e)(2) of this section.

(d) *Board's preliminary response to group appeal hearing requests.* (1) Upon receipt of a group appeal hearing request, the Board must take any necessary ministerial steps.

(2) The steps, include, for example—

(i) Acknowledging the request;

(ii) Assigning a case number to the appeal; or

(iii) If applicable, transferring a specific matter at issue from a single provider appeal filed under § 405.1835 of this subpart to a group appeal filed under this section.

(e) *Group appeal procedures pending full formation of the group and issuance of a Board decision.* (1) A provider (or providers) may file a group appeal hearing request with the Board under

this section before each provider member of the group identifies or complies with paragraphs (a)(1) and (a)(2) of this section, or before the group satisfies the $50,000 amount in controversy requirement under paragraph (a)(3) of this section. Proceedings before the Board in any partially formed group appeal are subject to the provisions of paragraphs (e)(2), (e)(3), and (e)(4) of this section. The Board will determine that a group appeal brought under paragraph (b)(1) of this section is fully formed upon a notice in writing from the group that it is fully formed. Absent such a notice from the group, the Board may issue an order, requiring the group to demonstrate (within a period of not less than 15 days) that at least one commonly owned or controlled provider has preserved the issue for appeal by claiming the relevant item on its cost report or by self-disallowing the item, but has not yet received its final determination with respect to the item for a cost year that is within the same calendar year as that covered by the group appeal (or that it has received its final determination with respect to the item for that period, and is still within the time to request a hearing on the issue). The Board determines that a group appeal brought under paragraph (b)(2) of this section is fully formed upon a notice in writing from the group that it is fully formed, or following an order from the Board that in its judgment, that the group is fully formed, or through general instructions that set forth a schedule for the closing of group appeals brought under paragraph (b)(2) of this section. When the Board has determined that a group appeal brought under paragraph (b)(1) of this section is fully formed, absent an order from the Board modifying its determination, no other provider under common ownership or control may appeal to the Board the issue that is the subject of the group appeal with respect to a cost reporting period that falls within the calendar year(s) covered by the group appeal.

(2) The Board may make jurisdictional findings under § 405.1840 at any time, including, but not limited to, following a request by the providers for the jurisdictional findings. The providers may request jurisdictional findings by notifying the Board in writing that the group appeal is fully formed, or that the providers believe they have satisfied all of the requirements for a group appeal hearing request, and the Board may proceed to make jurisdictional findings. The providers must include with the notice any additional information or documentary evidence that is required for group appeal hearing requests. The Board does not dismiss a group appeal hearing request for failure to meet the $50,000 amount in controversy requirement until the Board has determined, in accordance with paragraph (e)(1) of this section, that the group is fully formed.

(3) If the Board makes a preliminary determination of jurisdiction to conduct a hearing as a group appeal under this section, the Board then takes any further actions in the appeal it finds to be appropriate under this subpart (as described in § 405.1840(a) of this subpart). The Board may take further actions, even though the providers in the appeal may wish to add other providers to the group in accordance with paragraph (e)(4) of this section. The Board must make separate jurisdictional findings for each cost reporting period added subsequently to the group appeal (as described in §§ 405.1837(a) and 405.1839(b) of this subpart).

(4) A provider may submit a request to the Board to join a group appeal any time before the Board issues one of the decisions specified in § 405.1875(a)(2). By submitting a request, the provider agrees that, if the request is granted, the provider is bound by the Board's actions and decision in the appeal. If the Board denies a request, the Board's action is without prejudice to any separate appeal the provider may bring in accordance with § 405.1811, § 405.1835, or this section. For purposes of determining timeliness for the filing of any separate appeal and for the adding of issues to such appeal, the date of receipt of the provider's request to form or join the group appeal is considered the date of receipt for purposes of meeting the applicable 180-day period prescribed in § 405.1835(a)(3) or § 405.1835(c)(2).

(5)(i) Except as specified in paragraph (ii) of this paragraph, when a provider

has appealed an issue through electing to form, or joining, a group appeal under the procedures set forth in this section, it may not subsequently request that the Board transfer that issue to a single provider appeal brought in accordance with § 405.1811 or § 405.1835 of this subpart.

(ii) *Exception.* When the Board determines that the requirements for a group appeal are not met (that is, when there has been a failure to meet the amount in controversy or the common issue requirement), it transfers the issue that was the subject of the group appeal to a single provider appeal (or appeals) for the provider (or providers) that meets (or meet) the requirements for a single provider appeal.

(f) *Limitations on group appeals.* (1) After the date of receipt by the Board of a group appeal hearing request under paragraph (c) of this section, a provider may not add other questions of fact or law to the appeal, regardless of whether the question is common to other members of the appeal (as described in § 405.1837(a)(2) and (g) of this subpart).

(2) The Board may not consider, in one group appeal, more than one question of fact, interpretation of law, regulations, or CMS Rulings that is common to each provider in the appeal. If the Board finds jurisdiction over a group appeal hearing request under § 405.1840 of this subpart—

(i) The Board must determine whether the appeal involves specific matters at issue that raise more than one factual or legal question common to each provider; and

(ii) When the appeal is found to involve more than one factual or legal question common to each provider, the Board must assign a separate case number to the appeal of each common factual or legal question and conduct further proceedings in the various appeals separately for each case.

(g) *Issues not common to the group appeal.* A provider involved in a group appeal that also wishes to appeal a specific matter that does not raise a factual or legal question common to each of the other providers in the group must file a separate request for a single provider hearing in accordance with § 405.1811 or § 405.1835 of this subpart, or file a separate request for a hearing as part of a different group appeal under this section, as applicable.

[73 FR 30250, May 23, 2008, as amended at 80 FR 70600, Nov. 13, 2015]

§ 405.1839 Amount in controversy.

(a) *Single provider appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1811(a)(2) or § 405.1811(c)(3) for a contractor hearing or the amount in controversy requirement under § 405.1835(a)(2) or § 405.1835(c)(3) for a Board hearing for a single provider, the provider must demonstrate that if its appeal were successful, the provider's total program reimbursement for each cost reporting period under appeal would increase by at least $1,000 but by less than $10,000 for a contractor hearing, or by at least $10,000 for a Board hearing, as applicable.

(2) *Aggregation of claims.* For purposes of satisfying the applicable amount in controversy requirement for a single provider appeal to the contractor or the Board, the provider may aggregate claims for additional program payment for more than one specific matter at issue, provided each specific claim and issue is for the same cost reporting period. Aggregation of claims from more than one cost reporting period to meet the applicable amount in controversy requirement is prohibited, even if a specific claim or issue in the appeal recurs for multiple cost years.

(b) *Group appeals.* (1) In order to satisfy the amount in controversy requirement under § 405.1837(a)(3) of this subpart for a Board hearing as a group appeal, the group must demonstrate that if its appeal were successful, the total program reimbursement for the cost reporting periods under appeal would increase, in the aggregate, by at least $50,000.

(2) *Aggregation of claims.* (i) For purposes of satisfying the amount in controversy requirement, group members are not allowed to aggregate claims involving different issues.

(A) A group appeal must involve a single question of fact or interpretation of law, regulations, or CMS Ruling that is common to each provider (as described in § 405.1837(a)(2) of this subpart).

(B) The single issue that is common to each provider may exist over different cost reporting periods.

(ii) For purposes of satisfying the amount in controversy requirement, a provider may appeal multiple cost reporting periods and different providers in the group may appeal different cost reporting periods.

(c) *Limitations on change in Medicare reimbursement.* (1) In order to satisfy the applicable amount in controversy requirement for a single provider appeal or a group appeal, an appeal favorable to the provider(s) on all specific matters at issue in the appeal increases program reimbursement for the provider(s) in the cost reporting period(s) at issue by an amount that equals or exceeds the applicable amount in controversy threshold.

(2) The applicable amount in controversy requirement is not satisfied if the result of a favorable appeal decreases program reimbursement for the provider(s) in the cost reporting year(s) at issue in the appeal.

(3) Any effects that a favorable appeal might have on program reimbursement for the provider(s) in cost reporting period(s) not at issue in the appeal have no bearing on whether the amount in controversy requirement is satisfied for the cost year(s) at issue in the appeal.

(4) When a provider (or group of providers) has requested a hearing before a contractor under § 405.1811 of this subpart, and the amount in controversy is subsequently determined to be at least $10,000 (for example, due to a reassessment of the amount in controversy by the contractor hearing office or due to adding an issue), the appeal is transferred to the Board. The Board is not bound by any jurisdictional finding of the contractor hearing officer(s).

(5) When a provider or group of providers has requested a hearing before the Board under § 405.1835 or § 405.1837 of this subpart, and the amount in controversy changes to an amount less than the minimum for a Board appeal due to—

(A) The settlement or partial settlement of an issue, transfer of an issue to a group appeal, or the abandonment of an issue in an individual appeal, the change in the amount in controversy does not deprive the Board of jurisdiction.

(B) A more accurate assessment of the amount in controversy, the Board does not retain jurisdiction.

[73 FR 30252, May 23, 2008; 73 FR 49356, Aug. 21, 2008, as amended at 80 FR 70600, Nov. 13, 2015]

§ 405.1840 Board jurisdiction.

(a) *General rules.* (1) After a request for a Board hearing is filed under § 405.1835 or § 405.1837 of this part, the Board must determine in accordance with paragraph (b) of this section, whether or not it has jurisdiction to grant a hearing on each of the specific matters at issue in the hearing request.

(2) The Board must make a preliminary determination of the scope of its jurisdiction (that is, whether the request for hearing was timely, and whether the amount in controversy requirement has been met), if any, over the matters at issue in the appeal before conducting any of the following proceedings:

(i) Determining its authority to decide a legal question relevant to a matter at issue (as described in § 405.1842 of this subpart).

(ii) Permitting discovery (as described in § 405.1853 of this subpart).

(iii) Issuing a subpoena (as described in § 405.1857 of this subpart).

(iv) Conducting a hearing (as described in § 405.1845 of this subpart).

(3) The Board may revise a preliminary determination of jurisdiction at any subsequent stage of the proceedings in a Board appeal, and must promptly notify the parties of any revised determination. Under paragraph (c)(1) of this section, each expedited judicial review (EJR) decision (as described in § 405.1842 of this subpart) and hearing decision (as described in § 405.1871 of this subpart) by the Board must include a jurisdictional finding for each specific matter at issue in the appeal.

(4) If the Board finally determines it lacks jurisdiction over every specific matter at issue in the appeal, the Board must issue a dismissal decision under paragraph (c)(2) of this section.

(5) Final jurisdictional findings and dismissal decisions by the Board under

paragraphs (c)(1) and (c)(2) of this section are subject to Administrator and judicial review in accordance with paragraph (d) of this section.

(b) *Criteria.* Except with respect to the amount in controversy requirement, the jurisdiction of the Board to grant a hearing must be determined separately for each specific matter at issue in each contractor or Secretary determination for each cost reporting period under appeal. The Board has jurisdiction to grant a hearing over a specific matter at issue in an appeal only if the provider has a right to a Board hearing as a single provider appeal under § 405.1835 of this subpart or as part of a group appeal under § 405.1837 of this subpart, as applicable. Certain matters at issue are removed from jurisdiction of the Board. These matters include, but are not necessarily limited to, the following:

(1) A finding in a contractor determination that expenses incurred for certain items or services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act and part 411 of the regulations. Review of these findings is limited to the applicable provisions of sections 1155, 1869, and 1879(d) of the Act and of subpart I of part 405 and subpart B of part 478 of the regulations, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system, as provided in section 1886(d)(7) of the Act and § 405.1804 of this subpart.

(c) *Board's jurisdictional findings and jurisdictional dismissal decisions.* (1) In issuing an EJR decision under § 405.1842 of this subpart or a hearing decision under § 405.1871 of this subpart, as applicable, the Board must make a separate determination of whether it has jurisdiction for each specific matter at issue in each contractor or Secretary determination under appeal. A decision by the Board must include specific findings of fact and conclusions of law as to whether the Board has jurisdiction to grant a hearing on each matter at issue in the appeal.

(2) Except as provided in §§ 405.1836(e)(1) and 405.1842(f)(2)(i), where the Board determines it lacks jurisdiction to grant a hearing for every specific matter at issue in an appeal, it must issue a dismissal decision dismissing the appeal for lack of Board jurisdiction. The decision by the Board must include specific findings of fact and conclusions of law explaining the Board's determination that it lacks jurisdiction to grant a hearing on each matter at issue in the appeal. A copy of the Board's decision must be sent promptly to each party to the appeal (as described in § 405.1843).

(3) A dismissal decision by the Board under paragraph (c)(2) of this section is final and binding on the parties unless the decision is reversed, affirmed, modified or remanded by the Administrator under § 405.1875(a)(2)(ii) and § 405.1875(e) or § 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision. The Board decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies or remands that decision within that period. A final Board decision under paragraphs (c)(2) and (c)(3) of this section may be reopened and revised by the Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(d) *Administrator and judicial review.* Any finding by the Board as to whether it has jurisdiction to grant a hearing on a specific matter at issue in an appeal is not subject to further administrative and judicial review, except as provided in this paragraph. The Board's jurisdictional findings as to specific matters at issue in an appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart, or during the course of judicial review of a final agency decision as described in § 405.1877(a) of this subpart, as applicable.

[73 FR 30253, May 23, 2008, as amended at 80 FR 70600, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1842 Expedited judicial review.

(a) *Basis and scope.* (1) This section implements provisions in section

1878(f)(1) of the Act that give a provider the right to seek EJR of a legal question relevant to a specific matter at issue in a Board appeal if there is Board jurisdiction to conduct a hearing on the matter (as described in § 405.1840 of this subpart), and the Board determines it lacks the authority to decide the legal question (as described in § 405.1867 of this subpart, which explains the scope of the Board's legal authority).

(2) A provider may request a Board decision that the provider is entitled to seek EJR or the Board may consider issuing a decision on its own motion. Each EJR decision by the Board must include a specific jurisdictional finding on the matter(s) at issue, and, where the Board determines that it does have jurisdiction on the matter(s) at issue, a separate determination of the Board's authority to decide the legal question(s).

(3) The Administrator may review the Board's jurisdictional finding, but not the Board's authority determination.

(4) The provider has a right to seek EJR of the legal question under section 1878(f)(1) of the Act only if—

(i) The final EJR decision of the Board or the Administrator, as applicable, includes a finding of Board jurisdiction over the specific matter at issue and a determination by the Board that it has no authority to decide the relevant legal question; or

(ii) The Board fails to make a determination of its authority to decide the legal question no later than 30 days after finding jurisdiction over the matter at issue and notifying the provider that the provider's EJR request is complete.

(b) *General*—(1) *Prerequisite of Board jurisdiction.* The Board (or the Administrator) must find that the Board has jurisdiction over the specific matter at issue before the Board may determine its authority to decide the legal question.

(2) *Initiating EJR procedures.* A provider or group of providers may request the Board to grant EJR of a specific matter or matters under appeal, or the Board on its own motion may consider whether to grant EJR of a specific matter or matters under appeal. Under paragraph (c) of this section, the Board may initiate own motion consideration of its authority to decide a legal question only if the Board makes a preliminary finding that it has jurisdiction over the specific matter at issue to which the legal question is relevant. Under paragraphs (d) and (e) of this section, a provider may request a determination of the Board's authority to decide a legal question, but the 30-day period for the Board to make a determination under section 1878(f)(1) of the Act does not begin to run until the Board finds jurisdiction to conduct a hearing on the specific matter at issue in the EJR request and notifies the provider that the provider's request is complete.

(c) *Board's own motion consideration.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance with § 405.1840(a) of this part, it may then consider on its own motion whether it lacks the authority to decide a legal question relevant to the matter at issue.

(2) The Board must initiate its own motion consideration by issuing a written notice to each of the parties to the appeal (as described in § 405.1843 of this subpart). The notice must—

(i) Identify each specific matter at issue for which the Board has made a finding that it has jurisdiction under § 405.1840(a) of this part, and for each specific matter, identify each relevant statutory provision, regulation, or CMS Ruling; and

(ii) Specify a reasonable period of time for the parties to respond in writing.

(3) After considering any written responses made by the parties to its notice of own motion consideration, the Board must determine whether it has sufficient information to issue an EJR decision for each specific matter and legal question included in the notice. If necessary, the Board may request additional information regarding its jurisdiction or authority from a party (or parties), and the Board must give any other party a reasonable opportunity to comment on any additional submission. Once the Board determines it needs no further information from the parties (or that any information has

not been rendered timely), it must issue an EJR decision in accordance with paragraph (f) of this section.

(d) *Provider requests.* A provider (or, in the case of a group appeal, a group of providers) may request a determination by the Board that it lacks the authority to decide a legal question relevant to a specific matter at issue in an appeal. A provider must submit a request in writing to the Board and to each party to the appeal (as described in §405.1843 of this subpart), and the request must include—

(1) For each specific matter and question included in the request, an explanation of why the provider believes the Board has jurisdiction under §405.1840 of this subpart over each matter at issue and no authority to decide each relevant legal question; and

(2) Any documentary evidence the provider believes supports the request.

(e) *Board action on provider requests.* (1) If the Board makes a finding that it has jurisdiction to conduct a hearing on a specific matter at issue in accordance with §405.1840(a) of this part, then (and only then) it must consider whether it lacks the authority to decide a legal question relevant to the matter at issue. The Board is required to make a determination of its authority to decide the legal question raised in a review request under paragraph (d)(1) of this section by issuing an EJR decision no later than 30 days after receiving a complete provider request as defined in paragraph (e)(2) of this section.

(2) *Requirements of a complete provider request.* A complete provider request for EJR consists of the following:

(i) A request for an EJR decision by the provider(s).

(ii) All of the information and documents found necessary by the Board for issuing a decision in accordance with paragraph (f) of this section.

(3) *Board's response to provider requests.* After receiving a provider request for an EJR decision, the Board must review the request, along with any responses to the request submitted by other parties to the appeal (as described in §405.1843 of this subpart). The Board must respond to the provider(s) as follows:

(i) Upon receiving a complete provider request, issue an EJR decision in accordance with paragraph (f) of this section no later than 30 days after receipt of the complete provider request. If the Board does not issue a decision within that 30-day period, the provider has a right to file a complaint in Federal district court in order to obtain EJR over the specific matter(s) at issue.

(ii) If the provider has not submitted a complete request, issue no later than 30 days after receipt of the incomplete request a written notice to the provider describing in detail the further information that the provider must submit in order to complete the request.

(f) *Board's decision on EJR: Criteria for granting EJR.* Subject to paragraph (h)(3) of this section, the Board is required to issue an EJR decision following either the completion of the Board's own motion consideration under paragraph (c) of this section, or a notice issued by the Board in accordance with paragraph (e)(3)(i) of this section.

(1) The Board's decision must grant EJR for a legal question relevant to a specific matter at issue in a Board appeal if the Board determines the following conditions are satisfied:

(i) The Board has jurisdiction to conduct a hearing on the specific matter at issue in accordance with §405.1840 of this subpart.

(ii) The Board lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation or CMS Ruling.

(2) The Board's decision must deny EJR for a legal question relevant to a specific matter at issue in a Board appeal if any of the following conditions are satisfied:

(i) The Board determines that it does not have jurisdiction to conduct a hearing on the specific matter at issue in accordance with §405.1840 of this subpart.

(ii) The Board determines it has the authority to decide a specific legal

question relevant to the specific matter at issue because the legal question is neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling.

(iii) The Board does not have sufficient information to determine whether the criteria specified in paragraph (f)(1)(i) or (f)(1)(ii) of this section are met.

(3) A copy of the Board's decision must be sent promptly to—

(i) Each party to the Board appeal (as described in § 405.1843 of this subpart) and

(ii) The Office of the Attorney Advisor.

(g) *Further review after the Board issues an EJR decision*—(1) *General rules.* (i) Under § 405.1875(a)(2)(iii) of this subpart, the Administrator may review, on his or her own motion, or at the request of a party, the jurisdictional component only of the Board's EJR decision.

(ii) Any review by the Administrator is limited to the question of whether there is Board jurisdiction over the specific matter at issue; the Administrator may not review the Board's determination of its authority to decide the legal question.

(iii) An EJR decision by the Board becomes final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(a)(2)(iii), 405.1875(e), and 405.1875(f) of this subpart no later than 60 days after the date of receipt by the provider of the Board's decision.

(iv) A Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within that period.

(v) Any right of the provider to obtain EJR from a Federal district court is specified at paragraphs (g)(2) and (g)(3) of this section (when the Board issues a timely EJR decision) and paragraph (g)(4) of this section (in the absence of a timely Board decision).

(vi) A final Board decision under paragraph (f) of this section, and a final Administrator decision made upon review of a final Board decision (as described in § 405.1875(a)(2) and (e) of this subpart) may be reopened and revised in accordance with §§ 405.1885 through 405.1889 of this subpart.

(2) *Board grants EJR.* If the Board grants EJR, the provider may file a complaint in a Federal district court in order to obtain EJR of the legal question. If the Administrator renders, no later than 60 days after the date of receipt by the provider of the Board's decision granting EJR, a decision finding that the Board has no jurisdiction over the matter at issue, the Board's decision is nonfinal and the provider has no right to obtain judicial review based on the Board's decision (as described in § 405.1877(a)(3) and (b)(3) of this subpart).

(3) *Board denies EJR.* If the Board's decision denies EJR because the Board finds that it has the authority to decide the legal question relevant to the matter at issue, the Administrator may not review the Board's authority determination, and the provider has no right to obtain EJR. If the Board denies EJR based on a finding that it lacks jurisdiction over the specific matter, the provider has no right to obtain EJR unless—

(i) The Administrator renders timely a final decision reversing the Board, finding the Board has jurisdiction over the matter at issue, and remanding to the Board; or

(ii) A court reverses the Board's or Administrator's decision as to jurisdiction, the Administrator remands to the Board, and the Board subsequently issues on remand from the Administrator an EJR decision granting EJR on the basis that it lacks the authority to decide the legal question.

(4) *No timely EJR decision.* The Board must issue an EJR decision no later than 30 days after the date of a written notice under paragraph (e)(3)(i) of this section, when the provider submits a complete request for EJR. If the Board does not issue an EJR decision within a 30-day period, the provider(s) has a right to seek EJR under section 1878(f)(1) of the Act.

(h) *Effect of final EJR decisions and lawsuits on further Board proceedings*—(1) *Final decisions granting EJR.* If the

final decision of the Board or the Administrator, as applicable (as described in §§ 405.1842(g)(1) and 405.1875(e)(4) of this subpart), grants EJR, the Board may not conduct any further proceedings on the legal question. The Board must dismiss—

(i) The specific matter at issue from the appeal.

(ii) The entire appeal if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board.

(2) *Final decisions denying EJR.* If the final decision:

(i) Of the Board denies EJR solely on the basis that the Board determines it has the authority to decide the legal question relevant to the specific matter at issue, the Board must conduct further proceedings on the legal question and issue a decision on the matter at issue in accordance with this subpart.

Exception: If the provider(s) file(s) a lawsuit pertaining to the legal question, and for a period that is covered by the Board's decision denying EJR, the Board may not conduct any further proceedings under this subpart on the legal question or the matter at issue before the lawsuit is finally resolved.

(ii) Of the Board (or the Administrator) denies EJR on the basis that the Board lacks jurisdiction over the specific matter at issue, the Board (or the Administrator) must, as applicable, dismiss the specific matter at issue from the appeal, or dismiss the appeal entirely if there are no other matters at issue that are within the Board's jurisdiction and can be fully decided by the Board. If only the specific matter(s) is dismissed from the appeal, judicial review may be had only after a final decision on the appeal is made by the Board or Administrator, as applicable (as described in §§ 405.1840(d) and 405.1877(a) of this subpart). If the Board or the Administrator, as applicable, dismisses the appeal entirely, the decision is subject to judicial review under § 405.1877(a) of this subpart.

(3) *Provider lawsuits.* (i) If the provider files a lawsuit seeking judicial review (whether on the basis of the EJR provisions of section 1878(f)(1) of the Act or on some other basis) pertaining to a legal question that is allegedly relevant to a specific matter at issue in a Board appeal to which the provider is a party and that is allegedly not within the Board's authority to decide, the Office of the Attorney Advisor must promptly provide the Board with written notice of the lawsuit and a copy of the complaint.

(ii) If the lawsuit is filed after a final EJR decision by the Board or the Administrator, as applicable (as described in §§ 405.1842(g)(1) and 405.1875(e)(4) of this subpart), on the legal question, the Board must carry out the applicable provisions of paragraphs (h)(1) and (h)(2) of this section in any pending Board appeal on the specific matter at issue.

(iii) If the lawsuit is filed before a final EJR decision is issued on the legal question, the Board may not conduct any further proceedings on the legal question or the matter at issue until the lawsuit is resolved.

[73 FR 30254, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1843 Parties to proceedings in a Board appeal.

(a)(1) When a provider files a request for a hearing before the Board in accordance with § 405.1835 or § 405.1837, the parties to all proceedings in the Board appeal include the provider, a contractor, and, where applicable, any other entity found by the Board to be a related organization of the provider under the principles enunciated in § 413.17 of this chapter.

(2) All parties to a Board appeal are to familiarize themselves with the instructions for handling a Provider Reimbursement Review Board (PRRB) appeal, including any and all requirements related to the electronic/online filing of documents.

(b) Neither the Secretary nor CMS may be made a party to proceedings in a Board appeal.

(1) The Board may call as a witness any employee or officer of the Department of Health and Human Services or CMS having personal knowledge of the facts and the issues in controversy in an appeal.

(2) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply

as to whether such employee or officer will appear.

(c) A contractor may designate a representative from the Secretary or CMS, who may be an attorney, to represent the contractor in proceedings before the Board.

(d) Although CMS is not a party to proceedings in a Board appeal, there may be instances where CMS determines that the administrative policy implications of a case are substantial enough to warrant comment from CMS (as described in § 405.1863 of this subpart). CMS—

(1) May file *amicus curiae* (friend of the court) briefing papers with the Board in accordance with a schedule to be determined by the Board.

(2) Must promptly send copies of any documents filed with the Board to each party to the appeal.

(e) A nonparty other than CMS may seek leave from the Board to file *amicus curiae* briefing papers with the Board.

(f) The Board may exclude from the record all or part of an amicus curiae briefing paper. When the Board excludes from the record all or part of an amicus curiae briefing paper submitted by CMS, it states for the record its reason(s) in writing.

[73 FR 30256, May 23, 2008, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1845 Composition of Board; hearings, decisions, and remands.

(a) The Board will consist of five members appointed by the Secretary. All shall be knowledgeable in the field of cost reimbursement. At least one shall be a certified public accountant. Two Board members shall be representative of providers of services.

(b) The term of office for Board members shall be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office. No member shall serve more than two consecutive 3-year terms of office. The Secretary shall have the authority to terminate a Board member's term of office for good cause.

(c) *Composition of the Board.* The Secretary designates one member of the Board as Chairperson. The Chairperson coordinates and directs the administrative activities of the Board and the conduct of proceedings before the Board. CMS provides administrative support for the Board. Under the direction of the Chairperson, the Board is solely responsible for the content of its decisions.

(d) *Quorum.* (1) The Board must have a quorum in order to issue one of the decisions specified as final, or deemed final by the Administrator, under § 405.1875(a)(2)(i), (a)(2)(iii), and (a)(2)(iv), but a quorum is not required for other Board actions.

(2) Three Board members, at least one of whom is representative of providers, are required in order to constitute a quorum.

(3) The opinion of the majority of those Board members issuing a decision specified as final, or deemed as final by the Administrator, under § 405.1875(a)(2), constitutes the Board's decision.

(e) *Hearings.* The Board may conduct a hearing and issue a hearing decision (as described in § 405.1871 of this subpart) on a specific matter at issue in an appeal, provided it finds jurisdiction over the matter at issue in accordance with § 405.1840 of this part and determines it has the legal authority to fully resolve the issue (as described in § 405.1867 of this subpart).

(f) *Oral hearings.* (1) In accordance with paragraph (d) of this section, the Board does not need a quorum in order to hold an oral hearing (as described in § 405.1851 of this subpart). The Chairperson of the Board may designate one or more Board members to conduct an oral hearing (where less than a quorum conducts the hearing). Because the presence of all Board members is not required at an oral hearing, the Board, at its discretion, may hold more than one oral hearing at a time.

(2) *Waiver of oral hearings.* With the contractor's agreement and the Board's approval, the provider (or, in the case of group appeals, the group of providers) and any related organizations (as described in § 405.1843(a) of this subpart) may waive any right to an oral hearing and stipulate that the Board may issue a hearing decision on the written record. An on-the-written-

record hearing consists of all the evidence and written argument or comments submitted to the Board and included in the record (as described in § 405.1865 of this subpart).

(g) *Hearing decisions.* The Board's hearing decision must be based on the transcript of any oral hearing before the Board, any matter admitted into evidence at a hearing or deemed admissible evidence for the record (as described in § 405.1855 of this subpart), and any written argument or comments timely submitted to the Board (as described in § 405.1865 of this subpart).

(h) *Remands.* (1) Except as provided in paragraph (h)(3) of this section, a Board remand order may be reviewed solely during the course of Administrator review of one of the Board decisions specified in § 405.1875(a)(2) of this subpart), or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this part, as applicable.

(2) The Board may order a remand requiring specific actions of a party to the appeal. In ordering a remand, the Board must—

(i) Specify any actions required of the party and explain the factual and legal basis for ordering a remand;

(ii) Issue the remand order in writing; and

(iii) Send the remand order promptly to the parties and any affected nonparty, such as CMS, to the appeal.

(3) A Board remand order is not subject to immediate Administrator review unless the Administrator determines that the remand order might otherwise evade his or her review (as described in § 405.1875(a)(2)(iv) of this subpart).

[39 FR 34515, Sept. 26, 1974, as amended at 41 FR 52051, Nov. 26, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 73 FR 30256, May 23, 2008; 85 FR 59019, Sept. 18, 2020]

EFFECTIVE DATE NOTE: At 89 FR 69909, Aug. 28, 2024, § 405.1845 was amended by revising paragraphs (a) and (b) and the paragraph (c) paragraph heading, effective Jan. 1, 2025. For the convenience of the user, the revised text is set forth as follows:

§ 405.1845 Composition of Board; hearings, decisions, and remands.

(a) *Composition of the Board.* The Board consists of five members appointed by the Secretary.

(1) All members must be knowledgeable in the field of payment of providers under Medicare Part A.

(2) At least one member must be a certified public accountant.

(3) At least two Board members must be representative of providers of services.

(b) *Terms of office.* The term of office for Board members must be 3 years, except that initial appointments may be for such shorter terms as the Secretary may designate to permit staggered terms of office.

(1) No member may serve more than three consecutive terms of office.

(2) The Secretary has the authority to terminate a Board member's term of office for good cause.

(c) *Role of the Chairperson.* * * *

* * * * *

§ 405.1847 Disqualification of Board members.

No Board member shall join in the conduct of a hearing in a case in which he is prejudiced or partial with respect to any party or in which he has any interest in the matter pending for decision before him. Notice of any objection which a party may have with respect to a Board member shall be presented in writing to such Board member by the objecting party at its earliest opportunity. The Board member shall consider the objection and shall, in his discretion, either proceed to join in the conduct of the hearing or withdraw. If he does not withdraw, the objecting party may petition the Board, presenting its objection and reasons therefor, and be entitled to a ruling thereon before the hearing can proceed.

§ 405.1849 Establishment of time and place of hearing by the Board.

The Board shall fix the time and place for the hearing and shall send notice thereof to the parties' contact information on file, not less than 30 days prior to the scheduled time. Either on its own motion or for good cause shown by a party, the Board may, as appropriate, reschedule, adjourn, postpone, or reopen the hearing, provided that reasonable written notice is given to the parties.

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1851 Conduct of Board hearing.

The Board hearing shall be open to the parties, to representatives of the Centers for Medicare & Medicaid Services, and to such other persons as the Board deems necessary and proper. The Board shall inquire fully into all of the matters at issue and shall receive into evidence the testimony of witnesses and any documents which are relevant and material to such matters. If the Board believes that there is relevant and material evidence available which has not been presented at the hearing, it may at any time prior to the issuing of the notice of the decision, reconvene the hearing for the receipt of such evidence. The order in which the evidence and the allegations shall be presented and the conduct of the hearing shall be at the discretion of the Board.

[39 FR 34515, Sept. 26, 1974, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1853 Board proceedings prior to any hearing; discovery.

(a) *Preliminary narrowing of the issues.* Upon receiving notification that a request for a Board hearing is submitted, the contractor must—

(1) Promptly review both the materials submitted with the provider hearing request, and the information underlying each contractor or Secretary determination for each cost reporting period under appeal.

(2) Expeditiously attempt to join with the provider in resolving specific factual or legal issues and submitting to the Board written stipulations setting forth the specific issues that remain for Board resolution based on the review; and

(3) Ensure that the evidence it considered in making its determination, or, where applicable, the evidence the Secretary considered in making his or her determination, is included in the record.

(b) *Position papers.* (1) After any preliminary narrowing of the issues, the parties must file position papers in order to narrow the issues further. In each case, and as appropriate, the Board establishes the deadlines as to when the provider(s) and the contractor must submit position papers to the Board.

(2) The Board has the discretion to extend the deadline for submitting a position paper. Each position paper must set forth the relevant facts and arguments regarding the Board's jurisdiction over each remaining matter at issue in the appeal (as described in § 405.1840 of this subpart), and the merits of the provider's Medicare payment claims for each remaining issue.

(3) In the absence of a Board order or general instructions to the contrary, any supporting exhibits regarding Board jurisdiction must accompany the position paper. Exhibits regarding the merits of the provider's Medicare payment claims may be submitted in a timeframe to be decided by the Board through a schedule applicable to a specific case or through general instructions.

(c) *Initial status conference.* (1) Upon review of the parties' position papers, one or more members of the Board may conduct an initial status conference. An initial status conference may be conducted in person or telephone, at the discretion of the Board.

(2) The Board may use the status conference to discuss any of the following:

(i) Simplification of the issues.

(ii) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement.

(iii) Stipulations and admissions of fact or as to the content and authenticity of documents.

(iv) Whether the parties can agree to submission of the case on a stipulated record.

(v) Whether a party may waive appearance at an oral hearing and submit only documentary evidence (the admissibility of which is subject to objection from other parties) and written argument.

(vi) Limitation of the number of witnesses.

(vii) Scheduling dates for the exchange of witness lists and of proposed exhibits.

(viii) Discovery as permitted under this section.

(ix) The time and place for the hearing.

(x) Potential settlement of some or all of the issues.

(xi) Other matters that the Board deems necessary and appropriate. The Board may issue any orders at the conference found necessary and appropriate to narrow the issues further and expedite further proceedings in the appeal.

(3) After the status conference, the Board may—

(i) Issue in writing a report and order specifying what transpired and formalizing any orders issued at the conference; and

(ii) Require the parties to submit (jointly or otherwise) a proposed report and order, in order to facilitate issuance of a final report and order.

(d) *Further status conferences.* Upon a party's request, or on its own motion, the Board may conduct further status conferences where it finds the proceedings necessary and appropriate.

(e) *Discovery*—(1) *General rules.* (i) Discovery is limited in Board proceedings.

(ii) The Board may permit discovery of a matter that is relevant to the specific subject matter of the Board hearing, provided the matter is not privileged or otherwise protected from disclosure and the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(iii) Any discovery initiated by a party must comply with all requirements and limitations of this section, and with any further requirements or limitations ordered by the Board.

(iv) The applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence serve as guidance for any discovery that is permitted under this section or by Board order.

(2) *Limitations on discovery.* Any discovery before the Board is limited as follows:

(i) A party may request of another party, or of a nonparty other than CMS, the Secretary or any Federal agency, the reasonable production of documents for inspection and copying.

(ii) A party may also request another party to respond to a reasonable number of written interrogatories.

(iii)(A) A party may not take the deposition, upon oral or written examination, of another party or a nonparty, unless the proposed deponent agrees to the deposition or the Board finds that the proposed deposition is necessary and appropriate under the criteria set forth in Federal Rules of Civil Procedure 26 and 32(a)(3) in order to secure the deponent's testimony for a Board hearing.

(B) The regulations at 45 CFR Part 2 (Testimony by employees and production of documents in proceedings where the United States is not a party) apply as to whether an employee or officer of CMS or HHS will appear for a deposition.

(iv) A party may not request admissions or take any other form of discovery not authorized under this section.

(3) *Time limits.* (i) A party's discovery request is timely if the date the request is served on another party or nonparty, as applicable, is no later than 120 days before the initially scheduled starting date of the Board hearing, unless the Board extends the time for the request.

(ii)(A) *Depositions.* (*1*) In the absence of an order or instruction by the Board setting a schedule for the holding of a deposition, a party desiring to take a deposition must give reasonable notice in writing to the deponent of a scheduled deposition.

(*2*) A deposition may not be held any later than 45 days before the initially scheduled starting of the Board hearing, unless the Board orders otherwise.

(B) *Responses.* (*1*) In the absence of a Board order or general instructions of the Board setting a schedule for responses, responses to interrogatories and requests for production of documents are due according to the schedule agreed upon by the party serving discovery and the party to which the discovery is directed, or within the time allotted by the Federal Rules of Civil Procedure.

(*2*) Responses by a party to interrogatories, and responses by a party or nonparty to requests for production of documents, must be served no later than 45 days before the initially scheduled starting date of the Board hearing, unless the Board orders otherwise.

(iii) Before ruling on a request to extend the time for requesting discovery or for conducting or responding to discovery, the Board must give the other

parties to the appeal, and any nonparty subject to a discovery request, a reasonable period to respond to the extension request.

(iv) The Board has the discretion to extend the time in which to request discovery or conduct or respond to discovery.

(v) If the Board grants the extension request, it sets a new discovery deadline and has the discretion to reschedule the hearing date.

(4) *Rights of nonparties.* If a discovery request is made of a nonparty to the Board appeal, the nonparty has the rights any party has in responding to a discovery request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit discovery responses, objections, or motions to the Board.

(5) *Motions to compel or for protective order.* (i) Each party is required to make a good faith effort to resolve or narrow any discovery dispute, regardless of whether the dispute is with another party or a nonparty.

(ii) A party may submit to the Board a motion to compel discovery that is permitted under this section or any Board order, and a party or nonparty may submit a motion for a protective order regarding any discovery request to the Board.

(iii) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute.

(iv) A self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute must be included with any response to a motion to compel or for protective order.

(v) The Board must decide any motion in accordance with this section and any prior discovery ruling.

(vi)(A) The Board must issue and send to each party and any affected nonparty a discovery ruling that grants or denies, in whole or in part, the motion to compel or the motion for a protective order, if applicable.

(B) The discovery ruling must—

(*1*) Specifically identify any part of the disputed discovery request upheld and any part rejected, and

(*2*) Impose any limits on discovery the Board finds necessary and appropriate.

(vii) Nothing in this section authorizes the Board to compel any action from the Secretary or CMS.

(6) *Reviewability of discovery and disclosure rulings*—(i) *General rule.* A Board discovery ruling, or a Board disclosure ruling, such as one issued at a hearing, is not subject to immediate review by the Administrator (as described in § 405.1875(a)(3) of this subpart). The ruling may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final or deemed to be final, by the Administrator, under § 405.1875(a)(2)of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this subpart, as applicable.

(ii) *Exception.* To the extent a ruling authorizes discovery or 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 Board, that portion of the discovery or disclosure ruling may be reviewed immediately by the Administrator in accordance with § 405.1875(a)(3)(i) of this subpart. Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the ruling,—

(A)(*1*) The Board must stay all proceedings affected by the ruling.

(*2*) The Board determines the length of the stay under the circumstances of a given case, but in no event may the length of the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(B) If the Administrator—

(*1*) Grants a request for review, or takes own motion review, of a ruling, the ruling is stayed until the time the Administrator issues a written decision that affirms, reverses, modifies, or remands the Board's ruling.

(*2*) Does not grant a request or take own motion review within the time allotted for the stay, the stay is lifted

and the ruling is not subject to immediate review.

[73 FR 30257, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1855 Evidence at Board hearing.

Evidence may be received at the Board hearing even though inadmissible under the rules of evidence applicable to court procedure. The Board shall give the parties opportunity for submission and consideration of facts and arguments and during the course of the hearing should, in ruling upon admissibility of evidence, exclude irrelevant, immaterial, or unduly repetitious evidence. The Board shall render a final ruling on the admissibility of evidence.

§ 405.1857 Subpoenas.

(a) *Time limits.* (1) The Board may issue a subpoena—

(i) To a party to a Board appeal or to a nonparty other than CMS or the Secretary or any Federal agency, requiring the attendance and testimony of witnesses or the production of documents for inspection and copying, provided the Board makes a preliminary finding of its jurisdiction over the matters at issue in accordance with § 405.1840(a) of this subpart.

(ii) At the request of a party for purposes of discovery (as described in § 405.1853 of this subpart) or an oral hearing (as described in § 405.1845 of this subpart); and

(iii) On its own motion solely for purposes of a hearing.

(2) The date of receipt by the Board of a party's subpoena request may not be any later than for subpoenas requested for purposes of—

(i) Discovery, 120 days before the initially scheduled starting date of the Board hearing; and

(ii) An oral hearing, 45 days before the scheduled starting date of the Board hearing.

(3) Subject to paragraph (4) of this section, the Board may not issue a subpoena any later than for purposes of—

(i) Discovery, 90 days before the initially scheduled starting date of the Board hearing; and

(ii) An oral hearing, whether issued at a party's request or on the Board's own motion, 30 days before the scheduled starting date of the Board hearing.

(4) The Board may extend the deadlines specified in paragraphs (a)(2) and (a)(3) of this section provided the Board gives each party to the appeal and any nonparty subject to the subpoena request or subpoena a reasonable period of time to comment on any proposed extension. If the Board extends a deadline, it retains the discretion to reschedule the hearing date.

(b) *Criteria*—(1) *Discovery subpoenas.* The Board may issue a subpoena for purposes of discovery if all of the following are applicable:

(i) The subpoena was requested in accordance with the requirements of paragraph (c)(1) of this section.

(ii) The party's discovery request complies with the applicable provisions of § 405.1853(e) of this part.

(iii) A subpoena is necessary and appropriate to compel a response to the discovery request.

(2) *Hearing subpoenas.* The Board may issue a subpoena for purposes of an oral hearing if—

(i) The party's subpoena request meets the requirements of paragraph (c)(1) of this section;

(ii) A subpoena is necessary and appropriate to compel the attendance and testimony of witnesses or the production of documents for inspection or copying, provided the testimony or documents are relevant and material to a matter at issue in the appeal but not unduly repetitious (as described in § 405.1855 of this subpart); and

(iii) The subpoena does not compel the disclosure of matter that is privileged or otherwise protected from disclosure for reasons such as case preparation, confidentiality, or undue burden.

(iv) The subpoena does not impose undue burden or expense on the party or nonparty subject to the subpoena, and is not otherwise unreasonable or inappropriate.

(3) *Guiding principles.* In determining whether to issue, quash, or modify a subpoena under this section, the Board uses the applicable provisions of the Federal Rules of Civil Procedure and Rules 401 and 501 of the Federal Rules of Evidence for guidance.

(c) *Procedures*— (1) *Subpoena requests.* The requesting party must send any subpoena request submitted to the Board promptly to the party or nonparty subject to the subpoena, and to any other party to the Board appeal. If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena request must be sent by certified mail. The request must—

(i) Identify with particularity any witnesses (and their addresses, if known) or any documents (and their location, if known) sought by the subpoena, and the means, time, or location for securing any witness testimony or documents;

(ii) Describe specifically, in the case of a hearing subpoena, the facts any witnesses, documents, or tangible materials are expected to establish, and why those facts cannot be established without a subpoena; and

(iii) Explain why a subpoena is appropriate under the criteria prescribed in paragraph (b) of this section.

(2) *Contents of subpoenas.* A subpoena issued by the Board, whether on its own motion or at the request of a party, must be in writing and either sent promptly by the Board to the party or nonparty subject to the subpoena by certified mail or overnight delivery (and to any other party and affected nonparty to the appeal by regular mail), or hand-delivered. Each subpoena must—

(i) Be issued in the name of the Board, and include the case number and name of the appeal;

(ii) Provide notice that—

(A) The subpoena is issued in accordance with section 1878(e) of the Act and § 405.1857 of this subpart; and

(B) CMS must pay the fees and the mileage of any witnesses, as provided in section 205(d) of the Act.

(iii) If applicable, require named witnesses to attend a particular proceeding at a certain time and location and to testify on specific subjects; and

(iv) If applicable, require the production of specific documents for inspection or copying at a certain time and location.

(3) *Rights of nonparties.* If a nonparty to the Board appeal is subject to the subpoena or subpoena request, the nonparty has the rights any party has in responding to a subpoena or subpoena request. The rights of the nonparty include, but are not limited to, the right to select and use any attorney or other representative, and to submit responses, objections, motions, or any other pertinent materials to the Board regarding the subpoena or subpoena request.

(4) *Board action on subpoena requests and motions.* After issuing a subpoena or receiving a subpoena request, the Board must do the following:

(i) Give the party or nonparty subject to the subpoena or subpoena request a reasonable period of time for the submission of any responses, objections, or motions.

(ii) Consider the subpoena or subpoena request, and any responses, objections, or motions related thereto, under the criteria specified in paragraph (b) of this section.

(iii)(A) Issue in writing and send promptly to each party and any affected nonparty an order granting or denying any motion to quash or modify a subpoena, or granting or denying any subpoena request in whole or in part; and

(B) Issue, if applicable, an original or modified subpoena in accordance with paragraph (c)(2) of this section.

(d) *Reviewability*—(1) *General rules.* (i) If the Board issues, quashes, or modifies, or refuses to issue, quash, or modify, a subpoena under paragraphs (c)(2) or (c)(4) of this section, the Board's action is not subject to immediate review by the Administrator (as described in § 405.1875(a)(3) of this subpart).

(ii) Any Board action on a subpoena may be reviewed solely during the course of Administrator review of one of the Board decisions specified in § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) and (c)(3) of this subpart, as applicable.

(2) *Exception.* (i) 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 Board, the Administrator may review immediately that portion of the subpoena in accordance with § 405.1875(a)(3)(ii) of this subpart.

(ii) Upon notice to the Board that a party or nonparty, as applicable, intends to seek Administrator review of the subpoena, the Board must stay all proceedings affected by the subpoena.

(iii) The Board determines the length of the stay under the circumstances of a given case, but in no event may the stay be less than 15 days after the day on which the Board received notice of the party or nonparty's intent to seek Administrator review.

(iv) If the Administrator grants a request for review, or takes own motion review, of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until such time as the Administrator issues a written decision that affirms, reverses, modifies, or remands the Board's action on the subpoena.

(v) If the Administrator does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the Board's action is not immediately reviewable.

(e) *Enforcement.* (i) If the Board determines, whether on its own motion or at the request of a party, that a party or nonparty subject to a subpoena issued under this section has refused to comply with the subpoena, the Board may request the Administrator to seek enforcement of the subpoena in accordance with section 205(e) of the Act.

(ii) Any enforcement request by the Board must consist of a written notice to the Administrator describing in detail the Board'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 party or nonparty subject to the subpoena.

(iii) The Board must promptly mail a copy of the notice and related documents to the party or nonparty subject to the subpoena, and to any other party and affected nonparty to the appeal.

[73 FR 30258, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1859 Witnesses.

Witnesses at the hearing shall testify under oath or affirmation, unless excused by the Board for cause. The Board may examine the witnesses and shall allow the parties or their representatives to do so. Parties to the proceeding may also cross-examine witnesses.

§ 405.1861 Oral argument and written allegations.

The parties, upon their request, shall be allowed a reasonable time for the presentation of oral argument or for the filing of briefs or other written statements of allegations as to facts or law. Copies of any brief or other written statement shall be filed in sufficient number that they may be made available to all parties and to the Centers for Medicare & Medicaid Services.

§ 405.1863 Administrative policy at issue.

Where a party to the Board hearing puts into issue an administrative policy which is interpretative of the law or regulations, the Board will promptly notify to the Centers for Medicare & Medicaid Services.

§ 405.1865 Record of administrative proceedings.

(a)(1) The Board and, if applicable, the Administrator must maintain a complete record of all proceedings in each appeal.

(2) For proceedings before the Board, the administrative record consists of all evidence, documents and any other tangible materials submitted by the parties to the appeal and by any nonparty (as described in §§ 405.1853(e)(4) and 405.1857(c)(3) of this subpart), along with all Board correspondence, rulings, subpoenas, orders, and decisions.

(3) The term ''record'' is intended to encompass both the unappended record and any appendix to the record (as described in § 405.1865(b) of this subpart).

(4) The record includes a complete transcription of the proceedings at any oral hearing before the Board.

(5) A copy of any transcription must be made available to any party upon written request.

(b) Any evidence ruled inadmissible by the Board (as described in § 405.1855 of this subpart) and any other submitted matter that the Board declines to consider (whether as untimely or

otherwise) must be, to the extent practicable, clearly identified and segregated in an appendix to the record for purposes of any further review (as described in §§ 405.1875 and 405.1877 of this subpart).

(c) To the extent applicable, the administrative record also includes all documents (including written submissions) and any other tangible materials submitted to the Administrator by the parties to the appeal or by any nonparty (as described in §§ 405.1853(e)(4) and 405.1857(c)(3) of this subpart), in addition to all correspondence from the Administrator or the Office of the Attorney Advisor, and all rulings, orders, and decisions by the Administrator. The provisions of paragraph (b) of this section also pertain to any proceedings before the Administrator, to the extent the Administrator finds evidence inadmissible or declines to consider a specific matter (whether as untimely or otherwise).

[73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1867 Scope of Board's legal authority.

In exercising its authority to conduct proceedings under this subpart, the Board must comply with all the provisions of Title XVIII of the Act and regulations issued thereunder, as well as CMS Rulings issued under the authority of the Administrator as described in § 401.108 of this subchapter. The Board shall afford great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

[48 FR 22925, May 23, 1983, as amended at 73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008]

§ 405.1868 Board actions in response to failure to follow Board rules.

(a) The Board has full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out the provisions of section 1878 of the Act and of the regulations in this subpart. The Board's powers include the authority to take appropriate actions in response to the failure of a party to a Board appeal to comply with Board rules and orders or for inappropriate conduct during proceedings in the appeal.

(b) If a provider fails to meet a filing deadline or other requirement established by the Board in a rule or order, the Board may—

(1) Dismiss the appeal with prejudice;

(2) Issue an order requiring the provider to show cause why the Board should not dismiss the appeal; or

(3) Take any other remedial action it considers appropriate.

(c) If a contractor fails to meet a filing deadline or other requirement established by the Board, the Board may—

(1) Take other actions that it considers appropriate, such as—

(i) Issuing a decision based on the written record submitted to that point; or

(ii) Issuing a written notice to CMS describing the contractor's actions and requesting that CMS take appropriate action, such as review of the contractor's compliance with the contractual requirements of §§ 421.120, 421.122, and 421.124 of this chapter; and

(2) Not use its authority to take an action such as, a sanction, reversing or modifying the contractor's or Secretary's determination for the cost reporting period under appeal, or ruling against the contractor on a disputed issue of law or fact in the appeal.

(d)(1) If the Board dismisses the appeal with prejudice under this section, it must issue a dismissal decision dismissing the appeal. The decision by the Board must be in writing and include an explanation of the reason for the dismissal. A copy of the Board's dismissal decision must be sent promptly to each party to the appeal (as described in § 405.1843 of this subpart).

(2) A dismissal decision by the Board is final and binding on the parties unless the decision is reversed, affirmed, modified, or remanded by the Administrator under § 405.1875(a)(2)(ii), and § 405.1875(e) or § 405.1875(f) of this part, no later than 60 days after the date of receipt by the provider of the Board's decision.

(i) The Board decision is inoperative during the 60-day period for review by the Administrator, or in the event the

Administrator reverses, affirms, modifies, or remands the decision within the period.

(ii) The Board may reopen and revise a final Board decision in accordance with §§ 405.1885 through 405.1889 of this subpart.

(e)(1) Any action taken by the Board under this section other than dismissal of the appeal is not subject to immediate Administrator review (as described in § 405.1875(a)(3) of this subpart) or judicial review (as described in § 405.1877(a)(3) of this subpart).

(2) A Board action other than dismissal of the appeal may be reviewed solely during the course of Administrator review of one of the Board decisions specified as final, or deemed to be final by the Administrator, under § 405.1875(a)(2) of this subpart, or of judicial review of a final agency decision as described in § 405.1877(a) of this subpart, as applicable.

(f) *Ex parte* communications with Board staff concerning procedural matters are not prohibited.

(g) Upon receipt of a credible allegation that a party's representative has divulged to that party, or to the Board, information that was obtained during the course of the representative's relationship (such as legal counsel or employee) with an opposing party and that was intended by that party to be kept confidential, the Board—

(1) Investigates the allegation; and

(2) May take remedial action when it determines that it is appropriate to do so, against the party or the representative (such as prohibiting the representative from appearing before it, excluding such information from the record, or if the overall fairness of the hearing has been compromised, dismissing the case).

[73 FR 30260, May 23, 2008; 73 FR 49356, Aug. 21, 2008; 85 FR 59019, Sept. 18, 2020]

§ 405.1869 Scope of Board's authority in a hearing decision.

(a) If the Board has jurisdiction to conduct a hearing on a specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart, and the legal authority to fully resolve the matter in a hearing decision (as described in §§ 405.1842(f), 405.1867, and 405.1871 of this subpart), section 1878 of the Act, and paragraph (a) of this section give the Board the power to affirm, modify, or reverse the contractor's findings on each specific matter at issue in the contractor determination for the cost reporting period under appeal, and to make additional revisions on specific matters regardless of whether the contractor considered the matters in issuing the contractor determination. The Board's power to make additional revisions in a hearing decision does not authorize the Board to consider or decide a specific matter at issue for which it lacks jurisdiction (as described in § 405.1840(b) of this subpart) or which was not timely raised in the provider's hearing request. The Board's power under section 1878(d) of the Act and paragraph (a) of this section to make additional revisions is limited to those revisions necessary to resolve fully a specific matter at issue if—

(1) The Board has jurisdiction to grant a hearing on the specific matter at issue under section 1878(a) or (b) of the Act and § 405.1840 of this subpart; and

(2) The specific matter at issue was timely raised in an initial request for a Board hearing filed in accordance with § 405.1835 or § 405.1837 of this subpart, as applicable, or in a timely request to add issues to a single provider appeal submitted in accordance with § 405.1835(c) of this subpart.

(b)(1) If the Board has jurisdiction to conduct a hearing on a specific matter at issue solely under §§ 405.1840 and 405.1835 or § 405.1837 of this subpart, as applicable, and the legal authority to fully resolve the matter in a hearing decision (as described in §§ 405.1842(f), 405.1867, and 405.1871 of this subpart), the Board is authorized to do the following:

(i) Affirm, modify, or reverse the contractor's or Secretary's findings on each specific matter at issue in the contractor or Secretary determination under appeal.

(ii) Make additional revisions on each specific matter at issue regardless of whether the contractor considered these revisions in issuing the contractor determination under appeal, provided the Board does not consider or decide a specific matter for which it

lacks jurisdiction (as described in § 405.1840(b) of this subpart) or that was not timely raised in the provider's hearing request.

(2) The Board's authority under this section to make the additional revisions is limited to those revisions necessary to resolve a specific matter at issue.

[73 FR 30261, May 23, 2008]

§ 405.1871 Board hearing decision.

(a)(1) If the Board finds jurisdiction over a specific matter at issue and conducts a hearing on the matter (as described in §§ 405.1840(a) and 405.1845(e) of this subpart), the Board must issue a hearing decision deciding the merits of the specific matter at issue.

(2) A Board hearing decision must be in writing and based on the admissible evidence from the Board hearing and other admissible evidence and written argument or comments as may be included in the record and accepted by the Board (as described in §§ 405.1845(g) and 405.1865 of this subpart).

(3) The decision must include findings of fact and conclusions of law regarding the Board's jurisdiction over each specific matter at issue (see § 405.1840(c)(1)), and whether the provider carried its burden of production of evidence and burden of proof by establishing, by a preponderance of the evidence, that the provider is entitled to relief on the merits of the matter at issue.

(4) The decision must include appropriate citations to the record evidence and to the applicable law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS. Where the Board's decision reverses or modifies a contractor determination on an issue for which the policy expressed in an interpretive rule (other than a regulation or a CMS Ruling), general statement of policy or rule of agency organization, procedure or practice established by CMS would be dispositive of that issue (if followed by the Board), the Board decision must explain how it gave great weight to such interpretive rule or other such instruction but did not uphold the contractor's determination on the issue.

(5) A copy of the decision must be sent promptly to each party to the appeal.

(b)(1) A Board hearing decision issued in accordance with paragraph (a) of this section is final and binding on the parties to the Board appeal unless the hearing decision is reversed, affirmed, modified, or remanded by the Administrator under §§ 405.1875(a)(2)(i), 405.1875(e), and 405.1875(f) of this subpart, no later than 60 days after the date of receipt by the provider of the Board's decision.

(2) A Board hearing decision is inoperative during the 60-day period for review of the decision by the Administrator, or in the event the Administrator reverses, affirms, modifies, or remands that decision within the period.

(3) A Board hearing decision that is final under paragraph (b)(1) of this section is subject to the provisions of § 405.1803(d) of this subpart, unless the decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(4) A final Board decision under paragraph (a) and (b) of this section may be reopened and revised by the Board in accordance with §§ 405.1885 through 405.1889 of this subpart.

(5) When the contractor's denial of the relief that the provider seeks before the Board is based on procedural grounds (for example, the alleged failure of the provider to satisfy a time limit) or is based on the alleged failure to supply adequate documentation to support the provider's claim, and the Board rules that the basis of the contractor's denial is invalid, the Board remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30261, May 23, 2008, as amended at 85 FR 59019, Sept. 18, 2020]

§ 405.1873 Board review of compliance with the reimbursement requirement of an appropriate cost report claim.

(a) *General.* In order to receive or potentially receive reimbursement for a specific item, the provider must include in its cost report an appropriate claim for the specific item (as prescribed in § 413.24(j) of this chapter). If

the provider files an appeal to the Board seeking reimbursement for the specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item, the Board must address such question in accordance with the procedures set forth in this section.

(b) *Summary of procedures*—(1) *Preliminary steps.* The Board must give the parties an adequate opportunity to submit factual evidence and legal argument regarding the question of whether the provider's cost report included an appropriate claim for the specific item under appeal. Upon receipt of timely submitted factual evidence or legal argument (if any), the Board must review such evidence and argument and prepare written specific findings of fact and conclusions of law on the question of whether the provider's cost report complied with, for the specific item under appeal, the cost report claim requirements prescribed in §413.24(j) of this chapter. In reaching such specific factual findings and legal conclusions, the Board must follow the procedures set forth in §413.24(j)(3) of this chapter for determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The Board must promptly give a copy of such written specific factual findings and legal conclusions to each party to the appeal, and such factual findings and legal conclusions must be included in the record of administrative proceedings for the appeal (as prescribed in §405.1865).

(2) *Limits on Board actions.* The Board's specific findings of fact and conclusions of law (pursuant to paragraph (b)(1) of this section) must not be invoked or relied on by the Board as a basis to deny, or decline to exercise, jurisdiction over a specific item or take any other of the actions specified in paragraph (c) of this section. Upon giving the parties to the appeal the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) on the question of whether the provider's cost report included an appropriate cost report claim for the specific item under appeal, the Board must proceed to issue one of the four types of overall decisions specified in paragraphs (d) and (e) of this section with respect to the specific item. If the Board issues either of two types of overall Board decisions (as specified in paragraph (d) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must be included in such overall Board decision regarding the specific item, along with the other matters that are required by the regulations for the pertinent type of overall Board decision. However, if the Board issues either of two other types of overall Board decisions (as specified in paragraph (e) of this section) regarding the specific item under appeal, the Board's written specific factual findings and legal conclusions (pursuant to paragraph (b)(1) of this section) must not be included in the overall Board decision regarding the specific item. The Board may permit reimbursement for the specific item under appeal, as part of one of the two types of overall Board decisions that are specified in paragraph (d) of this section, but such reimbursement may be permitted only to the extent authorized by paragraph (f) of this section.

(c) *Prohibition of certain types of decisions, orders, and other actions.* (1) If the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section);

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section); or

(iii) Take any of the actions set forth in §405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the Board's factual

findings and legal conclusions (reached under paragraph (b)(1) of this section).

(2) Regardless of whether the Board determines, in its findings of fact and conclusions of law (as prescribed by paragraph (b)(1) of this section), that the provider's cost report did or did not include an appropriate claim for the specific item under appeal, the Board may not—

(i) Deny jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item. *Exception:* If the provider's appeal of the specific item is based on a reopening of such item (pursuant to § 405.1885) where the specific item is not revised, adjusted, corrected, or otherwise changed in a revised final contractor or Secretary determination, the Board must deny jurisdiction over the specific item under appeal (as prescribed in §§ 405.1887(d) and 405.1889(b));

(ii) Decline to exercise jurisdiction over the specific item under appeal, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item; or

(iii) Take any of the actions set forth in § 405.1868(b), (c), or (d), impose any sanction, or take any other action against the interests of any party to the appeal, except as provided in paragraph (f) of this section, based on (in whole or in part) the absence, in the final contractor determination or Secretary determination under appeal, of an adjustment, revision, correction, or other change to the specific item under appeal, or the lack of a particular determination by the contractor or the Secretary regarding the specific item.

(d) *Two types of Board decisions that must include any factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board hearing decision.* If the Board issues a hearing decision regarding the specific item under appeal (pursuant to § 405.1871), any specific findings of fact and conclusions of law by the Board (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such hearing decision along with the other matters prescribed by § 405.1871(a). The Board's factual findings and legal conclusions (reached under paragraph (b)(1) of this section), about whether there was an appropriate cost report claim for the specific item under appeal, are subject to the provisions of § 405.1871(b) just as those provisions apply to the other parts of the Board's hearing decision. If the Board determines that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter), the Board's hearing decision must also address whether the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate claim for the specific item under appeal, the Board has discretion whether or not to address in the Board's hearing decision whether the other substantive reimbursement requirements for the specific item are also satisfied.

(2) *Board expedited judicial review (EJR) decision, where EJR is granted.* If the Board issues an EJR decision where EJR is granted regarding a legal question that is relevant to the specific item under appeal (in accordance with § 405.1842(f)(1)), the Board's specific findings of fact and conclusions of law (reached under paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must be included in such EJR decision along with the other matters prescribed by § 405.1842(f)(1). The Board's factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) about whether there was an appropriate cost report claim for the specific item under appeal are subject to the provisions of § 405.1842(g)(1), (g)(2), (h)(1), and (h)(3) in the same manner as those provisions apply to

the other parts of the Board's EJR decision.

(e) *Two other types of Board decisions that must not include the Board's factual findings and legal conclusions under paragraph (b)(1) of this section*—(1) *Board jurisdictional dismissal decision.* If the Board issues a jurisdictional dismissal decision regarding the specific item under appeal (pursuant to §405.1840(c)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the specific item, must not be included in such jurisdictional dismissal decision.

(2) *Board expedited judicial review (EJR) decision, where EJR is denied.* If the Board issues an EJR decision where EJR is denied regarding a legal question that is relevant to the specific item under appeal (in accordance with §405.1842(f)(2)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section), on the question of whether the provider's cost report included an appropriate claim for the same item, must not be included in such EJR decision. If the Board conducts further proceedings and issues another decision (as specified in §405.1842(h)(2)(i)), the Board's specific findings of fact and conclusions of law (in accordance with paragraph (b)(1) of this section)—

(i) Must be included in any further hearing decision or EJR decision where EJR is granted regarding the specific item under appeal (as specified in paragraph (d) of this section); but

(ii) Must not be included in any further jurisdictional dismissal decision or EJR decision where EJR is denied regarding the specific item under appeal (as prescribed in paragraph (e) of this section).

(f) *Effects of the Board's factual findings and legal conclusions under paragraph (b)(1) of this section in two types of final decisions*—(1) *When part of a final hearing decision.* If the Board determines, or the Administrator of CMS determines (pursuant to §405.1875(a)(2)(v)), as applicable, in a final and binding hearing decision (in accordance with §405.1871(b) and paragraphs (b)(1) and (d)(1) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only if the Board further determines in such final hearing decision that all the other substantive reimbursement requirements for the specific item are also satisfied; or

(ii) Did not include an appropriate cost report claim for the specific item under appeal, the specific item is not reimbursable, regardless of whether the Board further determines in such final hearing decision that the other substantive reimbursement requirements for the specific item are or are not satisfied.

(2) *When part of a final EJR decision that grants EJR.* If the Board determines or the Administrator of CMS determines (pursuant to §405.1875(a)(2)(v)), as applicable, in a final and binding EJR decision that grants EJR regarding a legal question that is relevant to the specific item under appeal (in accordance with §405.1842(g)(1) and paragraphs (b)(1) and (d)(2) of this section), that the provider's cost report—

(i) Included an appropriate claim for the specific item under appeal (as prescribed in §413.24(j) of this chapter), the specific item is reimbursable in accordance with Medicare policy, but only to the extent permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§405.1842 and 405.1877); or

(ii) Did not include an appropriate claim for the specific item under appeal, the specific item is not reimbursable, unless—

(A) The specific factual findings and legal conclusions (in accordance with paragraph (b)(1) of this section) of the Board or the Administrator, as applicable, on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal, are reversed or modified by the final decision of a Federal court (in accordance with section 1878(f)(1) of the Act and §405.1877); and

(B) Only to the extent otherwise permitted by the final decision of a Federal court pursuant to the EJR provisions of section 1878(f)(1) of the Act (refer also to §§ 405.1842 and 405.1877) and by Medicare policy.

[80 FR 70600, Nov. 13, 2015]

§ 405.1875 Administrator review.

(a) *Basic rule: Time limit for rendering Administrator decisions, Board decisions, and action subject to immediate review.* The Administrator, at his or her discretion, may immediately review any decision of the Board specified in paragraph (a)(2) of this section. Nonfinal decisions or actions by the Board are not immediately reviewable, except as provided in paragraph (a)(3) of this section. The Administrator may exercise this discretionary review authority on his or her own motion, or in response to a request from: a party to the Board appeal; CMS; or, in the case of a matter specified in paragraph (a)(3)(i) or (a)(3)(ii) of this section, another affected nonparty to a Board appeal. All requests for Administrator review and any other submissions to the Administrator under paragraph (c) of this section must be sent to the Office of the Attorney Advisor. The Office of the Attorney Advisor must examine each Board decision specified in paragraph (a)(2) of this section, and each matter described in § 405.1845(h)(3), § 405.1853(e)(6)(ii), or § 405.1857(d)(2) of this subpart, of which it becomes aware, together with any review requests or any other submission made in accordance with the provisions of this section, in order to assist the Administrator's exercise of this discretionary review authority. The Board is required to send to the Office of the Attorney Advisor a copy of each decision specified in paragraphs (a)(2)(i), (ii), and (iii) of this section upon issuance of the decision.

(1) The date of rendering any decision after the review by the Administrator must be no later than 60 days after the date of receipt by the provider of a reviewable Board decision or action. For purposes of this section, the date of rendering is the date the Administrator signs the decision, and not the date the decision is mailed or otherwise transmitted to the parties.

(2) The Administrator may immediately review:

(i) A Board hearing decision (as described in § 405.1871 of this subpart).

(ii) A Board dismissal decision (as described in §§ 405.1836(e)(1) and (e)(2), 405.1840(c)(2) and (c)(3), 405.1868(d)(1) and (d)(2) of this subpart).

(iii) A Board EJR decision, but only the question of whether there is Board jurisdiction over a specific matter at issue in the decision; the Administrator may not review the Board's determination in a decision of its authority to decide a legal question relevant to the matter at issue (as described in § 405.1842(h) of this subpart).

(iv) Any other Board decision or action deemed to be final by the Administrator.

(v) If the Administrator reviews a Board hearing decision regarding a specific item, or for a Board EJR decision the question of whether there is Board jurisdiction over a specific item, the Administrator's review of such a hearing decision or EJR decision, as applicable, will include, and any decision issued by the Administrator (under paragraph (e) of this section) will address, the Board's specific findings of fact and conclusions of law in such hearing decision or EJR decision (as prescribed in § 405.1873(b)(1) and (d)) on the question of whether the provider's cost report included an appropriate claim for the specific item under appeal (as prescribed in § 413.24(j) of this chapter).

(3) Any decision or action by the Board not specified in paragraph (a)(2)(i) through (a)(2)(iii) of this section, or not deemed to be final by the Administrator under paragraph (a)(2)(iv) of this section, is nonfinal and not subject to Administrator review until the Board issues one of the decisions specified in paragraph (a)(2) of this section, except the Administrator may review immediately the following matters:

(i) A Board ruling authorizing discovery or disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in § 405.1853(e)(6)(ii) of this subpart).

(ii) A Board subpoena compelling disclosure of a matter for which an objection was made based on privilege or other protection from disclosure such as case preparation, confidentiality, or undue burden (as described in §405.1857(d)(2) of this subpart).

(b) *Illustrative list of criteria for deciding whether to review.* In deciding whether to review a Board decision or other matter specified in paragraphs (a)(2) and (a)(3) of this section, either on his or her own motion or in response to a request for review, the Administrator considers criteria such as whether it appears that—

(1) The Board made an erroneous interpretation of law, regulation, CMS Ruling, or other interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice established by CMS.

(2) A Board hearing decision meets the requirements of §405.1871(a) of this subpart.

(3) The Board erred in refusing to admit certain evidence or in not considering other submitted matter (as described in §§405.1855 and 405.1865(b) of this subpart), or in admitting certain evidence.

(4) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to the issuance of a CMS Ruling or other directive needed to clarify a statutory or regulatory provision.

(5) The Board has incorrectly found, assumed, or denied jurisdiction over a specific matter at issue or extended its authority in a manner not provided for by statute, regulation, CMS Ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(6) The decision or other action of the Board requires clarification, amplification, or an alternative legal basis.

(7) A remand to the Board may be necessary or appropriate under the criteria prescribed in paragraph (f) of this section.

(c) *Procedures*—(1) *Review requests.* (i)(A) A party to a Board appeal or CMS may request Administrator review of a Board decision specified in paragraph (a)(2) of this section or a matter described in paragraph (a)(3) of this section.

(B) A nonparty other than CMS may request Administrator review solely of a matter described in paragraph (a)(3)(i) or (a)(3)(ii) of this section.

(ii) The date of receipt by the Office of Attorney Advisor of any review request must be no later than 15 days after the date the party making the request received the Board's decision or other reviewable action.

(iii) A request for review (or a response to a request) must be submitted in writing, identify the specific issues for which review is requested, and explain why review is or is not appropriate, under the criteria specified in paragraph (b) of this section or for some other reason.

(iv) A copy of any review request (or response to a request) must be sent promptly to each party to the appeal, the Office of the Attorney Advisor, and, as applicable, CMS, and any other affected nonparty.

(2) *Exception to time for requesting review.* If a party, or nonparty, as applicable, seeks immediate review of a matter described in §405.1875(a)(3)(i) or (a)(3)(ii) of this subpart, the request for review must be made as soon as practicable, but in no event later than 5 business days after the day the party or nonparty seeking review received notice of the ruling or subpoena. The request must state the reason(s) why the ruling was in error and the potential harm that may be caused if immediate review is not granted.

(3) *Notice of review.* (i) When the Administrator decides to review a Board decision or other matter specified in paragraphs (a)(2) or (a)(3) of this section, respectively, whether on his or her own motion or upon request, the Administrator must send a written notice to the parties, CMS, and any other affected nonparty stating that the Board's decision is under review, and indicating the specific issues that are being considered.

(ii) The Administrator may decline to review a Board decision or other matter, or any issue in a decision or matter, even if a request for review is submitted in accordance with paragraph (c)(1) or (c)(2) of this section.

(4) *Written submissions on review.* If the Administrator accepts review of the Board's decision or other reviewable action, a party, CMS, or, another affected nonparty that requested review solely of a matter described in paragraph (a)(3)(i) or (a) (3)(ii) of this section, may tender written submissions regarding the review.

(i) The date of receipt by the Office of the Attorney Advisor of any material must be no later than 15 days after the date the party, CMS or other affected nonparty submitting comments received the Administrator's notice under paragraph (c)(3) of this section, taking review of the Board decision or other reviewable matter.

(ii) Any submission must be limited to the issues accepted for Administrator review (as identified in the notice) and be confined to the record of Board proceedings (as described in § 405.1865 of this subpart). The submission may include—

(A) Argument and analysis supporting or taking exception to the Board's decision or other reviewable action;

(B) Supporting reasons, including legal citations and excerpts of record evidence, for any argument and analysis submitted under paragraph (c)(4)(ii)(A) of this section;

(C) Proposed findings of fact and conclusions of law;

(D) Rebuttal to any written submission filed previously with the Administrator in accordance with paragraph (c)(4) of this section; or

(E) A request, with supporting reasons, that the decision or other reviewable action be remanded to the Board.

(d) *Ex parte communications prohibited.* The Administrator does not consider any communication that does not meet the following requirements or is not submitted within the required time limits. All communications from any party, CMS, or other affected nonparty, concerning a Board decision (or other reviewable action) that is being reviewed or may be reviewed by the Administrator must—

(1) Be in writing.

(2) Contain a certification that copies were served on all other parties, CMS, and any other affected nonparty, as applicable.

(3) Include, but are not limited to—

(i) Requests for review and responses to requests for review submitted under paragraph (c)(1) or (c)(2) of this section; and

(ii) Written submissions regarding review submitted under paragraph (c)(4) of this section.

(e) *Administrator's decision.* (1) Upon completion of any review, the Administrator may render a written decision that—

(i) For purposes of review of a Board decision specified in paragraph (a)(2) of this section, affirms, reverses, or modifies the Board's decision, or vacates that decision and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(i) of this section; or

(ii) For purposes of review of a matter described in paragraph (a)(3) of this section, affirms, reverses, modifies, or remands the Board's discovery or disclosure ruling, or subpoena, as applicable, and remands the case to the Board for further proceedings in accordance with paragraph (f)(1)(ii) of this section.

(2) The date of rendering of any decision by the Administrator must be no later than 60 days after the date of receipt by the provider of the Board's decision or other reviewable action. The Administrator must promptly send a copy of his or her decision to the Board, to each party to the appeal, to CMS, and, if applicable, to any other affected nonparty.

(3) Any decision by the Administrator may rely on—

(i) Applicable provisions of the law, regulations, CMS Rulings, and other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

(ii) Prior decisions of the Board, the Administrator, and the courts, and any other law that the Administrator finds applicable, whether or not cited in materials submitted to the Administrator.

(iii) The administrative record for the case (as described in § 405.1865 of this subpart).

(iv) Generally known facts that are not subject to reasonable dispute.

(4) A timely decision by the Administrator that affirms, reverses, or modifies one of the Board decisions specified

in paragraph (a)(2) of this section is final and binding on each party to the Board appeal (as described in § 405.1877(a)(4) of this subpart).

(i) If the final Administrator decision follows review of a Board hearing decision, the Administrator's decision is subject to the provisions of § 405.1803(d) of this subpart, unless that final decision is the subject of judicial review (as described in § 405.1877 of this subpart).

(ii) The Administrator, in accordance with §§ 405.1885 through 405.1889 of this subpart, may reopen and revise a final Administrator decision.

(iii) A decision by the Administrator remanding a matter to the Board for further proceedings in accordance with paragraph (f) of this section is not a final decision for purposes of judicial review (as described in § 405.1877(a)(4) of this subpart) or the provisions of § 405.1803(d).

(f) *Remand.* (1) A remand to the Board by the Administrator has the effect for purposes of review—

(i) With respect to a Board decision specified in paragraph (a)(2) of this section, vacating the Board's decision and requiring further proceedings in accordance with the Administrator's decision and this subpart; or

(ii) With respect to a matter described in paragraph (a)(3) of this section, affirming, reversing, modifying, or remanding the Board's remand order, discovery ruling, or subpoena, as applicable, and returning the case to the Board for further proceedings in accordance with the Administrator's decision and this subpart.

(2) The Administrator may direct the Board to take further action for the development of additional facts or new issues, or to consider the applicability of laws or regulations other than those considered by the Board. The following are not acceptable bases for remand:

(i) Presentation of evidence existing at the time of the Board hearing that was known or reasonably may be known.

(ii) Introduction of a favorable court ruling, regardless of whether the ruling was made or was available at the time of the Board hearing or at the time the Board issued its decision.

(iii) Change in a party's representation, regardless when made.

(iv) Presentation of an alternative legal basis concerning an issue in dispute.

(v) Attempted retraction of a waiver of a right, regardless when made.

(3) After remand, the Board must take the actions required in the Administrator's remand order and issue a new decision in accordance with paragraph (f)(1)(i) of this section, or issue under paragraph (f)(1)(ii) of this section an initial decision or a further remand order, discovery ruling, or subpoena ruling, as applicable.

(4) Administrator review of any decision or other action by the Board after remand is, to the extent applicable, subject to the provisions of paragraphs (a)(2) or (a)(3) of this section.

(5) In addition to ordering a remand to the Board, the Administrator may order a remand to any component of HHS or CMS or to a contractor under appropriate circumstances, including, but not limited to, for the purpose of effectuating a court order (as described in § 405.1877(g)(2) of this subpart). When the contractor's denial of the relief, that the provider sought before the Board and that is under review by the Administrator, was based on procedural grounds (such as the alleged failure of the provider to satisfy a time limit) or was based on the alleged failure to supply adequate documentation to support the provider's claim, and the Administrator rules that the basis of the contractor's denial is invalid, the Administrator remands to the contractor for the contractor to make a determination on the merits of the provider's claim.

[73 FR 30262, May 23, 2008; 73 FR 49356, 49357, Aug. 21, 2008, as amended at 80 FR 70602, Nov. 13, 2015; 85 FR 59019, Sept. 18, 2020]

§ 405.1877 Judicial review.

(a) *Basis and scope.* (1) Notwithstanding the provisions of 5 U.S.C. 704 or any other provision of law, sections 205(h) and 1872 of the Act provide that a decision or other action by a reviewing entity is subject to judicial review solely to the extent authorized by section 1878(f)(1) of the Act. This section, along with the EJR provisions of § 405.1842 of this subpart, implements section 1878(f)(1) of the Act.

(2) Section 1878(f)(1) of the Act provides that a provider has a right to obtain judicial review of a final decision of the Board, or of a timely reversal, affirmation, or modification by the Administrator of a final Board decision, by filing a civil action in accordance with the Federal Rules of Civil Procedure in a Federal district court with venue no later than 60 days after the date of receipt by the provider of a final Board decision or a reversal, affirmation, or modification by the Administrator. The Secretary (and not the Administrator or CMS itself, or the contractor) is the only proper defendant in a civil action brought under section 1878(f)(1) of the Act.

(3) A Board decision is final and subject to judicial review under section 1878(f)(1) of the Act only if the decision—

(i) Is one of the Board decisions specified in §405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or, in a particular case, is deemed to be final by the Administrator under §405.1875(a)(2)(iv) of this subpart; and

(ii) Is not reversed, affirmed, modified, or remanded by the Administrator under §§405.1875(e) and 405.1875(f) of this subpart within 60 days of the date of receipt by the provider of the Board's decision. A provider is not required to seek Administrator review under §405.1875(c) first in order to seek judicial review of a Board decision that is final and subject to judicial review under section 1878(f)(1) of the Act.

(4) If the Administrator timely reverses, affirms, or modifies one of the Board decisions specified in §405.1875(a)(2)(i) through (a)(2)(iii) of this subpart or deemed to be final by the Administrator in a particular case under §405.1875(a)(2)(iv) of this subpart, the Administrator's reversal, affirmation, or modification is the only decision subject to judicial review under section 1878(f)(1) of the Act. A remand of a Board decision by the Administrator to the Board vacates the decision. Neither the Board's decision nor the Administrator's remand is a final decision subject to judicial review under section 1878(f)(1) of the Act (as described in §405.1875(e)(4), §405.1875(f)(1), and §405.1875(f)(4) of this subpart).

(b) *Determining when a civil action may be filed*—(1) *General rule.* Under section 1878(f)(1) of the Act, the 60-day periods for Administrator review of a decision by the Board, and for judicial review of any final Board decision, respectively, both begin to run on the same day. Paragraphs (b)(2), (b)(3) and (b)(4) of this section identify how various actions or inaction by the Administrator within the 60-day review period determine the scope and timing of any right a provider may have to judicial review under section 1878(f)(1) of the Act.

(2) *Administrator declines review.* If the Administrator declines any review of a Board decision specified in §405.1875(a)(2) of this subpart, whether through inaction or in a written notice issued under §405.1875(c)(3) of this subpart, the provider must file any civil action seeking judicial review of the Board's final decision under section 1878(f)(1) of the Act no later than 60 days after the date of receipt by the provider of the Board's decision.

(3) *Administrator accepts review and renders timely decision.* When the Administrator decides to review, in a notice under §405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed as final by the Administrator, under §405.1875(a)(2) of this subpart, and he or she subsequently renders a decision within the 60-day review period (as described in §405.1875(a)(1) of this subpart), the provider has no right to obtain judicial review of the Board's decision under section 1878(f)(1) of the Act.

(i) If the Administrator timely reverses, affirms, or modifies the Board's decision, the provider's only right under section 1878(f)(1) of the Act is to request judicial review of the Administrator's decision by filing a civil action no later than 60 days after the date of receipt by the provider of the Administrator's decision (as described in §405.1877(a)(3) of this subpart).

(ii) If the Administrator timely vacates the Board's decision and remands for further proceedings (as described in §405.1875(f)(1)(i) of this subpart), a provider has no right to judicial review under section 1878(f)(1) of the Act of the Board's decision or of the Administrator's remand (as described in §405.1877(a)(3) of this subpart).

(4) *Administrator accepts review and timely decision is not rendered.* If the Administrator decides to review, in a notice under §405.1875(c)(3) of this subpart, any issue in a Board decision specified as final, or deemed to be final by the Administrator, under §405.1875(a)(2), but he or she does not render a decision within the 60-day review period, this subsequent inaction constitutes an affirmation of the Board's decision by the Administrator, for purposes of the time in which to seek judicial review. In this case, the provider must file any civil action requesting judicial review of the Administrator's final decision under section 1878(f)(1) of the Act no later than 60 days after the expiration of the 60-day period for a decision by the Administrator under §405.1875(a)(1) and §405.1875(e)(2) of this subpart.

(c) *Statutory limitations on and preclusion of judicial review.* The Act limits or precludes judicial review of certain matters at issue. Limitations on and preclusions of judicial review include the following:

(1) A finding in a contractor determination that expenses incurred for items and services furnished by a provider to an individual are not payable under title XVIII of the Act because those items or services are excluded from coverage under section 1862 of the Act, and the regulations at 42 CFR part 411, is not reviewable by the Board (as described in §405.1840(b)(1) of this subpart) and is not subject to judicial review under section 1878(f)(1) of the Act; the finding is subject to judicial review solely in accordance with the applicable provisions of sections 1155, 1869, and 1879(d) of the Act, and of subpart I of part 405 and subpart B of part 478, as applicable.

(2) Certain matters affecting payments to hospitals under the prospective payment system are completely removed from administrative and judicial review, as provided in section 1886(d)(7) of the Act, and §§405.1804 and 405.1840(b)(2) of this subpart.

(3) Any Board remand order, or discovery or disclosure ruling or subpoena specified in §405.1875(a)(3)(i) through (a)(3)(ii) of this subpart, or a decision by the Administrator following immediate review of a Board remand order, discovery ruling, or subpoena, is not subject to immediate judicial review under section 1878(f)(1) of the Act. Judicial review of all nonfinal Board actions, including any such Board remand order, discovery or disclosure ruling, or subpoena (except as provided in §405.1857(e) of this subpart), is limited to review of a final agency decision as described in §405.1877(a) of this subpart.

(d) *Group appeals.* If a final decision is issued by the Board or rendered by the Administrator, as applicable, in any group appeal brought under §405.1837, those providers in the group appeal that seek judicial review of the final decision under section 1878(f)(1) of the Act must file a civil action as a group (as described in §405.1877(e)(2) of this subpart) for the specific matter at issue and common factual or legal question that was addressed in the final agency decision in the group appeal.

(e) *Venue for civil actions*—(1) *Single provider appeals.* A civil action under section 1878(f)(1) of the Act requesting judicial review of a final decision of the Board or the Administrator, as applicable, in a single provider appeal under §405.1835 of this subpart must be brought in the District Court of the United States for the judicial district in which the provider is located or in the United States District Court for the District of Columbia.

(2) *Group appeals.* A civil action under section 1878(f)(1) of the Act seeking judicial review of a final decision of the Board or the Administrator, as applicable, in a group appeal under §405.1837 of this subpart must be brought in the District Court of the United States for the judicial district in which the greatest number of providers participating in both the group appeal and the civil action are located or in the United States District Court for the District of Columbia.

(f) *Service of process.* Process must be served as described under 45 CFR part 4.

(g) *Remand by a court*—(1) *General rule.* Under section 1874 of the Act, and §421.5(b) of this chapter, the Secretary is the real party in interest in a civil action seeking relief under title XVIII of the Act. The Secretary has delegated

to the Administrator the authority under section 1878(f)(1) of the Act to review decisions of the Board and, as applicable, render a final agency decision. If a court, in a civil action brought by a provider against the Secretary as the real party in interest regarding a matter pertaining to Medicare payment to the provider, orders a remand for further action by the Secretary, any component of HHS or CMS, or the contractor, the remand order must be deemed, except as provided in paragraph (g)(3) of this section, to be directed to the Administrator in the first instance, regardless of whether the court's remand order refers to the Secretary, the Administrator, the Board, any other component of HHS or CMS, or the contractor.

(2) *Procedures.* (i) Upon receiving notification of a court remand order, the Administrator must prepare an appropriate remand order and, if applicable, file the order in any Board appeal at issue in the civil action.

(ii) The Administrator's remand order must—

(A) Describe the specific requirements of the court's remand order;

(B) Require compliance with those requirements by the pertinent component of HHS or CMS or by the contractor, as applicable; and

(C) Remand the matter to the appropriate entity for further action.

(iii) After the entity named in the Administrator's remand order completes its response to that order, the entity's response after remand is subject to further proceedings before the Board or the Administrator, as applicable, in accordance with this subpart. For example—

(A) If the contractor issues a revised contractor determination after remand, the provider may request a Board hearing on the revised determination (as described in §§ 405.1803(d) and 405.1889 of this subpart); or,

(B) If the contractor hearing officer(s) or the Board issues a new decision after remand, a decision may be reviewed by a CMS reviewing official or the Administrator, respectively (as described in §§ 405.1834 and 405.1875(f)(4) of this subpart).

(3) *Exception.* The provisions of paragraphs (g)(1) and (g)(2) of this section do not apply to the extent they may be inconsistent with the court's remand order or any other order of the court regarding the civil action.

(h) *Implementation of final court judgment.* (1) When a final, non-appealable court judgment is issued in a civil action brought by a provider against the Secretary as the real party in interest regarding a matter affecting Medicare payment, a court judgment is subject to the provisions of § 405.1803(d) of this subpart.

(2) The provisions of paragraph (h)(1) of this section do not apply to the extent they may be inconsistent with the court's final judgment or any other order of a court regarding the civil action.

[73 FR 30264, May 23, 2008]

§ 405.1881 Appointment of representative.

A provider or other party may be represented by legal counsel or any other person it appoints to act as its representative at the proceedings, conducted in accordance with §§ 405.1819 and 405.1851.

§ 405.1883 Authority of representative.

A representative appointed by a provider or other party may accept or give on behalf of the provider or other party any request or notice relative to any proceeding before a hearing officer or the Board. A representative shall be entitled to present evidence and allegations as to facts and law in any proceeding affecting the party he represents and to obtain information with respect to a request for a contractor hearing or a Board hearing made in accordance with § 405.1811, § 405.1835, or § 405.1837 to the same extent as the party he represents. Notice to a provider or other party of any action, determination, or decision, or a request for the production of evidence by a hearing officer or the Board sent to the representative of the provider or other party shall have the same force and effect as if it had been sent to the provider or other party.

§ 405.1885 Reopening a contractor determination or reviewing entity decision.

(a) *General.* (1) A Secretary determination, a contractor determination, or a decision by a reviewing entity (as described in § 405.1801(a)) may be reopened, with respect to specific findings on matters at issue in a determination or decision, by CMS (with respect to Secretary determinations), by the contractor (with respect to contractor determinations), or by the reviewing entity that made the decision (as described in paragraph (c) of this section).

(i) A specific finding on a matter at issue may be legal or factual in nature or a mixed matter of both law and fact.

(ii) A specific finding on a matter at issue may include a factual matter that arose in or was determined for the same cost reporting period as the period at issue in an appeal filed, or a reopening requested by a provider or initiated by a contractor, under this subpart.

(iii) A specific finding on a matter at issue may include a predicate fact, which is a finding of fact based on a factual matter that first arose in or was first determined for a cost reporting period that predates the period at issue (in an appeal filed, or a reopening requested by a provider or initiated by a contractor, under this subpart), and once determined, was used to determine an aspect of the provider's reimbursement for one or more later cost reporting periods.

(iv) Except as provided for by this section, § 405.1887, and § 405.1889, a specific finding on a matter at issue may not be reopened and, if reopened, revised.

(2) A determination or decision may be reopened either through own motion of CMS (for Secretary determinations), the contractor or reviewing entity, by notifying the parties to the determination or decision (as specified in § 405.1887), or by granting the request of the provider affected by the determination or decision.

(3) A contractor's discretion to reopen or not reopen a matter is subject to a contrary directive from CMS to reopen or not reopen that matter.

(4) If CMS directs a contractor to reopen a matter, reopening is considered an own motion reopening by the contractor. A reopening may result in a revision of any matter at issue in the determination or decision.

(5) If a matter is reopened and a revised determination or decision is made, a revised determination or decision is appealable to the extent provided in § 405.1889 of this subpart.

(6) A determination or decision to reopen or not to reopen a determination or decision is not a final determination or decision within the meaning of this subpart and is not subject to further administrative review or judicial review.

(b) *Time limits*—(1) *Own motion reopening of a determination not procured by fraud or similar fault.* An own motion reopening is timely only if the notice of intent to reopen (as described in § 405.1887) is sent no later than 3 years after the date of the determination or decision that is the subject of the reopening. The date the notice is sent is presumed to be the date indicated on the notice unless it is shown by a preponderance of the evidence that the notice was sent on a later date.

(2) *Request for reopening of a determination not based on fraud or similar fault.* (i) A reopening made upon request is timely only if the request to reopen is received by CMS, the contractor, or reviewing entity, as appropriate, no later than 3 years after the date of the determination or decision that is the subject of the requested reopening. The date of receipt by CMS, the contractor, or the reviewing entity of the request to reopen is determined by applying the date of receipt presumption criteria for reviewing entities defined in § 405.1801(a), unless it is shown by clear and convincing evidence that CMS, the contractor, or the reviewing entity received the request on an earlier date.

(ii) A request to reopen does not toll the time in which to appeal an otherwise appealable determination or decision.

(iii) A request to reopen that is received within the 3-year period described in this paragraph is timely, notwithstanding that the notice of reopening required under § 405.1887 of this

subpart is issued after such 3-year period.

(iv) The 3-year period described in paragraphs (b)(2)(i) through (b)(2)(iii) of this section applies to, and is calculated separately for, each specific finding on a matter at issue (as described in paragraphs (a)(1)(i) through (a)(1)(iv) of this section, but not to such findings when made as part of a determination of reasonable cost under section 1861(v)(1)(A) of the Act.

(3) *Reopening of a determination procured by fraud or similar fault.* A Secretary or contractor determination or decision by the reviewing entity may be reopened and revised at any time if it is established that the determination or decision was procured by fraud or similar fault of any party to the determination or decision.

(c) *Jurisdiction for reopening.* Jurisdiction for reopening a contractor determination or contractor hearing decision rests exclusively with the contractor or contractor hearing officer(s) that rendered the determination or decision (or, when applicable, with the successor contractor), subject to a directive from CMS to reopen or not reopen the determination or decision. Jurisdiction for reopening a Secretary determination, CMS reviewing official decision, a Board decision, or an Administrator decision rests exclusively with CMS, the CMS reviewing official, Board or Administrator, respectively.

(1) *CMS-directed reopenings.* CMS may direct a contractor or contractor hearing officer(s) to reopen and revise any matter, subject to the time limits specified in paragraph (b) of this section, and subject to the limitation expressed in paragraph (c)(2) of this section, by providing explicit direction to the contractor or contractor hearing officer(s) to reopen and revise.

(i) *Examples.* A contractor determination or contractor hearing decision must be reopened and revised if CMS provides explicit notice to the contractor that the contractor determination or the contractor hearing decision is inconsistent with the applicable law, regulations, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS in effect, and as CMS understood those legal provisions, at the time the determination or decision was rendered by the contractor. CMS may also direct the contractor to reopen a particular contractor determination or decision in order to implement a final agency decision (as described in §§ 405.1833, 405.1871(b) and 405.1875 of this subpart), a final, non-appealable court judgment § 405.1877, or an agreement to settle an administrative appeal or a lawsuit, regarding the same determination or decision.

(ii) [Reserved]

(2) *Prohibited reopenings.* A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, a Board decision, or an Administrator decision, under this section.

(3) *Reopening by CMS or contractor of determination currently on appeal to the Board or Administrator.* CMS or a contractor may reopen, on its own motion or on request of the provider(s), a Secretary or contractor determination that is currently pending on appeal before the Board or Administrator.

(i) The scope of the reopening may include any matter covered by the determination, including those specific matters that are appealed to the Board or the Administrator.

(ii) The contractor must send a copy of the notice required under § 405.1887(a) to the Board or to the Administrator, through the Office of the Attorney Advisor, specifically informing that the matter(s) to be addressed by the reopening is currently under appeal to the Board or to the Administrator or is covered by the same determination that is under appeal.

(4) *Reopening of determination within the time for appealing that determination to the Board.* CMS or a contractor may reopen, on its own motion or on request of the provider(s), a Secretary or contractor determination for which no appeal was taken to the Board, but for which the time to appeal to the Board

has not yet expired, by sending the notice specified in § 405.1887(a) of this subpart.

[73 FR 30265, May 23, 2008, as amended at 78 FR 75195, Dec. 10, 2013; 85 FR 59019, Sept. 18, 2020]

§ 405.1887 Notice of reopening; effect of reopening.

(a) In exercising its reopening authority under § 405.1885, CMS (for Secretary determinations), the contractor or the reviewing entity, as applicable, must provide written notice to all parties to the determination or decision that is the subject of the reopening. Notices of—

(1) Reopening by a CMS reviewing official or the Board must be sent promptly to the Administrator.

(2) Contractor reopenings of determinations that are currently pending before the Board or the Administrator must meet the requirements specified in § 405.1885(c)(3) and (c)(4) of this subpart.

(b) Upon receipt of the notice required under § 405.1887(a) of this subpart, the parties to the prior Secretary or contractor determination or decision by a reviewing entity, as applicable, must be allowed a reasonable period of time in which to present any additional evidence or argument in support of their positions.

(c) Upon concluding its reopening, CMS, the contractor or the reviewing entity, as applicable, must provide written notice promptly to all parties to the determination or decision that is the subject of the reopening, informing the parties as to what matter(s), if any, is revised, with a complete explanation of the basis for any revision.

(d) A reopening by itself does not extend appeal rights. Any matter that is reconsidered during the course of a reopening, but is not revised, is not within the proper scope of an appeal of a revised determination or decision (as described in § 405.1889 of this subpart).

[73 FR 30266, May 23, 2008]

§ 405.1889 Effect of a revision; issue-specific nature of appeals of revised determinations and decisions.

(a) If a revision is made in a Secretary or contractor determination or a decision by a reviewing entity after the determination or decision is reopened as provided in § 405.1885 of this subpart, the revision must be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1834, 405.1835, 405.1837, 405.1875, 405.1877 and 405.1885 of this subpart are applicable.

(b)(1) Only those matters that are specifically revised in a revised determination or decision are within the scope of any appeal of the revised determination or decision.

(2) Any matter that is not specifically revised (including any matter that was reopened but not revised) may not be considered in any appeal of the revised determination or decision.

[73 FR 30266, May 23, 2008]

Subparts S–T [Reserved]

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

AUTHORITY: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

SOURCE: 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

§§ 405.2100–405.2101 [Reserved]

§ 405.2102 Definitions.

As used in this subpart, the following definitions apply:

Network, ESRD. All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

Network organization. The administrative governing body to the network and liaison to the Federal government.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48950, Oct. 19, 1978; 51 FR 30361, Aug. 26, 1986; 53 FR 6547, Mar. 1, 1988; 55 FR 9575, Mar. 14, 1990; 72 FR 15273, Mar. 30, 2007; 73 FR 20473, Apr. 15, 2008; 79 FR 66261, Nov. 6, 2014]

§ 405.2110 Designation of ESRD networks.

CMS designated ESRD networks in which the approved ESRD facilities

collectively provide the necessary care for ESRD patients.

(a) *Effect on patient choice of facility.* The designation of networks does not require an ESRD patient to seek care only through the facilities in the designated network where the patient resides, nor does the designation of networks limit patient choice of physicians or facilities, or preclude patient referral by physicians to a facility in another designated network.

(b) *Redesignation of networks.* CMS will redesignate networks, as needed, to ensure that the designations are consistent with ESRD program experience, consistent with ESRD program objectives specified in § 405.2101, and compatible with efficient program administration.

[51 FR 30361, Aug. 26, 1986]

§ 405.2111 [Reserved]

§ 405.2112 ESRD network organizations.

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(a) Developing network goals for placing patients in settings for self-care and transplantation.

(b) Encouraging the use of medically appropriate treatment settings most compatible with patient rehabilitation and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs.

(c) Developing criteria and standards relating to the quality and appropriateness of patient care and, with respect to working with patients, facilities, and providers of services, for encouraging participation in vocational rehabilitation programs.

(d) Evaluating the procedures used by facilities in the network in assessing patients for placement in appropriate treatment modalities.

(e) Making recommendations to member facilities as needed to achieve network goals.

(f) On or before July 1 of each year, submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for—

(i) Self-care;

(ii) Transplants; and

(iii) Vocational rehabilitation programs.

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care.

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(g) Evaluating and resolving patient grievances.

(h) Appointing a network council and a medical review board (each including at least one patient representative) and supporting and coordinating the activities of each.

(i) Conducting on-site reviews of facilities and providers as necessary, as determined by the medical review board or CMS, using standards of care as specified under paragraph (c) of this section.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

[53 FR 1620, Jan. 21, 1988]

§ 405.2113 Medical review board.

(a) *General.* The medical review board must be composed of physicians, nurses, and social workers engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients, and at least one patient representative.

(b) *Restrictions on medical review board members.* (1) A medical review board member must not review or provide advice with respect to any case in which he or she has, or had, any professional

involvement, received reimbursement or supplied goods.

(2) A medical review board member must not review the ESRD services of a facility in which he or she has a direct or indirect financial interest (as described in section 1126(a)(1) of the Act).

[51 FR 30361, Aug. 26, 1986, as amended at 53 FR 1620, Jan. 21, 1988]

§ 405.2114 [Reserved]

§§ 405.2131–405.2184 [Reserved]

Subparts V–W [Reserved]

Subpart X—Rural Health Clinic and Federally Qualified Health Center Services

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 43 FR 8261, Mar. 1, 1978, unless otherwise noted.

§ 405.2400 Basis.

Subpart X is based on the provisions of the following sections of the Act:

(a) Section 1833—Amounts of payment for supplementary medical insurance services.

(b) Section 1861(aa)—Rural health clinic services and Federally qualified health center services covered by the Medicare program.

(c) Section 1834(o)—Federally qualified health center prospective payment system beginning October 1, 2014.

(d) Section 1834(y)—Payment for certain services furnished by rural health clinics.

[79 FR 25473, May 2, 2014, as amended at 88 FR 82176, Nov. 22, 2023]

§ 405.2401 Scope and definitions.

(a) *Scope.* This subpart establishes the requirements for coverage and reimbursement of rural health clinic and Federally qualified health center services under Medicare.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise:

Allowable costs means costs that are incurred by a RHC or FQHC that is authorized to bill based on reasonable costs and are reasonable in amount and proper and necessary for the efficient delivery of RHC and FQHC services.

Beneficiary means an individual enrolled in the Supplementary Medical Insurance program for the Aged and Disabled (part of title XVIII of the Act).

Certified nurse midwife (CNM) means an individual who meets the applicable education, training, and other requirements of § 410.77(a) of this chapter.

Clinical psychologist (CP) means an individual who meets the applicable education, training, and other requirements of § 410.71(d) of this chapter.

Clinical social worker (CSW) means an individual who meets the applicable education, training, and other requirements of § 410.73(a) of this chapter.

CMS stands for Centers for Medicare & Medicaid Services.

Coinsurance means that portion of the RHC's charge for covered services or that portion of the FQHC's charge or PPS rate for covered services for which the beneficiary is liable (in addition to the deductible, where applicable).

Covered services means items or services for which the beneficiary is entitled to have payment made on his or her behalf under this subpart.

Deductible means the amount incurred by the beneficiary during a calendar year as specified in § 410.160 and § 410.161 of this chapter.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Federally qualified health center (FQHC) means an entity that has entered into an agreement with CMS to meet Medicare program requirements under § 405.2434 and—

(1) Is receiving a grant under section 330 of the Public Health Service (PHS) Act, or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under section 330 of the PHS Act;

(2) Is determined by the HRSA to meet the requirements for receiving such a grant;

(3) Was treated by CMS, for purposes of Medicare Part B, as a comprehensive federally funded health center as of January 1, 1990; or

(4) Is an outpatient health program or facility operated by a tribe or tribal organizations under the Indian Self-Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

HRSA means the Health Resources and Services Administration.

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

Marriage and family therapist (MFT) means an individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

Medicare Administrative Contractor (MAC) means an organization that has a contract with the Secretary to administer the benefits covered by this subpart as described in § 421.404 of this chapter.

Mental health counselor (MHC) means an individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

Nurse practitioner (NP) means individuals who meet the applicable education, training, and other requirements of § 410.75(b) of this chapter.

Physician assistant (PA) means an individual who meet the applicable education, training, and other requirements of § 410.74(c) of this chapter.

Prospective payment system (PPS) means a method of payment in which Medicare payment is made based on a predetermined, fixed amount.

Reporting period generally means a period of 12 consecutive months specified by the MAC as the period for which a RHC or FQHC must report required costs and utilization information. The first and last reporting periods may be less than 12 months.

Rural health clinic (RHC) means a facility that has—

(1) Been determined by the Secretary to meet the requirements of section 1861(aa)(2) of the Act and part 491 of this chapter concerning RHC services and conditions for approval; and

(2) Filed an agreement with CMS that meets the requirements in § 405.2402 to provide RHC services under Medicare.

Secretary means the Secretary of Health and Human Services or his or her delegate.

Visiting nurse services means part-time or intermittent nursing care and related medical supplies (other than drugs or biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound patient.

(Secs. 1102, 1833, 1861(aa), 1871, 1902(a)(13), Social Security Act; 49 Stat. 647, 79 Stat. 302, 322, and 331, 91 Stat. 1485 (42 U.S.C. 1302, 1395*l*, 1395hh, 1395x(aa), and 1396(a)(13))

[43 FR 8261, Mar. 1, 1978, as amended at 43 FR 30526, July 14, 1978; 47 FR 21049, May 17, 1982; 47 FR 23448, May 28, 1982; 51 FR 41351, Nov. 14, 1986; 57 FR 24975, June 12, 1992; 59 FR 26958, May 25, 1994; 60 FR 63176, Dec. 8, 1995; 61 FR 14657, Apr. 3, 1996; 69 FR 74815, Dec. 24, 2003; 71 FR 55345, Sept. 22, 2006; 79 FR 25473, May 2, 2014; 83 FR 60072, Nov. 23, 2018; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2402 Rural health clinic basic requirements.

(a) *Certification by the State survey agency.* The rural health clinic must be certified in accordance with part 491 of this chapter.

(b) *Acceptance of the clinic as qualified to furnish RHC services.* If the Secretary, after reviewing the survey agency or accrediting organization recommendation, as applicable, and other evidence relating to the qualifications of the clinic, determines that the clinic meets the requirements of this subpart and of part 491 of this chapter, the clinic is provided with—

(1) Written notice of the determination; and

(2) Two copies of the agreement to be filed as required by section 1861(aa)(1) of the Act.

(c) *Filing of agreement by the clinic.* If the clinic wishes to participate in the program, it must—

(1) Have both copies of the agreement signed by an authorized representative; and

(2) File them with the Secretary.

(d) *Acceptance by the Secretary.* If the Secretary accepts the agreement filed by the clinic, the Secretary returns to the clinic one copy of the agreement with a notice of acceptance specifying the effective date.

(e) *Appeal rights.* If CMS declines to enter into an agreement or if CMS terminates an agreement, the clinic is entitled to a hearing in accordance with § 498.3(b)(5) and (6) of this chapter.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014]

§ 405.2403 Rural health clinic content and terms of the agreement with the Secretary.

(a) Under the agreement, the RHC agrees to the following:

(1) *Maintaining compliance with conditions.* The RHC agrees to maintain compliance with the conditions set forth in part 491 of this chapter and to report promptly to CMS any failure to do so.

(2) *Charges to beneficiaries.* The RHC agrees not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part (or for which the beneficiary would have been entitled if the RHC had filed a request for payment in accordance with § 410.165 of this chapter), except for any deductible or coinsurance amounts for which the beneficiary is liable under § 405.2410.

(3) *Refunds to beneficiaries.* (i) The RHC agrees to refund as promptly as possible any money incorrectly collected from beneficiaries or from someone on their behalf.

(ii) As used in this section, *money incorrectly collected* means sums collected in excess of the amount for which the beneficiary was liable under § 405.2410. It includes amounts collected at a time when the beneficiary was believed not to be entitled to Medicare benefits but:

(A) The beneficiary is later determined to have been entitled to Medicare benefits; and

(B) The beneficiary's entitlement period falls within the time the RHC's agreement with the Secretary is in effect.

(4) *Beneficiary treatment.* (i) The RHC agrees to accept beneficiaries for care and treatment; and

(ii) The RHC agrees not to impose any limitations on the acceptance of beneficiaries for care and treatment that it does not impose on all other persons.

(b) *Additional provisions.* The agreement may contain any additional provisions that the Secretary finds necessary or desirable for the efficient and effective administration of the Medicare program.

[43 FR 8261, Mar. 1, 1978, as amended at 51 FR 41351, Nov. 14, 1986; 79 FR 25474, May 2, 2014]

§ 405.2404 Termination of rural health clinic agreements.

(a) *Termination by RHC*—(1) *Notice to Secretary.* If the RHC wishes to terminate its agreement it shall file with the Secretary a written notice stating the intended effective date of termination.

(2) *Action by the Secretary.* (i) The Secretary may approve the date proposed by the RHC, or set a different date no later than 6 months after the date of the RHC's notice.

(ii) The Secretary may approve a date which is less than 6 months after the date of notice if the Secretary determines that termination on that date would not:

(A) Unduly disrupt the furnishing of services to the community serviced by the RHC; or

(B) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) *Cessation of business.* If a RHC ceases to furnish services to the community, the Secretary deems it to be a voluntary termination of the agreement by the RHC, effective on the last day of business.

(b) *Termination by the Secretary*—(1) *Cause for termination.* The Secretary may terminate an agreement if he or she determines that the RHC:

(i) No longer meets the conditions for certification under part 491 of this chapter;

(ii) Is not in substantial compliance with the provisions of the agreement, the requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act; or

(iii) Has undergone a change of ownership.

(2) *Notice of termination.* The Secretary gives notice of termination to the RHC at least 15 days before the effective date stated in the notice.

(3) *Appeal by the RHC.* A RHC 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 will not be available for RHC services furnished on or after the effective date of termination.

(d) *Notice to the public.* Prompt notice of the date and effect of termination must be given to the public by either of the following:

(1) The RHC, after the Secretary has approved or set a termination date.

(2) The Secretary, when he or she has terminated the agreement.

(e) *Conditions for reinstatement after termination of agreement by the Secretary.* When an agreement with a RHC is terminated by the Secretary, the RHC may not file another agreement to participate in the Medicare program unless the Secretary:

(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.

[43 FR 8261, Mar. 1, 1978, as amended at 52 FR 22454, June 12, 1987; 79 FR 25474, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

§ 405.2410 Application of Part B deductible and coinsurance.

(a) *Application of deductible.* (1) Medicare payment for RHC services begins only after the beneficiary has incurred the deductible.

(2) Medicare payment for services covered under the FQHC benefit is not subject to the usual Part B deductible.

(b) *Application of coinsurance.* Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, a beneficiary's responsibility is either of the following:

(1) For RHCs that are authorized to bill on the basis of the reasonable cost system—

(i) A coinsurance amount that does not exceed 20 percent of the RHC's reasonable customary charge for the covered service; and

(ii)(A) The beneficiary's deductible and coinsurance amount for any one item or service furnished by the RHC may not exceed a reasonable amount customarily charged by the RHC for that particular item or service; or

(B) For any one item or service furnished by a FQHC, a coinsurance amount that does not exceed 20 percent of a reasonable customary charge by the FQHC for that particular item or service.

(2) For FQHCs authorized to bill under the PPS, a coinsurance amount which is 20 percent of the lesser of—

(i) The FQHC's actual charge; or

(ii) The FQHC PPS rate for the covered service.

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j).* (1) For RHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(1); or

(2) For FQHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(2).

[71 FR 55345, Sept. 22, 2006, as amended at 79 FR 25474, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 82176, Nov. 22, 2023]

§ 405.2411 Scope of benefits.

(a) The following RHC and FQHC services are reimbursable under this subpart:

(1) The physicians' services specified in § 405.2412.

(2) Services and supplies furnished as an incident to a physician's professional service.

(3) The nurse practitioner or physician assistant services specified in § 405.2414.

(4) Services and supplies furnished as incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(5) Visiting nurse services when provided in accordance with 1861(aa)(1) of the Act and § 405.2416.

(6) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services as specified in § 405.2450.

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(b) RHC and FQHC services are—

(1) Covered when furnished in a RHC, FQHC, or other outpatient setting, including a patient's place of residence;

(2) Covered when furnished during a Part A stay in a skilled nursing facility only when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed or under contract with the RHC or FQHC at the time the services are furnished;

(3) Inclusive of hospice attending physician services, and are covered when furnished during a patient's hospice election only when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant designated by the patient as his or her attending physician and employed or under contract with the RHC or FQHC at the time the services are furnished; and

(4) Not covered in a—

(i) Hospital as defined in section 1861(e) of the Act; or

(ii) Critical access hospital as defined in section 1861(mm)(1) of the Act.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79523, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2412 Physicians' services.

Physicians' services are professional services that are furnished by either of the following:

(a) By a physician at the RHC or FQHC.

(b) Outside of the RHC or FQHC by a physician whose agreement with the RHC or FQHC provides that he or she will be paid by the RHC or FQHC for such services and certification and cost reporting requirements are met.

[79 FR 25475, May 2, 2014]

§ 405.2413 Services and supplies incident to a physician's services.

(a) Services and supplies incident to a physician's professional service are reimbursable under this subpart if the service or supply is:

(1) Of a type commonly furnished in physicians' offices;

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill;

(3) Furnished as an incidental, although integral, part of a physician's professional services;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a physician, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care Model, and behavioral health services can be furnished under general supervision of a physician when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25475, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

§ 405.2414 Nurse practitioner, physician assistant, and certified nurse midwife services.

(a) Professional services are payable under this subpart if the services meet all of the following:

(1) Furnished by a nurse practitioner, physician assistant, or certified nurse midwife who is employed by, or receives compensation from, the RHC or FQHC.

(2) Furnished under the medical supervision of a physician.

(3) Furnished in accordance with any medical orders for the care and treatment of a patient prepared by a physician.

(4) Are of a type which the nurse practitioner, physician assistant or certified nurse midwife who furnished the service is legally permitted to perform by the State in which the service is rendered.

(5) The services would be covered if furnished by a physician.

(b) The physician supervision requirement is met if the conditions specified in § 491.8(b) of this chapter and

any pertinent requirements of State law are satisfied.

(c) The services of nurse practitioners, physician assistants or certified nurse midwives are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014]

§ 405.2415 Incident to services and direct supervision.

(a) Services and supplies incident to the services of a nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor are payable under this subpart if the service or supply is all of the following:

(1) Of a type commonly furnished in physicians' offices.

(2) Of a type commonly rendered either without charge or included in the RHC's or FQHC's bill.

(3) Furnished as an incidental, although integral part of professional services furnished by a nurse practitioner, physician assistant, certified nurse-midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Furnished in accordance with applicable State law.

(5) Furnished under the direct supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, except that services and supplies furnished incident to Transitional Care Management, General Care Management, the Psychiatric Collaborative Care model, and behavioral health services can be furnished under general supervision of a nurse practitioner, physician assistant, or certified nurse-midwife, when these services or supplies are furnished by auxiliary personnel, as defined in § 410.26(a)(1) of this chapter.

(b) The direct supervision requirement is met in the case of any of the following persons only if the person is permitted to supervise these services under the written policies governing the RHC or FQHC:

(1) Nurse practitioner.

(2) Physician assistant.

(3) Certified nurse-midwife.

(4) Clinical psychologist.

(5) Clinical social worker.

(6) Marriage and family therapist.

(7) Mental health counselor.

(c) Only drugs and biologicals which cannot be self-administered are included within the scope of this benefit.

[79 FR 25475, May 2, 2014, as amended at 79 FR 68001, Nov. 13, 2014; 81 FR 80552, Nov. 15, 2016; 82 FR 53358, Nov. 15, 2017; 88 FR 79523, Nov. 16, 2023]

§ 405.2416 Visiting nurse services.

(a) Visiting nurse services are covered if the services meet all of the following:

(1) The RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of home health agencies.

(2) The services are rendered to a homebound individual.

(3) The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC or FQHC.

(4) The services are furnished under a written plan of treatment that is both of the following:

(i)(A) Established and reviewed at least every 60 days by a supervising physician of the RHC or FQHC; or

(B)(*1*) Established by a nurse practitioner, physician assistant or certified nurse midwife; and

(*2*) Reviewed at least every 60 days by a supervising physician.

(ii) Signed by the supervising physician, nurse practitioner, physician assistant or certified nurse midwife of the RHC or FQHC.

(5) During a PHE, as defined in § 400.200 of this chapter, an area typically served by the RHC, and an area that is included in the FQHC's service area plan, is determined to have a shortage of home health agencies, and no request for this determination is required.

(b) The nursing care covered by this section includes the following:

(1) Services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved.

(2) Personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications.

(c) This benefit does not cover household and housekeeping services or other services that would constitute custodial care.

(d) For purposes of this section, *homebound* means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition. The individual may be considered homebound if he or she leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or long term care facility.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25475, May 2, 2014; 85 FR 19285, Apr. 6, 2020]

§ 405.2417 Visiting nurse services: Determination of shortage of agencies.

A shortage of home health agencies exists if the Secretary determines that the RHC or FQHC:

(a) Is located in a county, parish, or similar geographic area in which there is no participating home health agency or adequate home health services are not available to patients of the RHC or FQHC.

(b) Has (or expects to have) patients whose permanent residences are not within the area serviced by a participating home health agency.

(c) Has (or expects to have) patients whose permanent residences are not within a reasonable traveling distance, based on climate and terrain, of a participating home health agency.

[43 FR 8261, Mar. 1, 1978, as amended at 79 FR 25476, May 2, 2014]

FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24978, June 12, 1992, unless otherwise noted.

§ 405.2430 Basic requirements.

(a) *Filing procedures.* (1) In response to a request from an entity that wishes to participate in the Medicare program, CMS enters into an agreement with an entity when all of the following occur:

(i) HRSA approves the entity as meeting the requirements of section 330 of the PHS Act.

(ii) The entity assures CMS that it meets the requirements specified in this subpart and part 491 of this chapter, as described in § 405.2434(a).

(iii) The FQHC terminates other provider agreements, unless the FQHC assures CMS that it is not using the same space, staff and resources simultaneously as a physician's office or another type of provider or supplier. A corporate entity may own other provider types as long as the provider types are distinct from the FQHC.

(2) CMS sends the entity a written notice of the disposition of the request.

(3) When the requirement of paragraph (a)(1) of this section is satisfied, CMS sends the entity two copies of the agreement. The entity must sign and return both copies of the agreement to CMS.

(4) If CMS accepts the agreement filed by the FQHC, CMS returns to the center one copy of the agreement with the notice of acceptance specifying the effective date (see § 489.11), as determined under § 405.2434.

(b) *Prior HRSA FQHC determination.* An entity applying to become a FQHC must do the following:

(1) Be determined by HRSA as meeting the applicable requirements of the PHS Act, as specified in § 405.2401(b).

(2) Receive approval by HRSA as a FQHC under section 330 of the PHS Act (42 U.S.C. 254b).

(c) *Appeals.* An entity is entitled to a hearing in accordance with part 498 of this chapter when CMS fails to enter into an agreement with the entity.

[57 FR 24978, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25476, May 2, 2014]

§ 405.2434 Content and terms of the agreement.

Under the agreement, the FQHC must agree to the following:

(a) *Maintain compliance with the requirements.* (1) The FQHC must agree to maintain compliance with the FQHC requirements set forth in this subpart and part 491, except that the provisions of § 491.3 do not apply.

(2) FQHCs must promptly report to CMS any changes that result in noncompliance with any of these requirements.

(b) *Effective date of agreement.* The effective date of the agreement is determined in accordance with the provisions of § 489.13 of this chapter.

(c) *Charges to beneficiaries.* (1) For non-FQHC services that are billed to Part B, the beneficiary is responsible for payment of a coinsurance amount which is 20 percent of the amount of Part B payment made to the FQHC for the covered services.

(2) The beneficiary is responsible for blood deductible expenses, as specified in § 410.161.

(3) The FQHC agrees not to charge the beneficiary (or any other person acting on behalf of a beneficiary) for any FQHC services for which the beneficiary is entitled to have payment made on his or her behalf by the Medicare program (or for which the beneficiary would have been entitled if the FQHC had filed a request for payment in accordance with § 410.165 of this chapter), except for coinsurance amounts.

(4) The FQHC may charge the beneficiary for items and services that are not FQHC services. If the item or service is covered under Medicare Part B, the FQHC may not charge the beneficiary more than 20 percent of the Part B payment amount.

(d) *Refunds to beneficiaries.* (1) The FQHC must agree to refund as promptly as possible any money incorrectly collected from Medicare beneficiaries or from someone on their behalf.

(2) As used in this section, ''money incorrectly collected'' means any amount for covered services that is greater than the amount for which the beneficiary was liable because of the coinsurance requirements specified in part 410, subpart E.

(3) Amounts also are considered incorrectly collected if the FQHC believed the beneficiary was not entitled to Medicare benefits but—

(i) The beneficiary was later determined to have been so entitled;

(ii) The beneficiary's entitlement period fell within the time the FQHC's agreement with CMS was in effect; and

(iii) The amounts exceed the beneficiary's coinsurance liability.

(e) *Treatment of beneficiaries.* (1) The FQHC must agree to accept Medicare beneficiaries for care and treatment.

(2) The FQHC may not impose any limitations with respect to care and treatment of Medicare beneficiaries that it does not also impose upon all other persons seeking care and treatment from the FQHC. Failure to comply with this requirement is a cause for termination of the FQHC's agreement with CMS in accordance with § 405.2436(d).

(3) If the FQHC does not furnish treatment for certain illnesses and conditions to patients who are not Medicare beneficiaries, it need not furnish such treatment to Medicare beneficiaries.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2436 Termination of agreement.

(a) *Termination by FQHC.* The FQHC may terminate its agreement by—

(1) Filing with CMS a written notice stating its intention to terminate the agreement; and

(2) Notifying CMS of the date on which the FQHC requests that the termination take effect.

(b) *Effective date.* (1) Upon receiving a FQHC's notice of intention to terminate the agreement, CMS will set a date upon which the termination takes effect. This effective date may be—

(i) The date proposed by the FQHC in its notice of intention to terminate, if that date is acceptable to CMS; or

(ii) Except as specified in paragraph (2) of this section, a date set by CMS, which is no later than 6 months after the date CMS receives the FQHC's notice of intention to terminate.

(2) The effective date of termination may be less than 6 months following CMS's receipt of the FQHC's notice of intention to terminate if CMS determines that termination on such a date would not—

(i) Unduly disrupt the furnishing of FQHC services to the community; or

(ii) Otherwise interfere with the effective and efficient administration of the Medicare program.

(3) The termination is effective at the end of the last day of business as a FQHC.

(c) *Termination by CMS.* (1) CMS may terminate an agreement with a FQHC if it finds that the FQHC—

(i) No longer meets the requirements specified in this subpart; or

(ii) Is not in substantial compliance with—

(A) The provisions of the agreement; or

(B) The requirements of this subpart, any other applicable regulations of this part, or any applicable provisions of title XVIII of the Act.

(2) *Notice by CMS.* CMS will notify the FQHC in writing of its intention to terminate an agreement at least 15 days before the effective date stated in the written notice.

(3) *Appeal.* A FQHC may appeal CMS's decision to terminate the agreement in accordance with part 498 of this chapter.

(d) *Effect of termination.* When a FQHC's agreement is terminated whether by the FQHC or CMS, payment will not be available for FQHC services furnished on or after the effective date of termination.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2440 Conditions for reinstatement after termination by CMS.

When CMS has terminated an agreement with a FQHC, CMS does not enter into another agreement with the FQHC to participate in the Medicare program unless CMS—

(a) Finds that the reason for the termination no longer exists; and

(b) Is assured that the reason for the termination of the prior agreement will not recur.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2442 Notice to the public.

(a) When the FQHC voluntarily terminates the agreement and an effective date is set for the termination, the FQHC must notify the public in the area serviced by the FQHC prior to a prospective effective date or on the actual day that business ceases, if no prospective date of termination has been set. The notice must include—

(1) Effective date of termination of the provision of services; and

(2) Effect of termination of the agreement.

(b) When CMS terminates the agreement, CMS will notify the public in the area serviced by the FQHC.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014; 82 FR 38509, Aug. 14, 2017]

§ 405.2444 Change of ownership.

(a) *What constitutes change of ownership*—(1) *Incorporation.* The incorporation of an unincorporated FQHC constitutes change of ownership.

(2) *Merger.* The merger of the FQHC corporation into another corporation, or the consolidation of two or more corporations, one of which is the FQHC corporation, resulting in the creation of a new corporation, constitutes a change of ownership. (The merger of another corporation into the FQHC corporation does not constitute change of ownership.)

(3) *Leasing.* The lease of all or part of an entity constitutes a change of ownership of the leased portion.

(b) *Notice to CMS.* A FQHC which is contemplating or negotiating change of ownership must notify CMS.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the agreement with the existing FQHC is automatically assigned to the new owner if it continues to meet the conditions to be a FQHC.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Compliance with applicable health and safety standards.

(2) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C of this subchapter.

[57 FR 24978, June 12, 1992, as amended at 79 FR 25476, May 2, 2014]

§ 405.2446 Scope of services.

(a) For purposes of this section, the terms rural health clinic and RHC

when they appear in the cross references in paragraph (b) of this section also mean Federally qualified health centers and FQHCs.

(b) FQHC services that are paid for under this subpart are outpatient services that include the following:

(1) Physician services specified in § 405.2412.

(2) Services and supplies furnished as incident to a physician's professional service, as specified in § 405.2413.

(3) Nurse practitioner, physician assistant or certified nurse midwife services as specified in § 405.2414.

(4) Services and supplies furnished as incident to a nurse practitioner, physician assistant, or certified nurse midwife service, as specified in § 405.2415.

(5) Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services specified in § 405.2450.

(6) Services and supplies furnished as incident to the services of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor, as specified in § 405.2452.

(7) Visiting nurse services specified in § 405.2416.

(8) Preventive primary services specified in § 405.2448 of this subpart.

(9) Medical nutrition therapy services as specified in part 410, subpart G of this chapter, and diabetes outpatient self-management training services as specified in part 410, subpart H of this chapter.

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

(c) FQHC services are covered when provided in outpatient settings only, including a patient's place of residence, which may be a skilled nursing facility or a nursing facility, other institution used as a patient's home, or are hospice attending physician services furnished during a hospice election.

(d) FQHC services are not covered in a hospital, as defined in section 1861(e)(1) of the Act.

[57 FR 24979, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 71 FR 69782, Dec. 1, 2006; 79 FR 25476, May 2, 2014; 86 FR 65660, Nov. 19, 2021; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2448 Preventive primary services.

(a) Preventive primary services are those health services that—

(1) A FQHC is required to provide as preventive primary health services under section 330 of the PHS Act; and

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor employed by or under contract with the FQHC.

(i) By a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor; or

(ii) By a member of the FQHC's health care staff who is an employee of the FQHC or by a physician under arrangements with the FQHC.

(3) Except as specifically provided in section 1861(s) of the Act, include only drugs and biologicals that cannot be self-administered.

(b) Preventive primary services which may be paid for when provided by FQHCs are the following:

(1) Medical social services.

(2) Nutritional assessment and referral.

(3) Preventive health education.

(4) Children's eye and ear examinations.

(5) Prenatal and post-partum care.

(6) Perinatal services.

(7) Well child care, including periodic screening.

(8) Immunizations, including tetanus-diptheria booster and influenza vaccine.

(9) Voluntary family planning services.

(10) Taking patient history.

(11) Blood pressure measurement.

(12) Weight.

(13) Physical examination targeted to risk.

(14) Visual acuity screening.

(15) Hearing screening.

(16) Cholesterol screening.

(17) Stool testing for occult blood.

(18) Dipstick urinalysis.

(19) Risk assessment and initial counseling regarding risks.

(20) Tuberculosis testing for high risk patients.

(21) For women only.

(i) Clinical breast exam.

(ii) Referral for mammography; and

(iii) Thyroid function test.

(c) Preventive primary services do not include group or mass information programs, health education classes, or group education activities, including media productions and publications.

(d) Screening mammography is not considered a FQHC service, but may be provided at a FQHC if the FQHC if the center meets the requirements applicable to that service specified in § 410.34 of this subchapter. Payment is made under applicable Medicare requirements.

(e) Preventive primary services do not include eyeglasses, hearing aids, or preventive dental services.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25477, May 2, 2014; 80 FR 71371, Nov. 16, 2015; 88 FR 79524, Nov. 16, 2023]

§ 405.2449 Preventive services.

For services furnished on or after January 1, 2011, preventive services covered under the Medicare FQHC benefit are those preventive services defined in section 1861(ddd)(3) of the Act, and § 410.2 of this chapter. Specifically, these include the following:

(a) The specific services currently listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms.

(b) The Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act as added by section 611 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) and § 410.16 of this chapter).

(c) The Personalized Prevention Plan Services (PPPS), also known as the ''Annual Wellness Visit'' (as specified by section 1861(hhh) of the Act as added by section 4103 of the Affordable Care Act (Pub. L. 111–148) and § 410.15 of this chapter).

[75 FR 73613, Nov. 29, 2010, as amended at 79 FR 25477, May 2, 2014]

§ 405.2450 Clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) For clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor professional services to be payable under this subpart, the services must be—

(1) Furnished by an individual who owns, is employed by, or furnishes services under contract to the FQHC;

(2) Of a type that the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor who furnishes the services is legally permitted to perform by the State in which the service is furnished;

(3) Performed by a clinical social worker, clinical psychologist, marriage and family therapist, or mental health counselor who is legally authorized to perform such services under State law or the State regulatory mechanism provided by the law of the State in which such services are performed; and

(4) Covered if furnished by a physician.

(b) If State law prescribes a physician supervision requirement, it is met if the conditions specified in § 491.8(b) of this chapter and any pertinent requirements of State law are satisfied.

(c) The services of clinical psychologists, clinical social workers, marriage and family therapist, or mental health counselors are not covered if State law or regulations require that the services be performed under a physician's order and no such order was prepared.

[57 FR 24980, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 88 FR 79524, Nov. 16, 2023]

§ 405.2452 Services and supplies incident to clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor services.

(a) Services and supplies incident to a clinical psychologist's, clinical social worker's, marriage and family therapist's, and mental health counselor's services are reimbursable under this subpart if the service or supply is —

(1) Of a type commonly furnished in a physician's office;

(2) Of a type commonly furnished either without charge or included in the FQHC's bill;

(3) Furnished as an incidental, although integral part of professional services furnished by a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor;

(4) Services and supplies must be furnished in accordance with applicable State law; and

(5) Furnished under the direct supervision of a clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(b) The direct supervision requirement in paragraph (a)(5) of this section is met only if the clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor is permitted to supervise such services under the written policies governing the FQHC.

[43 FR 8261, Mar. 1, 1978, as amended at 78 FR 74810, Dec. 10, 2013; 79 FR 25477, May 2, 2014; 79 FR 68001, Nov. 13, 2014; 88 FR 79524, Nov. 16, 2023]

PAYMENT FOR RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES

SOURCE: 57 FR 24976, 24977, June 12, 1992, unless otherwise noted.

§ 405.2460 Applicability of general payment exclusions.

The payment conditions, limitations, and exclusions set out in subpart C of this part, part 410 and part 411 of this chapter are applicable to payment for services provided by RHCs and FQHCs, except that preventive primary services, as defined in § 405.2448, are statutorily authorized for FQHCs and not excluded by the provisions of section 1862(a) of the Act.

[79 FR 25477, May 2, 2014]

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate, subject to a payment limit per visit determined in paragraph (b) of this section, for each beneficiary visit for covered services. This rate is determined by the Medicare Administration Contractor (MAC), in accordance with this subpart and general instructions issued by CMS.

(2) The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(b) *RHC payment limit per visit.* (1) In establishing limits on payment for rural health clinic services provided by rural health clinics the limit for services provided prior to April 1, 2021:

(i) In 1988, after March 31, at $46 per visit; and

(ii) In a subsequent year (before April 1, 2021), at the limit established for the previous year increased by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3) of the Act) applicable to primary care services (as defined in section 1842(i)(4) of the Act) furnished as of the first day of that year.

(2) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by rural health clinics or any rural health clinic that is enrolled on or after January 1, 2021 under section 1866(j) of the Act), the limit for services provided:

(i) In 2021, after March 31, at $100 per visit;

(ii) In 2022, at $113 per visit;

(iii) In 2023, at $126 per visit;

(iv) In 2024, at $139 per visit;

(v) In 2025, at $152 per visit;

(vi) In 2026, at $165 per visit;

(vii) In 2027, at $178 per visit; and

(viii) In 2028, at $190 per visit.

(ix) In a subsequent year, at the limit established for the previous year increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such year.

(3) In establishing limits on payment for rural health services furnished on or after April 1, 2021, by provider-based rural health clinics as described in section (c)(4) of this part, the limit for services provided:

(i) In 2021, after March 31, at an amount equal to the greater of:

(A) For rural health clinics that had an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2020, increased by the percentage increase in the MEI applicable to primary care services furnished as of the first day of 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(B) For rural health clinics that did not have an all-inclusive rate established for services furnished in 2020—

(*1*) The all-inclusive rate applicable to the rural health clinic for services furnished in 2021, or

(*2*) The payment limit per visit applicable in paragraph (b)(2) of this section.

(ii) In a subsequent year, at an amount equal to the greater of:

(A) The amount established under paragraph (b)(3)(i)(A) or (B) of this section, as applicable for the previous year, increased by the percentage increase in MEI applicable to primary care services furnished as of the first day of such subsequent year, or

(B) The payment limit per visit applicable under paragraph (b)(2) of this section for such subsequent year.

(c) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* (1) An RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

(i) An integral and subordinate part of a hospital, skilled nursing facility or home health agency participating in Medicare (that is, a provider of services); and

(ii) Operated with other departments of the provider under common licensure, governance and professional supervision.

(2) An RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraphs (b)(1) and (2) of this section, for each beneficiary visit for covered services when in a hospital with greater than 50 beds as determined in §412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(3) Prior to April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate and is not subject to a payment limit per visit described in paragraphs (b)(1) and (2) of this section for each beneficiary visit for covered services when in a hospital with less than 50 beds as determined in §412.105(b) of this subchapter. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(4) On or after April 1, 2021, an RHC, described in paragraph (c)(1) of this section, is paid on the basis of an all-inclusive rate, subject to a payment limit per visit, described in paragraph (b)(3) of this section, for each beneficiary visit for covered services when it meets the specified qualifications in paragraph(d) of this section. This all-inclusive rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS. The amount payable by the MAC for a visit is determined in accordance with paragraphs (i)(1) and (2) of this section.

(d) *Specified qualifications.* A provider-based rural health clinic must meet the following qualifications to have a payment limit per visit established in accordance with paragraph (b)(3) of this section.

(1) As of December 31, 2020, was in a hospital with less than 50 beds (as determined in §412.105(b) of this subchapter) and after December 31, 2020, in a hospital that continues to have less than 50 beds (not taking into account any increase in the number of beds pursuant to a waiver during the COVID–19 Public Health Emergency (PHE)); and one of the following circumstances:

(i) As of December 31, 2020, was enrolled under section 1866(j) of the Act (including temporary enrollment during the COVID–19 PHE); or

(ii) Submitted an application for enrollment under section 1866(j) of the Act (or a request for temporary enrollment during the COVID–19 PHE) that

was received not later than December 31, 2020.

(2) [Reserved]

(e) *Payment to FQHCs that are authorized to bill under the PPS.* A FQHC that is authorized to bill under the PPS is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. Except as noted in paragraph (f) of this section, this rate is adjusted for the following:

(1) Geographic differences in cost based on the Geographic Practice Cost Indices (GPCIs) in accordance with section 1848(e) of the Act and 42 CFR 414.2 and 414.26 are used to adjust payment under the physician fee schedule during the same period, limited to only the work and practice expense GPCIs.

(2) Furnishing of care to a beneficiary that is a new patient with respect to the FQHC, including all sites that are part of the FQHC. A new patient is one that has not been treated by the FQHC's organization within the previous 3 years.

(3) Furnishing of care to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit) or a subsequent annual wellness visit.

(f) *Payment to grandfathered tribal FQHCs.* (1) A ''grandfathered tribal FQHC'' is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was billing as if it were provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider-based department of an IHS hospital.

(2) A grandfathered tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS.

(3) The payment rate is not adjusted:

(i) By the FQHC Geographic Adjustment Factor;

(ii) For new patients, annual wellness visits, or initial preventive physical examinations; or

(iii) Annually by the Medicare Economic Index or a FQHC PPS market basket.

(4) The payment rate is adjusted annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

(g)(1) Except for preventive services for which Medicare pays 100 percent under § 410.152(l) of this chapter, Medicare pays—

(i) Eighty (80) percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS; or

(ii) Eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge, or the outpatient rate for Medicare as set annually by the IHS for grandfathered tribal FQHCs that are authorized to bill at this rate.

(2) No deductible is applicable to FQHC services.

(h) For RHCs visits, payment is made in accordance with one of the following:

(1) If the deductible has been fully met by the beneficiary prior to the RHC visit, Medicare pays 80 percent of the all-inclusive rate.

(2) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is less than the all-inclusive rate, the amount applied to the deductible is subtracted from the all-inclusive rate and 80 percent of the remainder, if any, is paid to the RHC.

(3) If the deductible has not been fully met by the beneficiary before the visit, and the amount of the RHC's reasonable customary charge for the services that is applied to the deductible is equal to or exceeds the all-inclusive rate, no payment is made to the RHC.

(i) To receive payment, the RHC or FQHC must do all of the following:

(1) Furnish services in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter.

(2) File a request for payment on the form and manner prescribed by CMS.

(3) *HCPCS coding.* FQHCs and RHCs are required to submit HCPCS and other codes as required in reporting services furnished.

(j) *Payment amount for intensive outpatient services.* An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(1) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under paragraph (j)(1) of this section.

(2) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under paragraph (j)(1) of this section; or

(3) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under paragraph (j)(1) of this section.

(4) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate, except that grandfathered tribal FQHCs are paid pursuant to paragraph (j)(4)(ii) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(2) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (3) of this section.

(iii) No deductible is applicable to FQHC services.

[79 FR 25477, May 2, 2014, as amended at 80 FR 71371, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 86 FR 65660, Nov. 19, 2021; 88 FR 82176, Nov. 22, 2023]

§ 405.2463 What constitutes a visit.

(a) *Visit—General.* (1) For RHCs, a visit is either of the following:

(i) Face-to-face encounter (or, for mental health disorders only, an encounter that meets the requirements under paragraph (b)(3) of this section) between an RHC patient and one of the following:

(A) Physician.

(B) Physician assistant.

(C) Nurse practitioner.

(D) Certified nurse midwife.

(E) Visiting registered professional or licensed practical nurse.

(G) Clinical psychologist.

(H) Clinical social worker.

(I) Marriage and family therapist.

(J) Mental health counselor.

(ii) Qualified transitional care management service.

(2) For FQHCs, a visit is either of the following:

(i) A visit as described in paragraph (a)(1)(i) or (ii) of this section.

(ii) A face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

(b) *Visit—Medical.* (1) A medical visit is a face-to-face encounter between a RHC or FQHC patient and one of the following:

(i) Physician.

(ii) Physician assistant.

(iii) Nurse practitioner.

(iv) Certified nurse midwife.

(v) Visiting registered professional or licensed practical nurse.

(2) A medical visit for a FQHC patient may be either of the following:

(i) Medical nutrition therapy visit.

(ii) Diabetes outpatient self-management training visit.

(3) *Visit-Mental health.* A mental health visit is a face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology for the purposes of diagnosis, evaluation or treatment of a mental health disorder, including an in-person mental health service, beginning January 1, 2025, furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology)

must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record, between an RHC or FQHC patient and one of the following:

(i) Clinical psychologist.

(ii) Clinical social worker.

(iii) Marriage and family therapist.

(iv) Mental health counselor.

(v) Other RHC or FQHC practitioner, in accordance with paragraph (b)(1) of this section, for mental health services.

(c) *Visit—Multiple.* (1) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and at a single location constitute a single visit, except when the patient—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day;

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day; or

(iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

(2) For RHCs and FQHCs that are authorized to bill under the reasonable cost system, Medicare pays RHCs and FQHCs for more than 1 visit per day when the conditions in paragraph (c)(1) of this section are met.

(3) For FQHCs that are authorized to bill under the reasonable cost system, Medicare pays for more than 1 visit per day when a DSMT or MNT visit is furnished on the same day as a visit described in paragraph (c)(1) of this section are met.

(4) For FQHCs billing under the PPS, and grandfathered tribal FQHCs that are authorized to bill as a FQHC at the outpatient per visit rate for Medicare as set annually by the Indian Health Service—

(i) Suffers an illness or injury subsequent to the first visit that requires additional diagnosis or treatment on the same day; or

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day.

[79 FR 68001, Nov. 13, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65661, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2464 Payment rate.

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraphs (d) and (e) of this section, an RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC services.

(3) The rate determination is subject to any tests of reasonableness that may be established in accordance with this subpart.

(4) The MAC, during each reporting period, periodically reviews the rate to assure that payments approximate actual allowable costs and visits and adjusts the rate if:

(i) There is a significant change in the utilization of services;

(ii) Actual allowable costs vary materially from allowable costs; or

(iii) Other circumstances arise which warrant an adjustment.

(5) The RHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Payment rate for FQHCs that are authorized to bill under the prospective payment system.* (1) Except as specified in paragraphs (d) and (e) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

(2) The per diem rate is adjusted as follows:

(i) For geographic differences in the cost of inputs according to § 405.2462(c)(1).

(ii) When the FQHC furnishes services to a new patient, as defined in § 405.2462(c)(2).

(iii) When a beneficiary receives either of the following:

(A) A comprehensive initial Medicare visit (that is, an initial preventive physical examination or an initial annual wellness visit).

(B) A subsequent annual wellness visit.

(c) *Payment for care management services.* For chronic care management services furnished between January 1, 2016 and December 31, 2017, payment to RHCs and FQHCs is at the physician fee schedule national non-facility payment rate. For care management services furnished between January 1, 2018 and December 31, 2023, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for care management services. For general care management services furnished on or after January 1, 2024, the payment amount is based on a weighted average of the services that comprise HCPCS code G0511 using the most recently available PFS utilization data.

(d) *Payment for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* Grandfathered tribal FQHCs are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

(e) *Payment for communication technology-based and remote evaluation services.* For communication technology-based and remote evaluation services furnished on or after January 1, 2019, payment to RHCs and FQHCs is at the rate set for each of the RHC and FQHC payment codes for communication technology-based and remote evaluation services.

(f) *Payment for intensive outpatient services.* Payment to RHCs and FQHCs is at the rate determined under § 405.2462(j).

[79 FR 25478, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 88 FR 79524, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2466 Annual reconciliation.

(a) *General.* Payments made to RHCs or FQHCs that are authorized to bill under the reasonable cost system during a reporting period are subject to annual reconciliation to assure that those payments do not exceed or fall short of the allowable costs attributable to covered services furnished to Medicare beneficiaries during that period.

(b) *Calculation of reconciliation for RHCs or FQHCs that are authorized to bill under the reasonable cost system.* (1) The total reimbursement amount due the RHC or FQHC for covered services furnished to Medicare beneficiaries is based on the report specified in § 405.2470(c)(2) and is calculated by the MAC as follows:

(i) The average cost per visit is calculated by dividing the total allowable cost incurred for the reporting period by total visits for RHC or FQHC services furnished during the period. The average cost per visit is subject to tests of reasonableness which may be established in accordance with this subpart.

(ii) The total cost of RHC or FQHC services furnished to Medicare beneficiaries is calculated by multiplying the average cost per visit by the number of visits for covered RHC or FQHC services by beneficiaries.

(iii) The total payment due the RHC is 80 percent of the amount calculated by subtracting the amount of deductible incurred by beneficiaries that is attributable to RHC services from the cost of these services. FQHC services are not subject to a deductible and the payment computation for FQHCs does not include a reduction related to the deductible.

(iv) For RHCs and FQHCs, payment for pneumococcal, influenza, and COVID–19 vaccine and their administration is 100 percent of Medicare reasonable cost.

(2) The total reimbursement amount due is compared with total payments made to the RHC or FQHC for the reporting period, and the difference constitutes the amount of the reconciliation.

(c) *Notice of program reimbursement.* The MAC notifies the RHC or FQHC

that is authorized to bill under the reasonable-cost system:

(1) Setting forth its determination of the total reimbursement amount due the RHC or FQHC for the reporting period and the amount, if any, of the reconciliation; and

(2) Informing the RHC or FQHC of its right to have the determination reviewed at a hearing under the procedures set forth in subpart R of this part.

(d) *Payment of reconciliation amount*—(1) *Underpayments.* If the total reimbursement due the RHC or FQHC that is authorized to bill under the reasonable cost system exceeds the payments made for the reporting period, the MAC makes a lump-sum payment to the RHC or FQHC to bring total payments into agreement with total reimbursement due the RHC or FQHC.

(2) *Overpayments.* If the total payments made to a RHC or FQHC for the reporting period exceed the total reimbursement due the RHC or FQHC for the period, the MAC arranges with the RHC or FQHC for repayment through a lump-sum refund, or, if that poses a hardship for the RHC or FQHC, through offset against subsequent payments or a combination of offset and refund. The repayment must be completed as quickly as possible, generally within 12 months from the date of the notice of program reimbursement. A longer repayment period may be agreed to by the MAC if the MAC is satisfied that unusual circumstances exist which warrant a longer period.

[57 FR 24976, June 12, 1992, as amended at 61 FR 14657, Apr. 3, 1996; 79 FR 25478, May 2, 2014; 86 FR 65662, Nov. 19, 2021]

§ 405.2467 Requirements of the FQHC PPS.

(a) *Cost reporting.* For cost reporting periods beginning on or after October 1, 2014, FQHCs are paid the lesser of their actual charges or the FQHC PPS rate that does all of the following:

(1) Includes a process for appropriately describing the services furnished by FQHCs.

(2) Establishes payment rates for specific payment codes based on such appropriate descriptions of services.

(3) Takes into account the type, intensity and duration of services furnished by FQHCs.

(4) May include adjustments (such as geographic adjustments) determined by the Secretary.

(b) *Initial payments.* (1) Beginning October 1, 2014, for the first 15 months of the PPS, the estimated aggregate amount of PPS rates is equal to 100 percent of the estimated amount of reasonable costs that would have occurred for that period if the PPS had not been implemented.

(2) Payment rate is calculated based on the reasonable cost system, prior to productivity adjustments and any payment limitations.

(c) *Payments in subsequent years.* (1) Beginning January 1, 2016, PPS payment rates will be increased by the percentage increase in the Medicare economic index.

(2) Beginning January 1, 2017, PPS rates will be increased by the percentage increase in a market basket of FQHC goods and services as established through regulations, or, if not available, the Medicare economic index.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015]

§ 405.2468 Allowable costs.

(a) *Applicability of general Medicare principles.* In determining whether and to what extent a specific type or item of cost is allowable, such as interest, depreciation, bad debts and owner compensation, the MAC applies the principles for reimbursement of provider costs, as set forth in part 413 of this subchapter.

(b) *Typical RHC and FQHC costs.* The following types and items of cost are included in allowable costs to the extent that they are covered and reasonable:

(1) Compensation for the services of a physician, physician assistant, nurse practitioner, certified nurse-midwife, visiting registered professional or licensed practical nurse, clinical psychologist, clinical social worker, marriage and family therapist, and mental health counselor who owns, is employed by, or furnishes services under contract to a FQHC or RHC.

(2) Compensation for the duties that a supervising physician is required to

perform under the agreement specified in § 491.8 of this chapter.

(3) Costs of services and supplies incident to the services of a physician, physician assistant, nurse practitioner, nurse-midwife, qualified clinical psychologist, clinical social worker, marriage and family therapist, or mental health counselor.

(4) Overhead costs, including RHC or FQHC administration, costs applicable to use and maintenance of the entity, and depreciation costs.

(5) Costs of services purchased by the RHC or FQHC.

(c) *Tests of reasonableness of cost and utilization.* Tests of reasonableness authorized by sections 1833(a) and 1861(v)(1)(A) of the Act may be established by CMS or the MAC with respect to direct or indirect overall costs, costs of specific items and services, or costs of groups of items and services. For RHCs and FQHCs that are authorized to bill under the reasonable cost system, these tests include, but are not limited to, screening guidelines and payment limits.

(d) *Screening guidelines.* (1) Costs in excess of amounts established by the guidelines are not included unless the RHC or FQHC that is authorized to bill under the reasonable cost system provides reasonable justification satisfactory to the MAC.

(2) Screening guidelines are used to assess the costs of services, including the following:

(i) Compensation for the professional and supervisory services of physicians and for the services of physician assistants, nurse practitioners, and nurse-midwives.

(ii) Services of physicians, physician assistants, nurse practitioners, nurse-midwives, visiting nurses, qualified clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors.

(iii) The level of administrative and general expenses.

(iv) Staffing (for example, the ratio of other RHC or FQHC personnel to physicians, physician assistants, and nurse practitioners).

(v) The reasonableness of payments for services purchased by the RHC or FQHC, subject to the limitation that the costs of physician services purchased by the RHC or FQHC may not exceed amounts determined under the applicable provisions of subpart E of part 405 or part 415 of this chapter.

(e) *Payment limitations.* Limits on payments may be set by CMS, on the basis of costs estimated to be reasonable for the provision of such services.

(f) *Graduate medical education.* (1) Effective for portions of cost reporting periods occurring on or after January 1, 1999, if an RHC or an FQHC incurs ''all or substantially all'' of the costs for the training program in the nonhospital setting as defined in § 413.75(b) of this chapter, the RHC or FQHC may receive direct graduate medical education payment for those residents. However, in connection with cost reporting periods for which ''all or substantially all of the costs for the training program in the nonhospital setting'' is not defined in § 413.75(b) of this chapter, if an RHC or an FQHC incurs the salaries and fringe benefits (including travel and lodging where applicable) of residents training at the RHC or FQHC, the RHC or FQHC may receive direct graduate medical education payments for those residents.

(2) Direct graduate medical education costs are not included as allowable cost under § 405.2466(b)(1)(i); and therefore, are not subject to the limit on the all-inclusive rate for allowable costs.

(3) Allowable graduate medical education costs must be reported on the RHC's or the FQHC's cost report under a separate cost center.

(4) Allowable graduate medical education costs are non-reimbursable if payment for these costs are received from a hospital or a Medicare Advantage organization.

(5) Allowable direct graduate medical education costs under paragraphs (f)(6) and (f)(7)(i) of this section, are subject to reasonable cost principles under part 413 and the reasonable compensation equivalency limits in §§ 415.60 and 415.70 of this chapter.

(6) The allowable direct graduate medical education costs are those costs incurred by the nonhospital site for the educational activities associated with patient care services of an approved program, subject to the redistribution

and community support principles in § 413.85(c).

(i) The following costs are allowable direct graduate medical education costs to the extent that they are reasonable—

(A) The costs of the residents' salaries and fringe benefits (including travel and lodging expenses where applicable).

(B) The portion of teaching physicians' salaries and fringe benefits that are related to the time spent teaching and supervising residents.

(C) Facility overhead costs that are allocated to direct graduate medical education.

(ii) The following costs are not allowable graduate medical education costs—

(A) Costs associated with training, but not related to patient care services.

(B) Normal operating and capital-related costs.

(C) The marginal increase in patient care costs that the RHC or FQHC experiences as a result of having an approved program.

(D) The costs associated with activities described in § 413.85(h) of this chapter.

(7) Payment is equal to the product of—

(i) The RHC's or the FQHC's allowable direct graduate medical education costs; and

(ii) Medicare's share, which is equal to the ratio of Medicare visits to the total number of visits (as defined in § 405.2463).

(8) Direct graduate medical education payments to RHCs and FQHCs made under this section are made from the Federal Supplementary Medical Insurance Trust Fund.

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section 1834(o)(2)(B) of the Act as described in § 405.2464(b).

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24977, June 12, 1992; 60 FR 63176, Dec. 8, 1995; 61 FR 14658, Apr. 3, 1996; 63 FR 41002, July 31, 1998; 66 FR 39932, Aug. 1, 2001; 70 FR 47484, Aug. 12, 2005; 79 FR 25479, May 2, 2014; 79 FR 50351, Aug. 22, 2014; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2469 FQHC supplemental payments.

(a) *Eligibility for supplemental payments.* FQHCs under contract (directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive under one of the following:

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) *Calculation of supplemental payment.* The supplemental payment for FQHC covered services provided to Medicare patients enrolled in MA plans is based on the difference between—

(1) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHCs all-inclusive cost-based per visit rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(3) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC outpatient rate as set forth in this section under paragraph (a)(2) of this section, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(4) Payments received by the FQHC from the MA plan as determined on a

per visit basis and the payment rate as determined in § 405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

(c) *Financial incentives.* Any financial incentives provided to FQHCs under their MA contracts, such as risk pool payments, bonuses, or withholds, are prohibited from being included in the calculation of supplemental payments due to the FQHC.

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter or an encounter furnished using interactive, real-time, audio and video telecommunications technology or audio-only interactions in cases where beneficiaries do not wish to use or do not have access to devices that permit a two-way, audio/video interaction for the purposes of diagnosis, evaluation or treatment of a mental health disorder occurs between a MA enrollee and a practitioner as set forth in § 405.2463. Additionally, beginning January 1, 2025, there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

[79 FR 25479, May 2, 2014, as amended at 80 FR 71372, Nov. 16, 2015; 86 FR 65662, Nov. 19, 2021; 87 FR 70222, Nov. 18, 2022; 88 FR 79525, Nov. 16, 2023; 88 FR 82176, Nov. 22, 2023]

§ 405.2470 Reports and maintenance of records.

(a) *Maintenance and availability of records.* The RHC or FQHC must:

(1) Maintain adequate financial and statistical records, in the form and containing the data required by CMS, to allow the MAC to determine payment for covered services furnished to Medicare beneficiaries in accordance with this subpart;

(2) Make the records available for verification and audit by HHS or the General Accounting Office;

(3) Maintain financial data on an accrual basis, unless it is part of a governmental institution that uses a cash basis of accounting. In the latter case, appropriate depreciation on capital assets is allowable rather than the expenditure for the capital asset.

(b) *Adequacy of records.* (1) The MAC may suspend reimbursement if it determines that the RHC or FQHC does not maintain records that provide an adequate basis to determine payments under Medicare.

(2) The suspension continues until the RHC or FQHC demonstrates to the MAC's satisfaction that it does, and will continue to, maintain adequate records.

(c) *Reporting requirements*—(1) *Initial report.* At the beginning of its initial reporting period, the RHC or FQHC must submit an estimate of budgeted costs and visits for RHC or FQHC services for the reporting period, in the form and detail required by CMS, and such other information as CMS may require to establish the payment rate.

(2) *Annual reports.* Within 90 days after the end of its reporting period, the RHC or FQHC must submit, in such form and detail as may be required by CMS, a report of:

(i) Its operations, including the allowable costs actually incurred for the period and the actual number of visits for RHC or FQHC services furnished during the period; and

(ii) The estimated costs and visits for RHC services or FQHC services for the succeeding reporting period and such other information as CMS may require to establish the payment rate.

(3) *Late reports.* If the RHC or FQHCdoes not submit an adequate annual report on time, the MAC may reduce or suspend payments to preclude excess payment to the RHC or FQHC.

(4) *Inadequate reports.* If the RHC or FQHC does not furnish a report or furnishes a report that is inadequate for the MAC to make a determination of

program payment, CMS may deem all payments for the reporting period to be overpayments.

(5) *Postponement of due date.* For good cause shown by the RHC or FQHC, the MAC may, with CMS's approval, grant a 30-day postponement of the due date for the annual report.

(6) *Reports following termination of agreement or change of ownership.* The report from a RHC or FQHC which voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change in ownership (see §§ 405.2436–405.2438) is due no later than 45 days following the effective date of the termination of agreement or change of ownership.

(d) *Collection of additional claims data.* Beginning January 1, 2011, a Medicare FQHC must report on its Medicare claims such information as the Secretary determines is needed to develop and implement a prospective payment system for FQHCs including, but not limited to all pertinent HCPCS (Healthcare Common Procedure Coding System) code(s) corresponding to the service(s) provided for each Medicare FQHC visit (as defined in § 405.2463).

[43 FR 8261, Mar. 1, 1978, as amended at 75 FR 73613, Nov. 29, 2010; 79 FR 25479, May 2, 2014]

§ 405.2472 Beneficiary appeals.

A beneficiary may request a hearing by an intermediary (subject to the limitations and conditions set forth in subpart H of this part) if:

(a) The beneficiary is dissatisfied with a MAC's determination denying a request for payment made on his or her behalf by a RHC or FQHC;

(b) The beneficiary is dissatisfied with the amount of payment; or

(c) The beneficiary believes the request for payment is not being acted upon with reasonable promptness.

[43 FR 8261, Mar. 1, 1978. Redesignated and amended at 57 FR 24978, June 12, 1992; 79 FR 25480, May 2, 2014]

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

Subpart A—General Provisions

Sec.

Subpart B—Hospital Insurance Without Monthly Premiums

Subpart C—Premium Hospital Insurance

Subpart D—Special Circumstances That Affect Entitlement to Hospital Insurance

AUTHORITY: 42 U.S.C. 1302, 1395i–2, 1395i–2a, 1395p, 1395q and 1395hh.

SOURCE: 48 FR 12536, Mar. 25, 1983, unless otherwise noted. Redesignated at 51 FR 41338, Nov. 14, 1986.

Subpart A—General Provisions

§ 406.1 Statutory basis.

Sections 226, 226A, 1818 and 1818A of the Social Security Act and section 103

of Public Law 89–97 establish the conditions for entitlement to hospital insurance benefits. Sections 202 (t) and (u) of the Act specify limitations that apply to certain aliens and to persons convicted of certain offenses.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 56 FR 38078, Aug. 12, 1991]

§ 406.2 Scope.

Subparts A through D of this part specify the conditions of eligibility for hospital insurance and set forth certain specific conditions that affect entitlement to benefits. Hospital insurance is authorized under Part A of title XVIII and is also referred to as Medicare Part A. It includes inpatient hospital care, posthospital SNF care, home health services, and hospice care.

[48 FR 56026, Dec. 16, 1983, as amended at 50 FR 33033, Aug. 16, 1985. Redesignated and amended at 51 FR 41338, Nov. 14, 1986]

§ 406.3 Definitions.

First month of eligibility means the first month in which an individual meets all the requirements for entitlement to hospital insurance except application or enrollment if that is required.

First month of entitlement means the first month for which the individual meets all the requirements for entitlement to Part A benefits.

Insured individual means an individual who has the number of quarters of coverage required for monthly social security benefits.

Quarter of coverage means a calendar quarter that is counted toward the number of covered quarters required to make the individual eligible for monthly social security benefits. A quarter is counted if during that quarter (or that calendar year) the individual earned a required minimum amount of money. (For details, see 20 CFR part 404, subpart B.)

§ 406.5 Basis of eligibility and entitlement.

(a) *Hospital insurance without premiums.* Hospital insurance is available to most individuals without payment of a premium if they:

(1) Are age 65 or over, or

(2) Have received social security or railroad retirement disability benefits for 25 months; or

(3) Have end-stage renal disease. Subpart B of this part explains the requirements such individuals must meet to obtain hospital insurance without premiums.

(b) *Premium hospital insurance.* Many individuals who are age 65 or over, but do not meet the requirements set forth in subpart B of this part, and certain individuals under age 65, may obtain the benefits by paying a premium. Section 406.20 of this part explains the requirements individuals must meet to obtain premium hospital insurance.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 56 FR 38078, Aug. 12, 1991]

§ 406.6 Application or enrollment for hospital insurance.

(a) *Basic provision.* In most cases, eligibility for Medicare Part A is a result of entitlement to monthly social security or railroad retirement cash benefits or eligibility for monthly social security cash benefits. This section specifies the individuals who need not file an application to become entitled to hospital insurance, those who must file an application, and those who must enroll.

(b) *Individuals who need not file an application for hospital insurance.* An individual who meets any of the following conditions need not file an application for hospital insurance:

(1) Is under age 65 and has been entitled, for more than 24 months, to monthly social security or railroad retirement benefits based on disability.

(2) At the time of attainment of age 65, is entitled to monthly social security or railroad retirement benefits.

(3) Establishes entitlement to monthly social security or railroad retirement benefits at any time after attaining age 65.

(c) *Individuals who must file an application for hospital insurance.* An individual must file an application for hospital insurance if he or she seeks entitlement to hospital insurance on the basis of—

(1) The transitional provisions set forth in § 406.11;

(2) Deemed entitlement to disabled widow's or widower's benefit under certain circumstances as provided in § 406.12;

(3) A diagnosis of end-stage renal disease, as specified in § 406.13;

(4) Effective January 1, 1981, eligibility for social security cash benefits, as specified in § 406.10(a)(3), if the individual has attained age 65 without applying for those benefits; or

(5) The special provisions applicable to government employment as set forth in § 406.15.

(d) *When application is deemed to be filed.* (1) An application based on the transitional provisions or on ESRD is deemed to be filed in the first month of eligibility if it is filed not more than 3 months before the first month, and is retroactive to that month if filed within 12 months after the first month. An application filed more than 12 months after the first month of eligibility is retroactive to the 12th month before the month it is filed.

(2) An application for deemed entitlement to disabled widow's or widower's benefits, that is filed before the first month in which the individual meets all conditions of entitlement for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed. An application validly filed within 12 months after the first month of eligibility is retroactive to that first month. If filed more than 12 months after that first month, it is retroactive to the 12th month before the month of filing.

(3) Effective June 8, 1980, an application based on eligibility for social security benefits at or after age 65, that is filed before the first month in which the individual meets all eligibility conditions for this benefit, will be deemed a valid application if those conditions are met before an initial determination, reconsideration, or hearing decision is made on the application. If the conditions are met after the date of any hearing decision, a new application will have to be filed.

(4) Effective March 1, 1981, an application under § 406.10 that is validly filed within 6 months after the first month of eligibility is retroactive to that first month. If filed more than 6 months after that first month, it is retroactive to the 6th month before the month of filing.

(e) *Individuals who must enroll for hospital insurance.* An individual who must pay a monthly premium for hospital insurance must enroll in accordance with the procedures set forth in § 406.21.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 53 FR 47202, Nov. 22, 1988; 61 FR 40345, Aug. 2, 1996]

§ 406.7 Forms to apply for entitlement under Medicare Part A.

Forms used to apply for Medicare entitlement are available free of charge by mail from CMS or at any Social Security branch or district office or online at the CMS and SSA websites. An individual who files an application for monthly social security cash benefits as defined in § 400.200 of this chapter also applies for Medicare entitlement if he or she is eligible for hospital insurance at that time.

[87 FR 66503, Nov. 3, 2022]

Subpart B—Hospital Insurance Without Monthly Premiums

§ 406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.

(a) *Requirements.* An individual is entitled to hospital insurance benefits under section 226 of the Act if he or she has attained aged 65 and is:

(1) Entitled to monthly social security benefits under section 202 of the Social Security Act;

(2) A qualified railroad retirement beneficiary who has been certified as such to the Social Security Administration by the Railroad Retirement Board in accordance with section 7(d) of the Railroad Retirement Act of 1974; or

(3) Effective January 1, 1981, eligible for monthly social security benefits under section 202 of the Act and has filed an application for hospital insurance.

(b) *Beginning and end of entitlement.* (1) Entitlement begins with the first day of the first month in which the individual meets the requirements of paragraph (a) of this section.

(2) Entitlement continues until the individual dies or no longer meets the requirements of paragraph (a) of this section. An individual is not entitled to railroad retirement benefits and is neither entitled to, nor eligible for, monthly social security benefits in the month in which he or she dies. However, an individual who meets all other requirements for hospital insurance entitlement is entitled to hospital insurance in the month in which he or she dies if he or she—

(i) Would have been entitled to monthly railroad retirement benefits or social security benefits in that month if he or she had not died; or

(ii) Has filed an application for hospital insurance and would have been eligible for monthly social security benefits in that month if he or she had not died.

§ 406.11 Individual age 65 or over who is not eligible as a social security or railroad retirement benefits beneficiary, or on the basis of government employment.

(a) *Basis.* Section 103 of the law that established the Medicare program in 1965 (Pub. L. 89–97) provided for eligibility for certain individuals who were age 65 or would soon attain age 65 but would not be able to qualify for social security or railroad retirement benefits.

(b) *Requirements.* Unless he or she is excluded under paragraph (c) of this section, an individual age 65 or over who does not meet the requirements of § 406.10 or § 406.15 (and who would not meet those requirements if he or she filed an application), is entitled to Medicare Part A benefits if he or she meets the following requirements:

(1) *Age and quarters of coverage.* (i) He or she attained age 65 before 1968; or

(ii) If he or she attained age 65 in 1968 or later, he or she must have at least 3 quarters of coverage for each year that elapsed after 1966 and before the year in which he or she attained age 65. (The quarters of coverage may have been acquired at any time, not necessarily during the elapsed years.)

(2) *Residence and citizenship.* He or she is a resident of the United States and—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has continuously resided in the United States for 5 years immediately preceding the first month in which he or she meets all other requirements for entitlement to hospital insurance.

(3) *Application.* He or she has filed an application for Medicare Part A no earlier than the third month before the first month of eligibility.

(c) *Bases for exclusion.* An individual who meets the requirements of paragraph (b) of this section is excluded from Medicare Part A if he or she—

(1) Has been convicted of spying, sabotage, or treason, sedition, and subversive action under chapter 37, 105, or 115 of title 18 of the United States Code;

(2) Has been convicted of conspiracy to establish a dictatorship under section 4 of the Internal Security Act of 1950;

(3) On February 16, 1965, was or could have been covered under the Federal Employees Health Benefits Act (FEHBA) of 1959; or

(4) In his or her first month of eligibility;

(i) Is covered by an enrollment under the FEHBA; or

(ii) Could have been covered by an enrollment under that Act if he or she (or any other person who could provide him or her with coverage) was a Federal employee at any time after February 15, 1965, and had enrolled and retained coverage under that Act.

(d) *End of exclusion.* An individual excluded under paragraph (c)(3) or (4) of this section can become entitled beginning with the first month in which he or she loses the right to FEHBA coverage solely because he or she or the other person leaves Federal employment.

(e) *Beginning and end of entitlement.* (1) Entitlement begins—

(i) In the first month of eligibility if the application is filed no later than 12 months after the first month of eligibility:

(ii) In the 12th month before the month of application if the application is filed more than 12 months after the first month of eligibility.

(2) Entitlement continues until death or until the month before the month in which the individual becomes entitled under § 406.10 or § 406.15.

[48 FR 12536, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 53 FR 47202, Nov. 22, 1988]

§ 406.12 Individual under age 65 who is entitled to social security or railroad retirement disability benefits.

(a) *Basic requirements.* An individual under age 65 is entitled to hospital insurance benefits if, for 25 months, he or she has been—

(1) Entitled or deemed entitled to social security disability benefits as an insured individual, child, widow, or widower who is ''under a disability'' or

(2) A disabled qualified beneficiary certified under Section 7(d) of the Railroad Retirement Act.

(b) *Previous periods of disability benefits entitlement.* Months of a previous period of entitlement or deemed entitlement to disability benefits count toward the 25-month requirement if any of the following conditions is met:

(1) Entitlement was as an insured individual or a disabled qualified railroad retirement beneficiary, and the previous period ended within the 60 months preceding the month in which the current disability began.

(2) Entitlement was as a disabled child, widow, or widower, and the previous period ended within the 84 months preceding the month in which the current disability began.

(3) The previous period ended on or after March 1, 1988 and the current impairment is the same as, or directly related to, the impairment on which the previous period of entitlement was based.

(c) *Deemed entitlement to disabled widow's or widower's monthly benefits*—(1) *Purpose.* The provisions of paragraphs (c) (2), (3), and (4) of this section are intended to enable individuals—

(i) To meet the 25-month requirement of paragraph (a) of this section; or

(ii) To retain hospital insurance entitlement when they are no longer entitled to monthly disability benefits.

(2) *Deemed entitlement for certain individuals entitled to old-age insurance benefits.* An individual who becomes entitled to monthly old-age insurance benefits before age 65, is, by law, precluded from establishing or retaining entitlement to disabled widow's or widower's monthly benefits. However, for purposes of meeting the 25-month requirement, a widow or widower who meets all other requirements for disability benefits and is excluded solely because of entitlement to old-age insurance benefits, shall be deemed to be (or to continue to be) entitled to disability benefits. A widow or widower who is not entitled to disability benefits for the month before attaining age 60 must file two applications, one for old-age insurance benefits and one for hospital insurance.

(3) *Deemed entitlement for certain individuals entitled to mother's benefits.* An individual entitled to mother's insurance benefits under section 202(g) of the Social Security Act cannot at the same time be entitled to disabled widow's benefits. However, if she applies for hospital insurance, she will be deemed to be entitled to disabled widow's monthly benefits in the first month (of the 12 months before application) in which she would have been entitled to those benefits if she had filed an application for them.

(4) *Deemed entitlement for certain individuals entitled to father's benefits.* An individual who is entitled to father's insurance benefits under section 202(g) of the Act cannot at the same time be entitled to disabled widower's benefits. However, if he applies for hospital insurance benefits, he will be deemed to be entitled to disabled widower's monthly benefits as follows:

(i) If he applied for hospital insurance benefits before May 1984, he was deemed entitled to disabled widower's benefits for any month after April 1981 for which he would have been entitled to those benefits if he had filed an application for them.

(ii) If he applies for hospital insurance benefits in or after May 1984, he is deemed entitled to disabled widower's benefits for any month, up to 12 months before the month of application, for which he would have been entitled to those benefits if he had filed an application for them.

(iii) Hospital insurance entitlement under this paragraph (c)(4) could not begin before May 1983.

(5) *Deemed retroactive entitlement for certain disabled widows and widowers.* In some cases, disabled widows or widowers cannot become entitled to monthly cash benefits before the month in which they file application. However, for purposes of meeting the 25-month requirement, disability benefit entitlement will be deemed to have begun with the earliest month (of the 12 months before the application for cash benefits) in which the individual met all the requirements except the filing of an application. (This provision is effective for applications filed on or after January 1, 1978.)

(d) *When entitlement begins and ends.* (1) Entitlement to hospital insurance begins with the 25th month of an individual's entitlement or deemed entitlement to disability benefits. Although an individual is not entitled to disability benefits for the month in which he or she dies, for purposes of this paragraph the individual will be deemed to be entitled for the month of death.

(2) Except as provided in paragraph (e) of this section, entitlement to hospital insurance ends with the earliest of the following:

(i) The last day of the last month in which he or she was entitled or deemed entitled to disability benefits or was qualified as a disabled railroad retirement beneficiary, if he or she was notified of the termination of entitlement before that month.

(ii) The last day of the month following the month in which he or she is mailed a notice that his or her entitlement or deemed entitlement to disability benefits, or his or her status as a qualified disabled railroad retirement beneficiary, has ended.

(iii) The last day of the month before the month he or she attains age 65. (An individual who is entitled to social security or railroad retirement cash benefits for the month of attainment of age 65 is automatically entitled to hospital insurance under § 406.10.)

(iv) The day of death.

(e) *Continuation of Medicare entitlement when disability benefit entitlement* ends because of substantial gainful activity (SGA)—(1) *Definitions.* As used in this section—

Trial work period means the 9-month period provided under title II of the Act and as defined 20 CFR 404.1592, during which the individual may test his or her ability to work and still receive disability cash benefits; and

Reentitlement period means a period as defined in 20 CFR 404.1592a that begins with the first month after the trial work period and ends with the 36th month after the trial work period or, if earlier, with the first month in which the impairment no longer exists or is no longer disabling. (During the reentitlement period, benefits may be discontinued because of SGA. However, if SGA is later discontinued, benefits may be reinstated without a new application and a new disability determination.)

(2) *Duration of continued Medicare entitlement.* If an individual's entitlement to disability benefits or status as a qualified disabled railroad retirement beneficiary ends because he or she engaged in, or demonstrated the ability to engage in, substantial gainful activity after the 36 months following the end of the trial work period, Medicare entitlement continues until the earlier of the following:

(i) The last day of the 78th month following the first month of substantial gainful activity occurring after the 15th month of the individual's reentitlement period or, if later, the end of the month following the month the individual's disability benefit entitlement ends.

(ii) The last day of the month following the month in which notice is mailed to the individual indicating that he or she is no longer entitled to hospital insurance because of an event or circumstance (for example, there has been medical improvement, or the disabled widow has remarried) that would terminate disability benefit entitlement if it had not already been terminated because of substantial gainful activity.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47202, Nov. 22, 1988; 56 FR 38078, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991; 61 FR 40345, Aug. 2, 1996; 69 FR 57225, Sept. 24, 2004]

§ 406.13 Individual who has end-stage renal disease.

(a) *Statutory basis and applicability.* This section explains the conditions of entitlement to hospital insurance benefits on the basis of end-stage renal disease, and specifies the beginning and end of the period of entitlement. It implements section 226A of the Social Security Act.

(b) *Definitions.* As used in this section:

End-stage renal disease (ESRD) means that stage of kidney impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life.

Child or *spouse* means a child or spouse whose relationship to the parent or spouse meets the relationship requirements for entitlement to child's monthly social security benefits or to wife's, husband's, widow's, widower's, mother's or father's monthly benefits, as set forth in 20 CFR part 404. However, the duration of relationship requirements apply only to divorced spouses. (See 20 CFR 404.331.)

Dependent child means a person who, on the first day he or she has end-stage renal disease, is unmarried and meets the dependency requirements for entitlement to child's social security benefits on the basis of a parent's earnings (see 20 CFR 404.350–404.365) and who—

(1) Is under age 22;

(2) Is under a disability that began before age 22; or

(3) Is under age 26, is receiving at least one-half support from that parent, and has continuously received at least one-half support from that parent since the day before attaining age 22.

One-half support means regular contributions, in cash or in kind, that equals or exceeds one-half of the child's total support.

(c) *Requirements.* An individual is entitled to hospital insurance benefits if—

(1) He or she is medically determined to have ESRD;

(2) He or she is:

(i) Fully or currently insured under the social security program (title II of the Act) or would be fully or currently insured if his or her employment (after 1936) as defined under the Railroad Retirement Act were considered ''employment'' under the Social Security Act;

(ii) Entitled to monthly social security or railroad retirement benefits; or

(iii) The spouse or dependent child of a person who meets the requirements of paragraph (c)(2)(i) or (c)(2)(ii) of this section;

(3) He or she has filed an application for Medicare Part A; and

(4) He or she has satisfied the waiting period explained in paragraph (e) of this section.

(d) *Filing an application.* (1) An individual may obtain an application form, and help in completing it, from any social security office.

(2) An application is not valid if it is filed earlier than the third month before the month in which the individual meets the conditions of paragraphs (c)(1), (c)(2), and (c)(4) of this section.

(3) If an individual who has ESRD dies before he or she has filed an application, or is unable to file because of physical or mental condition, a relative or other person responsible for his or her affairs may file in his or her behalf. If a responsible person is not available, the hospital or dialysis facility that furnished treatment may file the application.

(e) *Beginning of entitlement*—(1) *Basic limitations.* Entitlement can begin no earlier than the first month in which the individual meets the conditions specified in paragraph (c) of this section, or the 12th month before the month of application, whichever is later.

(2) *Waiting period.* Entitlement begins on the first day of the third month after the month in which the individual initiates a regular course of renal dialysis, if the course is maintained throughout the waiting period, unless entitlement would begin earlier under paragraph (e) (3) or (4) of this section. This means that if dialysis began in January, entitlement would begin April 1.

(3) *Exceptions: Early kidney transplant.* If the individual receives a transplant, entitlement begins with the first day of the month in which the transplant was performed. However, if the individual

is admitted as an inpatient to a hospital that is an approved renal transplantation center or renal dialysis center (see § 405.2102) for procedures preliminary to transplant surgery, entitlement begins—

(i) On the first day of the month in which he or she initially enters the hospital, if the transplant is performed in that month or in either of the next 2 months; or

(ii) On the first day of the second month before the month of kidney transplantation, if the transplant is delayed more than 2 months after the month of initial hospital stay.

For example, if an individual enters the hospital in January, and the transplant is performed in January, February, or March, entitlement would begin January 1. However, if the transplant is performed in April, entitlement would begin February 1.

(4) *Exceptions: Self-dialysis training.* Entitlement begins on the first day of the month in which a regular course of renal dialysis began if:

(i) Before the end of the waiting period, the individual participates in a self-dialysis training program offered by a participating Medicare facility that is approved to provide such training;

(ii) The patient's physician has certified that it is reasonable to expect the individual will complete the training program and will self-dialyze on a regular basis; and

(iii) The regular course of dialysis is maintained throughout the time that would otherwise be the waiting period (unless it is terminated earlier because the individual dies).

(f) *End of entitlement.* Entitlement ends with—

(1) The end of the 12th month after the month in which a regular course of dialysis ends; or

(2) The end of the 36th month after the month in which the individual received a kidney transplant. Beginning January 1, 2023, an individual who is no longer entitled to Part A benefits due to this paragraph may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55 of this subchapter.

(g) *Resumption of entitlement.* Entitlement is resumed under the following conditions:

(1) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 12-month period after the previous course of dialysis ended is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis is resumed or the month the kidney is transplanted.

(2) An individual who initiates a regular course of renal dialysis or has a kidney transplant during the 36-month period after an earlier kidney transplant is entitled to Part A benefits and eligible to enroll in Part B with the month the regular course of dialysis begins or with the month the subsequent kidney transplant occurs.

(3) An individual who initiates a regular course of renal dialysis more than 12 months after the previous course of regular dialysis ended or more than 36 months after the month of a kidney transplant is eligible to enroll in Part A and Part B with the month in which the regular course of dialysis is resumed. If he or she is otherwise entitled under the conditions specified in paragraph (c) of this section, including the filing of an application, entitlement begins with the month in which dialysis is initiated or resumed, without a waiting period, subject to the limitations of paragraph (e)(1) of this section.

[48 FR 12536, Mar. 25, 1983, as amended at 60 FR 22535, May 8, 1995; 87 FR 66503, Nov. 3, 2022]

§ 406.15 Special provisions applicable to Medicare qualified government employment.

(a) *Definition.* As used in this section, *Medicare-qualified government employment* means Federal, State, or local government employment that is subject only to the hospital insurance portion of the tax imposed by the Federal Insurance Contributions Act (F.I.C.A.). This includes—

(1) Wages paid for Federal employment after December 1982.

(2) Wages paid to State and local government employees hired after March 31, 1986.

(3) Wages paid to State and local government employees hired before April 1, 1986 but whose employment after March 31, 1986 is covered, for Medicare purposes only, under an agreement under section 218 of the Act.

(b) *Crediting of wages that are taxable only for Medicare purposes.* Medicare qualified government employment is credited in the same way and in the same amount as social security covered employment is credited for monthly social security cash benefit purposes. However, since only the Medicare portion (not the social security portion) of the F.I.C.A. tax is imposed, Medicare qualified government employment does not help qualify the individual for monthly Social Security cash benefits.

(c) *Required quarters of coverage.* (1) To qualify for hospital insurance on the basis of Medicare qualified government employment, an individual must have the number of quarters of coverage necessary to qualify for hospital insurance under § 406.10, § 406.12, or § 406.13.

(2) An individual who has worked in Medicare qualified government employment may qualify for hospital insurance on the basis of Medicare qualified government employment exclusively, or a combination of Medicare qualified government employment and social security covered employment.

(d) *Transitional provision for Federal employment.* Any individual who was a Federal employee at any time both during and before January 1983 will receive credit for quarters of Federal employment before January 1983 without paying tax. This transitional provision applies even if the Federal employee did not receive Federal wages for January 1983, for instance, because he or she was on approved leave without pay or on loan to a State or foreign agency.

(e) *Conditions of entitlement.* An individual who has worked in Medicare qualified government employment (or any related individual who would be entitled to social security cash benefits on the employee's record if Medicare qualified government employment qualified for those benefits) is entitled to hospital insurance benefits if he or she—

(1) Would meet the requirements of § 406.10, § 406.12, or § 406.13 if Medicare qualified government employment were social security covered employment; and

(2) Has filed an application for hospital insurance.

For purposes of this section not more than 12 months before the month of application may be counted towards the 25-month qualifying period specified in § 406.12(a).

(f) *Beginning and end of entitlement—*(1) *Basic rule.* Subject to the limitations specified in paragraph (f)(2) and (f)(3) of this section, entitlement begins and ends as specified in § 406.10, § 406.12 or § 406.13, whichever is used to establish hospital insurance entitlement for the Federal, State, or local government employee or related individual.

(2) *Limitations: Federal government employment.* (i) Hospital insurance entitlement based on Federal employment could not begin before January 1983.

(ii) No months before January 1983 may be used to satisfy the qualifying period required for entitlement based on disability.

(3) *Limitations: State and local government employment.* (i) Hospital insurance entitlement based on State or local government employment cannot begin before April 1986.

(ii) No months before April 1986 may be used to satisfy the qualifying period required for entitlement based on disability.

[53 FR 47202, Nov. 22, 1988]

Subpart C—Premium Hospital Insurance

§ 406.20 Basic requirements.

(a) *General provisions.* Hospital insurance benefits are available to most individuals age 65 or over and to certain individuals under age 65 who do not qualify for those benefits under subpart B of this part and are willing to pay a monthly premium. This is called premium hospital insurance.

(b) *Eligibility of individuals age 65 or over to enroll for premium hospital insurance.* Any individual is eligible to enroll for Medicare Part A if he or she—

(1) Has attained age 65;

(2) Is a resident of the United States and is either—

(i) A citizen of the United States; or

(ii) An alien lawfully admitted for permanent residence who has resided in the United States continuously for the 5-year period immediately preceding the month in which he or she meets all other requirements;

(3) Is not eligible for Part A benefits under subpart B of this part; and

(4) Is entitled to supplementary medical insurance (Part B of Medicare) or is eligible and has enrolled for it during an enrollment period.

(c) *Eligibility of individuals under age 65 to enroll for premium hospital insurance.* An individual who has not attained age 65 is eligible to enroll for Medicare Part A if he or she meets the following conditions:

(1) Has been entitled to Medicare Part A (under § 406.12 or § 406.15) on the basis of entitlement or deemed entitlement to social security disability benefits, as provided under section 226(b) of the Act.

(2) Continues to have a disabling physical or mental impairment.

(3) Loses entitlement to disability benefits (and therefore also loses entitlement to Medicare Part A under § 406.12) solely because his or her earnings exceed the amount allowed under the social security regulations pertaining to ''substantial gainful activity'' (20 CFR 404.1571–404.1574); and

(4) Is not otherwise entitled to Medicare Part A.

[56 FR 38078, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991]

§ 406.21 Individual enrollment.

(a) *Basic provision.* An individual who meets the requirements of § 406.20(b) or (c), except as provided in § 406.26(b)(2), may enroll for premium hospital insurance only during his or her—

(1) Initial enrollment period as set forth in paragraph (b) of this section;

(2) A general enrollment period as set forth in paragraph (c) of this section;

(3) A special enrollment period as set forth in §§ 406.24, 406.25, and 406.27; or

(4) For HMO/CMP enrollees, a transfer enrollment period as set forth in paragraph (f) of this section.

(b) *Initial enrollment periods*—(1) *Initial enrollment period for individual age 65 or over.* The initial enrollment period extends for 7 months, from the third month before the month the individual first meets the requirements of § 406.20 (b)(1) through (b)(3) through the third month after that first month of eligibility.

(2) *Initial enrollment period of individual under age 65.* The initial enrollment period begins with the month in which the individual receives notice that entitlement to Medicare Part A will end because he or she has lost entitlement to disability benefits solely because of earnings in excess of the amounts allowed under the social security regulations on substantial gainful activity (20 CFR 404.1571–404.1574). It continues for 7 full months after that month.

(c) *General enrollment period.* (1) Except as specified in paragraph (c)(4) of this section, the general enrollment period extends from January 1 to March 31 of each calendar year.

(2) General enrollment periods are for individuals who do not enroll during the special enrollment period, who failed to enroll during the initial enrollment period, or whose previous period of entitlement had terminated.

(3) If the individual enrolls or reenrolls during a general enrollment period—

(i) Before January 1, 2023, his or her entitlement begins on July 1 of the calendar year; or

(ii) On or after January 1, 2023, his or her entitlement begins on the first day of the month after the month of enrollment.

(4) During the period April 1 through September 30, 1981, the general enrollment period was any time after the end of the individual's initial enrollment period. Any eligible individual whose initial enrollment period has ended, or whose previous period of entitlement had terminated, could enroll or reenroll during that 6-month period.

(5) If an individual resides in a State that pays premium hospital insurance for Qualified Medicare Beneficiaries under § 406.32(g) and enrolls or reenrolls during a general enrollment period after January 1, 2023, QMB coverage is effective the month entitlement begins (if the individual is determined eligible for QMB before the month following the month of enrollment), or a month

later than the month entitlement begins (if the individual is determined eligible for QMB the month entitlement begins or later).

(d) *''Deemed'' initial enrollment period for individual age 65 or over.* (1) If an individual who has attained age 65 fails to enroll during the initial enrollment period because of reliance on incorrect documentary information which led him or her to believe that he or she was not yet age 65, an initial enrollment period may be established for him or her as though he or she had attained age 65 on the date indicated by the incorrect documentary information.

(2) The deemed initial enrollment period will be used to determine the individual's premium and right to enroll in a general enrollment period if such use is advantageous to the individual.

(e) [Reserved]

(f) *Transfer enrollment period for HMO/CMP enrollees*—(1) *Terminology. HMO* or *CMP* means an eligible organization as defined in §417.401 which has a contract with CMS under part 417, subpart L of this chapter.

(2) *Basic rule.* Effective February 1, 1991, individuals enrolled in an HMO or CMP under part 417, subpart K of this chapter who meet the requirements of §406.20(b) may enroll in premium hospital insurance during a transfer enrollment period. This transfer enrollment period begins with any month or any part of a month in which the individual is enrolled in an HMO or CMP and ends with the last day of the 8th consecutive month in which the individual is no longer enrolled in the HMO or CMP.

(3) *Effective date of coverage.* (i) If the individual enrolls in premium hospital insurance while still enrolled in an HMO or CMP, or during the first month that he or she is no longer enrolled in the HMO or CMP, part A coverage will begin on the first day of the month of part A enrollment, or, at the option of the individual, on the first day of any of the following 3 months.

(ii) If the individual enrolls in premium hospital insurance during any of the last 7 months of the transfer enrollment period, coverage will begin on the first day of the month after the month of enrollment.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988; 56 FR 38079, Aug. 12, 1991; 57 FR 36014, Aug. 12, 1992; 61 FR 40345, Aug. 2, 1996; 87 FR 66503, Nov. 3, 2022; 88 FR 65269, Sept. 21, 2023]

§ 406.22 Effect of month of enrollment on entitlement.

(a) *Individual age 65 or over.* For an individual who has attained age 65, before January 1, 2023, the following rules apply:

(1) If the individual enrolls during the 3 months before the first month of eligibility, entitlement begins with the first month of eligibility.

(2) If the individual enrolls in the first month of eligibility, entitlement begins with the following month.

(3) If the individual enrolls during the month after the first month of eligibility, entitlement begins with the second month after the month of enrollment.

(4) If the individual enrolls in either of the last 2 months of the enrollment period, entitlement begins with the third month after the month of enrollment.

(b) *Individual age 65 or over.* For an individual who has attained age 65 on or after January 1, 2023, the following rules apply:

(1) If the individual enrolls during the first 3 months of their initial enrollment period, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the last 4 months of their initial enrollment period, entitlement begins with the month following the month of enrollment.

(c) *Individual under age 65.* For an individual who has not attained age 65 and who satisfies the requirements of §406.20(c) before January 1, 2023, the following rules apply:

(1) If the individual enrolls before the month in which he or she meets the requirements of §406.20(c), entitlement begins with the month in which the individual meets those requirements.

(2) If the individual enrolls in the month in which he or she first meets the requirements of §406.20(c), entitlement begins with the following month.

(3) If the individual enrolls in the month following the month in which he or she meets the requirements of § 406.20(c), entitlement begins with the second month after the month of enrollment.

(4) If the individual enrolls more than one month after the month in which he or she first meets the requirements of § 406.20(c), entitlement begins with the third month after the month of enrollment.

(d) *Individual under age 65.* For an individual who has not attained age 65 and who first satisfies the requirements of § 406.20(c) on or after January 1, 2023, the following rules apply:

(1) For individuals who enroll during the first 3 months of their IEP, entitlement begins with the first month of eligibility.

(2) If an individual enrolls during the month in which they first become eligible or any subsequent month of their IEP, entitlement begins with month following the month of enrollment.

[56 FR 38079, Aug. 12, 1991, as amended at 87 FR 66503, Nov. 3, 2022]

§ 406.24 Special enrollment period related to coverage under group health plans.

(a) *Terminology.* As used in this subpart, the following terms have the indicated meanings.

(1) *Current employment status* has the meaning given this term in § 411.104 of this chapter.

(2) *Family member* has the meaning given this term in § 411.201 of this chapter.

(3) *Group health plan (GHP)* and *large group health plan (LGHP)* have the meanings given those terms in § 411.101 of this chapter, except that the ''former employee'' language of those definitions does not apply with respect to SEPs because—

(i) Section 1837(i)(1)(A) of the Act explicitly requires that GHP coverage of an individual age 65 or older, be by reason of the individual's (or the individual's spouse's) current employment status; and

(ii) The sentence following section 1837(i)(1)(B), of the Act refers to ''large group health plan''. Under section 1862(b)(1)(B)(i), as amended by OBRA '93, LGHP coverage of a disabled individual must be ''by virtue of the individual's or a family member's current employment status with an employer''.

(4) *Special enrollment period (SEP)* is a period provided by statute to enable certain individuals to enroll in Medicare without having to wait for the general enrollment period.

(b) *Duration of SEP.*[2] (1) The SEP includes any month during any part of which—

(i) An individual over age 65 is enrolled in a GHP by reason of the current employment status of the individual or the individual's spouse; or

(ii) An individual under age 65 and disabled—

(A) Is enrolled in a GHP by reason of the current employment status of the individual or the individual's spouse; or

(B) Is enrolled in an LGHP by reason of the current employment status of the individual or a member of the individual's family.

(2) The SEP ends on the last day of the eighth consecutive month during which the individual is at no time enrolled in a GHP or an LGHP by reason of current employment status.

(c) *Conditions for use of a SEP.*[3] In order to use a SEP, the individual must meet the following conditions:

(1) When first eligible to enroll for premium hospital insurance under § 406.20(b) or (c), the individual was—

(i) Age 65 or over and covered under a GHP by reason of the current employment status of the individual or the individual's spouse;

(ii) Under age 65 and covered under an LGHP by reason of the current employment status of the individual or a member of the individual's family ; or

(iii) Under age 65 and covered under a GHP by reason of the current employment status of the individual or the individual's spouse.

[2] Before March 1995, SEPs began on the first day of the first month the individual was no longer covered under a GHP or LGHP by reason of current employment status.

[3] Before August 10, 1993, an individual under age 65 could qualify for a SEP only if he or she had LGHP coverage as an ''active individual'', which the statute defined as ''an employee, employer, self-employed individual (such as the employer), individual associated with the employer in a business relationship, or as a member of the family of any of those persons''.

(2) For all the months thereafter, the individual has maintained coverage either under hospital insurance or a GHP or LGHP.

(d) *Special rule: Additional SEPs.* (1) Generally, if an individual fails to enroll during any available SEP, he or she is not entitled to any additional SEPs.

(2) However, if an individual fails to enroll during a SEP, because coverage under the same or a different GHP or LGHP was restored before the end of that particular SEP, that failure to enroll does not preclude additional SEPs.

(e) *Effective date of coverage.* (1) If the individual enrolls in a month during any part of which he or she is covered under a GHP or LGHP on the basis of current employment status, or in the first full month when no longer so covered, coverage begins on the first day of the month of enrollment or, at the individual's option, on the first day of any of the three following months.

(2) If the individual enrolls in any month of the SEP other than the months specified in paragraph (e)(1) of this section, coverage begins on the first day of the month following the month of enrollment.

[61 FR 40346, Aug. 2, 1996]

§ 406.25 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual that meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of Internal Revenue Code of 1986.

(3) The individual can demonstrate that he or she has health insurance that covers medical services that the individual receives outside the United States while serving in the program.

(4) The individual—

(i) At the time he or she first met the requirements of § 406.10 through 406.15 or § 406.20(b), elected not to enroll in premium hospital insurance during the individual's initial enrollment period; or

(ii) Terminated enrollment in premium hospital insurance during a month in which the individual met the requirements of this section for a SEP.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer meets the requirements of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section begins on the first day of the month following the month in which the individual enrolls.

[73 FR 36468, June 27, 2008]

§ 406.26 Enrollment under State buy-in.

(a) *Enrollment of QMBs under a State buy-in agreement*—(1) *Effective date.* Beginning with calendar year 1990, a State may request and be granted a modification of its buy-in agreement to include enrollment and payment of Part A premiums for QMBs (as defined in section 1905(p)(1) of the Act) who can become entitled to Medicare Part A only by paying a premium.

(i) Any State that has a buy-in agreement in effect must participate in daily exchanges of enrollment data with CMS.

(ii) [Reserved]

(2) *Amount of premium.* Premiums paid under State buy-in are not subject to increase because of late enrollment or reenrollment.

(3) *Enrollment without discrimination.* A State that has a buy-in agreement in effect must enroll in premium health insurance any applicant who meets the eligibility requirement for the QMB eligibility group, with the State paying the premiums on the individual's behalf.

(b) *Beginning of coverage under buy-in.* The coverage period begins with the latest of the following:

(1) The third month following the month in which the agreement modification covering QMBs is effectuated.

(2) The first month in which the individual is entitled to premium hospital insurance under § 406.20(b) and has QMB

status. Under a State buy-in agreement, as defined in § 407.40 of this subchapter, QMB-eligible individuals can enroll in premium hospital insurance at any time of the year, without regard to Medicare enrollment periods.

(3) The date specified in the agreement modification.

(c) *End of coverage under buy-in.* Buy-in coverage ends with the earlier of the following:

(1) *Death.* Coverage ends on the last day of the month in which the QMB dies.

(2) *Loss of QMB status.* If the individual loses eligibility for QMB status, coverage ends on the last day of the month in which CMS receives the State's notice of ineligibility.

(3) *Termination of buy-in agreement.* If the State's buy-in agreement is terminated, coverage ends on the last day of the last month for which the agreement is in effect.

(4) *Entitlement to premium-free Part A.* If the individual becomes entitled to premium-free Part A, buy-in coverage ends on the last day of entitlement to premium Part A.

(d) *Continuation of coverage: Individual enrollment following termination of buy-in coverage*—(1) *Deemed enrollment.* If coverage under a buy-in agreement ends because the agreement is terminated or the individual loses QMB status, the individual—

(i) Is considered to have enrolled during his or her initial enrollment period; and

(ii) Is entitled to Part A benefits and liable for Part A premiums beginning with the first month for which he or she is no longer covered under the buy-in agreement.

(2) *Voluntary termination.* (i) An individual may voluntarily terminate entitlement acquired under paragraph (d)(1) of this section by filing, with SSA or CMS, a request for disenrollment.

(ii) Voluntary disenrollment is effective as follows:

(A) If the individual files a request within 30 days after the date of CMS's notice that buy-in coverage has ended, the individual's entitlement ends on the last day of the last month for which the State paid the premium.

(B) If the individual files the request more than 30 days but not more than 6 months after buy-in coverage ends, entitlement ends on the last day of the month in which the request is filed.

(C) If the individual files the request later than the 6th month after buy-in coverage ends, entitlement ends at the end of the month after the month in which request is filed.

[56 FR 38080, Aug. 12, 1991, as amended at 85 FR 25632, May 1, 2020; 87 FR 66504, Nov. 3, 2022]

§ 406.27 Special enrollment periods for exceptional conditions.

(a) *General rule.* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4), are provided for individuals that missed a Medicare enrollment period, (as specified in § 406.21, § 406.24, or § 406.25), due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e) of this section.

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, State, or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they (or their SSA-authorized representative as defined at 42 CFR 405.910), their legal guardian, or person who makes healthcare decisions on behalf of that individual reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual (or the individual's authorized representative, legal guardian, or person who makes healthcare decisions on behalf of that individual) must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the

start date identified in such declaration. The SEP ends 6 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in premium Part A is unintentional, inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, agents or brokers of health plans, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate (by documentation or written attestation) both of the following:

(i) He or she did not enroll in premium Part A during another enrollment period in which they were eligible based on information received from an employer or GHP, agents or brokers of health plans, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP, agent or broker of a health plan, or their representative materially misrepresented information or provided incorrect information relating to enrollment in premium Part A.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation and ends 6 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from the custody of penal authorities as described in § 411.4(b) of this subchapter on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or re-enroll in Medicare premium Part A due to being in custody of penal authorities and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement retroactive to the month of their release from incarceration provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31). The retroactive period cannot exceed 6 months.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that—

(i) They are eligible for premium Part A under § 406.5(b); and

(ii) Their Medicaid eligibility is terminated on or after January 1, 2023, or is terminated after the last day of the Coronavirus Disease 2019 public health emergency (COVID–19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs—

(i) After the last day of the COVID–19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is after the last day of the COVID–19 PHE or on after January 1, 2023, whichever is earlier.

(ii) *Special COVID–19 PHE rule.* An individual whose Medicaid eligibility is terminated after the end of the COVD–19 PHE, but before January 1, 2023 (if applicable), has the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31).

(iii) *Other special rule.* After January 1, 2023, an individual has the option of requesting entitlement for a retroactive period back to the date of termination from Medicaid provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID–19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 406.32(d) reimbursed and ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in premium Part A.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case-by-case basis, but will be no less than 6 months.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

[87 FR 66504, Nov. 3, 2022]

§ 406.28 End of entitlement.

Any of the following actions or events ends entitlement to premium hospital insurance:

(a) *Filing of request for termination.* The beneficiary may at any time give CMS or the Social Security Administration written notice that he or she no longer wishes to participate in the premium hospital insurance program.

(1) If he or she files the notice before entitlement begins, he or she will be deemed not to have enrolled.

(2) If he or she files the notice after entitlement begins, that entitlement will end at the close of the month following the month in which he or she filed the notice.

(b) *Eligibility for hospital insurance without premiums.* (1) If an individual meets the eligibility requirements for hospital insurance specified in § 406.10, § 406.11, § 406.13 or § 406.15, entitlement to premium hospital insurance ends with the month before the month in which he or she meets those requirements.

(2) If an individual meets the requirements of § 406.10, § 406.11, § 406.13, or § 406.15, he or she will be deemed to have filed the required application for hospital insurance benefits in his or her first month of eligibility under that section.

(c) *End of entitlement to supplementary medical insurance (SMI) for individual who has attained age 65.* In the case of an individual enrolled on the basis of § 406.20(b), entitlement to premium hospital insurance ends on the same date that entitlement to SMI ends.

(d) *Nonpayment of premium.* (1) If an individual fails to pay the premium bill, entitlement will end on the last day of the third month after the billing month.

(2) CMS may reinstate entitlement if the individual shows good cause for failure to pay on time, and pays all overdue premiums within 3 calendar months after the date specified in paragraph (d)(1) of this section.

(e) *Death.* Entitlement ends with the day of death. (A premium is due for the month of death.)

(f) *End of disabling impairment for individual under age 65.* In the case of an individual enrolled on the basis of § 406.20(c), entitlement to premium hospital insurance ends on the last day of the month after the month in which

the individual is notified that he or she no longer has a disabling impairment.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47204, Nov. 22, 1988. Redesignated and amended at 56 FR 38080, Aug. 12, 1991]

§ 406.32 Monthly premiums.

(a) *Promulgation and effective date.* Beginning with 1984, premiums are promulgated each September, effective for the succeeding calendar year.

(b) *Monthly premiums: Determination of dollar amount.* (1) Effective for calendar years beginning January 1989, the dollar amount is determined based on an estimate of one-twelfth of the average per capita costs for benefits and administrative costs that will be payable with respect to individuals age 65 or over from the Federal Hospital Insurance Trust Fund during the succeeding calendar year.

(2) Before 1989, the dollar amount was determined by multiplying $33 by the ratio of the next year's inpatient deductible to $76, which was the inpatient deductible determined for 1973. (Because of cost controls, the deductible actually charged for that year was $72.)

(3) Effective for months beginning January 1994, if an individual meets the requirements in paragraph (c) of this section, the monthly premium determined under paragraph (b)(1) of this section is reduced in each month in which the individual meets the requirements by 25 percent in 1994, 30 percent in 1995, 35 percent in 1996, 40 percent in 1997 and 45 percent in 1998 and thereafter.

(4) The amount determined under paragraphs (b) (1), (2), or (3) of this section is rounded to the next nearest multiple of $1. (Fifty cents is rounded to the next higher dollar.)

(c) *Qualifying for a reduction in monthly premium.* An individual who qualifies for the reduction described in paragraph (b)(3) of this section must be an individual who—

(1) Has 30 or more quarters of coverage (QCs) as defined in 20 CFR 404.140 through 404.146;

(2) Has been married for at least the previous one year period to a worker who has 30 or more QCs;

(3) Had been married to a worker who had 30 or more QCs for a period of at least one year before the death of the worker;

(4) Is divorced from, after at least 10 years of marriage to, a worker who had 30 or more QCs at the time the divorce became final; or

(5) Is divorced from, after at least 10 years of marriage to, a worker who subsequently died and who had 30 or more QCs at the time the divorce became final.

(d) *Monthly premiums: Increase for late enrollment and for reenrollment.* For an individual who enrolls after the close of the initial enrollment period or reenrolls, the amount of the monthly premium, as determined under paragraph (b) of this section, is increased by 10 percent for each full 12 months in the periods described in §§ 406.33 and 406.34. Effective beginning with premiums due for July 1986, the premium increase is limited to 10 percent and is payable for twice the number of full 12-month periods determined under those sections.

(e) *Collection of monthly premiums.* (1) CMS will bill the enrollee on a monthly basis and include an addressed return envelope with the bill.

(2) The enrollee must pay by check or money order that is payable to ''CMS Medicare Insurance,'' and shows his or her name and the claim number that appears on his or her Medicare card. He or she must return the bill with the check or money order.

(f) *Months for which payment is due.* (1) A premium payment is due for each month beginning with the first month of coverage and continuing through the month of death or if earlier, the month in which coverage ends.

(2) A premium is due for the month of death if coverage is still in effect, even if the individual dies on the first day of the month.

(g) *Option for group payments.* A public or private organization may pay the premiums on behalf of one or more enrollees under a contract or other arrangement with CMS if CMS determines that this method of payment is administratively feasible. (The rules set forth in subpart E of part 408 of this

chapter, for SMI premiums, also apply to group payment of Part A premiums.)

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988; 56 FR 8839, Mar. 1, 1991. Redesignated and amended at 56 FR 38079, 38080, Aug. 12, 1991; 57 FR 36014, Aug. 12, 1992; 57 FR 58717, Dec. 11, 1992; 59 FR 26959, May 25, 1994]

§ 406.33 Determination of months to be counted for premium increase: Enrollment.

(a) *Enrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the general enrollment period, the special enrollment period, or the transfer enrollment period in which the individual enrolls, excluding the following:

(1) Any months before September 1973.

(2) For premiums due for months after May 1986, any months beginning with January 1983 during which the individual was enrolled in an employer group health plan based on the current employment of the individual or the individual's spouse.

(3) Any months during the SEP under § 406.24 of this subpart, during which premium hospital insurance coverage is in effect.

(4) Any months that the individual was enrolled in an HMO or CMP under part 417, subpart K of this chapter as described in § 406.21(f).

(5) For premiums due for months after December 2006, any months during which the individual met the requirements for a SEP under § 406.25(a) of this subpart.

(6) Any months during the 6-month SEP described in § 406.25(b) of this subpart during which premium hospital insurance coverage is in effect.

(b) *Enrollment during the period April 1 through September 30, 1981.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the month in which the individual enrolled, excluding any months before September 1973.

(c) *Enrollment on or after January 1, 2023.* The months to be counted for premium increase are the months from the end of the initial enrollment period through the end of the month in which the individual enrolls, excluding both of the following:

(1) The months described in paragraphs (a)(1) through (6) of this section.

(2) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 406.27 provided the individual enrolls within the duration of the SEP.

(d) *Examples.* (1) John F's initial enrollment period ended July 1979 but he did not enroll until January 1980. The months to be counted are August 1979 through March 1980. Since only 8 months elapsed, there is no premium increase.

(2) Mary T's initial enrollment period ended in April 1980 but she did not enroll until May 1981. The months to be counted are May 1980 through May 1981. Since 13 months has elapsed, the premium would be increased by 10 percent.

(3) Effective with July 1986, Mary T, in Example 2, would no longer have to pay an increased premium because she had paid it for twice the number of full 12-month periods during which she could have been, but was not, enrolled in the program.

(4) Vincent C's initial enrollment period ended August 31, 1986. He was covered under his wife's employer group health plan until she retired on May 31, 1989. He enrolled during June 1989, the first month of the special enrollment period under § 406.21(e). No months are countable for premium increase purposes because the exclusions of paragraph (a) of this section apply to all months.

(5) Terry P enrolled in the 1987 general enrollment period, with coverage effective July 1987. There were 28 months after the end of his initial enrollment period through the end of the 1987 general enrollment period. His premium is increased by 10 percent. The increase will be eliminated after he has paid the additional 10 percent for 48 months.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986, as amended at 53 FR 47203, Nov. 22, 1988. Further redesignated and amended at 57 FR 36014, Aug. 12, 1992; 73 FR 36468, June 27, 2008; 87 FR 66505, Nov. 3, 2022]

§ 406.34 Determination of months to be counted for premium increase: Reenrollment.

(a) *First reenrollment before April 1, 1981 or after September 30, 1981 and before January 1, 2023.* The months to be counted for premium increase are:

(1) The months specified in § 406.33(a) or (b); plus

(2) The months from the end of the first period of entitlement through the end of the general enrollment period in which the individual reenrolled.

(b) *First reenrollment during the period April 1, 1981* through September 30, 1981. The months to be counted for premium increase are—

(1) The months specified in § 406.33(a); plus

(2) The months from the end of the first period of entitlement through the month in which the individual reenrolled.

(c) *Subsequent reenrollment during the period April 1, 1981 through September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) of this section; plus

(2) The months from April 1981 through the month in which the individual reenrolled for the second time. (Since only one reenrollment was permitted before April 1981, any months from the end of the individual's first enrollment period of entitlement through March 1981 are not counted.)

(d) *Subsequent reenrollment after September 30, 1981.* The months to be counted for premium increase are—

(1) The months specified in paragraph (a) or (b) of this section, for the first and second periods of coverage; plus

(2) The months from the end of each subsequent period of entitlement through the end of the general enrollment period in which the individual reenrolled, excluding any months before April 1981.

(e) *Reenrollments on or after January 1, 2023.* (1) The months to be counted for premium increase are as follows:

(i) The months specified in § 406.33(c).

(ii) The months specified in paragraphs (b) and (d) of this section (if applicable).

(iii) The months from the end of the first period of entitlement through the end of the month during the general enrollment period in which the individual reenrolled.

(2) The months excluded from premium increase are the months of noncoverage in accordance with an individual's use of an exceptional conditions SEP under § 406.27, provided the individual enrolls within the duration of the SEP.

(f) *Example.* Peter M enrolled during his initial enrollment period, terminated his first coverage period in August 1979 and reenrolled for the first time in January 1980. The 7 months to be counted (September 1979 through March, 1980) were not enough to require any increase in the premium. Peter terminated his second period of coverage in February 1981 and reenrolled for the second time in July 1981. Since the 4 months (April through July 1981), when added to the previous 7 months, bring the total to only 11 months, no premium increase is required.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated and amended at 57 FR 58717, Dec. 11, 1992; 87 FR 66505, Nov. 3, 2022]

§ 406.38 Prejudice to enrollment rights because of Federal Government error.

(a) If an individual's enrollment or nonenrollment for premium hospital insurance 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, the Social Security Administration or CMS may take whatever action it determines is necessary to provide appropriate relief.

(b) The action may include—

(1) Designation of a special initial or general enrollment period;

(2) Designation of an entitlement period;

(3) Adjustment of premiums;

(4) Any combination of the actions specified in paragraph (b) (1) through (3) of this section; or

(5) Any other remedial action which may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 56 FR 38080, Aug. 12, 1991]

Subpart D—Special Circumstances That Affect Entitlement to Hospital Insurance

§ 406.50 Nonpayment of benefits on behalf of certain aliens.

(a) Hospital insurance benefit payments may not be made for services furnished to an alien in any month in which his or her monthly social security benefits are suspended (or would be suspended if he or she were entitled to those benefits) because the alien remains outside the United States for more than 6 months.

(b) Benefits will be payable beginning with services furnished in the first full calendar month the alien is back in the United States.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 57 FR 58717, Dec. 11, 1992]

§ 406.52 Conviction of certain offenses.

(a) *Penalty that affects entitlement.* (1) If an individual is convicted of any of the crimes listed in §406.11(c) (1) and (2), the court may impose, in addition to all other penalties, a penalty that affects entitlement to hospital insurance, beginning with the month of conviction.

(2) The additional penalty is that the individual's income (or the income of the insured individual on whose earnings record he or she became or seeks to become entitled) for the year of conviction and any previous year may not be counted in determining the insured status necessary for entitlement to hospital insurance.

(b) *Effect of pardon.* If the President of the United States pardons the convicted individual, that individual regains (or may again seek) entitlement effective with the month following the month in which the pardon is granted.

[48 FR 12536, Mar. 25, 1983. Redesignated at 51 FR 41338, Nov. 14, 1986. Further redesignated at 57 FR 58717, Dec. 11, 1992]

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

Subpart A—General Provisions

Subpart B—Individual Enrollment and Entitlement for SMI

Subpart C—State Buy-in Agreements

Subpart D—Part B Immunosuppressive Drug Benefit

AUTHORITY: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

SOURCE: 53 FR 47204, Nov. 22, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 407.1 Basis and scope.

(a) *Statutory basis.* The supplementary medical insurance (SMI) program is authorized by Part B of title XVIII of the Social Security Act.

(1) Section 1831 of the Act establishes the program.

(2) Sections 1836 and 1837 set forth the eligibility and enrollment requirements.

(3) Section 1838 specifies the entitlement periods, which vary depending on the time and method of enrollment and on the basis for termination.

(4) Section 1843 sets forth the requirements for State buy-in agreements under which States may enroll, and pay the SMI premiums for, eligible individuals who are also eligible for cash assistance or Medicaid.

(5) Section 104(b) of the Social Security Amendments of 1965 (Pub. L. 89–87) specifies the limitations that apply to certain aliens and persons convicted of subversive activities.

(6) Sections 1836(b) and 1837(n) of the Act provide for coverage of immunosuppressive drugs as described in section 1861(s)(2)(J) of the Act under Part B beginning on or after January 1, 2023, for eligible individuals whose benefits under Medicare Part A and eligibility to enroll in Part B on the basis of ESRD would otherwise end with the 36th month after the month in which the individual receives a kidney transplant by reason of section 226A(b)(2) of the Act.

(b) *Scope.* This part sets forth the eligibility, enrollment, and entitlement requirements and procedures for the following:

(1) Supplementary medical insurance. (The rules about premiums are in part 408 of this chapter.)

(2) The immunosuppressive drug benefit provided for under sections 1836(b) and 1837(n) of the Act, hereinafter referred to as the Part B-Immunosuppressive Drug Benefit (Part B–ID).

[53 FR 47204, Nov. 22, 1988, as amended at 87 FR 66505, Nov. 3, 2022]

§ 407.2 General description of program.

Part B of Title XVIII of the Act provides for voluntary ''supplementary medical insurance'' available to most individuals age 65 or over and to disabled individuals who are under age 65 and entitled to hospital insurance. The SMI program is financed by premiums paid by (or for) each individual enrolled in the program, plus contributions from Federal funds. It covers certain physicians' services, outpatient services, home health services, services furnished by rural health clinics (RHCs), Federally qualified health centers (FQHCS), ambulatory surgical centers (ASCs), and comprehensive outpatient rehabilitation facilities (CORFs), and other medical and other health services.

[57 FR 24980, June 12, 1992]

§ 407.4 Basic requirements for entitlement.

(a) An individual must meet the following requirements to be entitled to SMI:

(1) *Eligibility.* The individual must meet the eligibility requirements specified in § 407.10(a).

(2) *Enrollment.* The individual must enroll for SMI, or must be enrolled by a State under a buy-in agreement as specified in § 407.40.

(b) SMI pays only for covered expenses incurred during an individual's period of entitlement.

Subpart B—Individual Enrollment and Entitlement for SMI

§ 407.10 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll for SMI if he or she—

(1) Is entitled to hospital insurance under any of the rules set forth in §§ 406.10 through 406.15 of this chapter; or

(2) Meets the following requirements:

(i) Has attained age 65. (An individual is considered to have attained age 65 on the day before the 65th anniversary of his or her birth.)

(ii) Is a resident of the United States.

(iii) Is a citizen of the United States, or an alien lawfully admitted for permanent residence who has resided continuously in the United States during the 5 years preceding the month in which he or she applies for enrollment.

(b) *Exception.* An individual is not eligible to enroll for SMI if he or she has been convicted of—

(1) Spying, sabotage, treason, or subversive activities under chapter 37, 105, or 115 of title 18 of the United States Code; or

(2) Conspiracy to establish dictatorship under section 4 of the Internal Security Act of 1950.

§ 407.11 Forms used to apply for enrollment under Medicare Part B.

Forms used to apply for enrollment under the supplementary medical insurance program are available free of charge by mail from CMS, or at any Social Security branch or district office and online at the CMS and SSA websites. As an alternative, the individual may request enrollment by signing a simple statement of request, if he or she is eligible to enroll at that time.

[87 FR 66505, Nov. 3, 2022]

§ 407.12 General enrollment provisions.

(a) *Opportunity to enroll.* (1) An individual who is eligible to enroll for SMI may do so during an initial enrollment period or a general enrollment period as specified in §§ 407.14, and 407.15. An individual who meets the conditions specified in § 407.20 may enroll during a special enrollment period, as provided in that section.

(2) An individual who fails to enroll during his or her initial enrollment period or whose enrollment has been terminated may enroll or reenroll during a general enrollment period, or, if he or she meets the specified conditions, during a special enrollment period.

(b) *Enrollment periods ending on a nonworkday.* (1) If an enrollment period ends on a Federal nonworkday, that period is automatically extended to the next succeeding workday.

(2) A Federal nonworkday is any Saturday, Sunday, or Federal legal holiday or a day that is declared by statute or executive order to be a day on which Federal employees are not required to work.

§ 407.14 Initial enrollment period.

(a) *Duration.* (1) The initial enrollment period is the 7-month period that begins 3 months before the month an individual first meets the eligibility requirements of § 407.10 and ends 3 months after that first month of eligibility.

(2) In determining the initial enrollment period of an individual who is age 65 or over and eligible for enrollment solely because of entitlement to hospital insurance, the individual is considered as first meeting the eligibility requirements for SMI n the first day he or she becomes entitled to hospital insurance or would have been entitled if he or she filed an application for that program.

(b) *Deemed initial enrollment period.* (1) SSA or CMS will establish a deemed initial enrollment period for an individual who fails to enroll during the initial enrollment period because of a belief, based on erroneous documentary evidence, that he or she had not yet attained age 65. The period will be established as though the individual had attained age 65 on the date indicated by the incorrect information.

(2) A deemed initial enrollment period established under paragraph (b)(1) of this section is used to determine the individual's premium and right to enroll in a general enrollment period if that is advantageous to the individual.

§ 407.15 General enrollment period.

(a) Except as specified in paragraph (b) of this section, the general enrollment period is January through March of each calendar year.

(b) An unlimited general enrollment period existed between April 1 and September 30, 1981. Any eligible individual whose initial enrollment period had ended, or whose previous period of entitlement had terminated, could have enrolled or reenrolled during any month of that 6-month period.

§ 407.17 Automatic enrollment.

(a) *Who is automatically enrolled.* An individual is automatically enrolled for SMI if he or she:

(1) Resides in the United States, except in Puerto Rico;

(2) Becomes entitled to hospital insurance under any of the provisions set forth in §§ 406.10 through 406.15 of this chapter; and

(3) Does not decline SMI enrollment.

(b) *Opportunity to decline automatic enrollment.* (1) SSA will notify an individual that he or she is automatically enrolled under paragraph (a) of this section and grant the individual a specified period (at least 2 months after the month the notice is mailed) to decline enrollment.

(2) The individual may decline enrollment by submitting to SSA or CMS a signed statement that he or she does not wish SMI.

(3) The statement must be submitted before entitlement begins, or if later, within the time limits set in the notice of enrollment.

§ 407.18 Determining month of automatic enrollment.

(a) An individual who is automatically enrolled in SMI under § 407.17 will have the month of enrollment determined in accordance with paragraphs (b) through (f) of this section. The month of enrollment determines the month of entitlement.

(b) An individual is automatically enrolled in the third month of the initial enrollment period if he or she—

(1) Is entitled to social security benefits under section 202 of the Act on the first day of the initial enrollment period;

(2) Is entitled to hospital insurance based on end-stage renal disease; on entitlement to disability benefits as a social security or railroad retirement beneficiary; or on deemed entitlement to disability benefits on the basis of Medicare-qualified government employment; or

(3) Establishes entitlement to hospital insurance by filing an application and meeting all other requirements (as set forth in subpart B of part 406 of this chapter) during the first 3 months of the initial enrollment period.

(c) If an individual establishes entitlement to hospital insurance on the basis of an application filed in the last 4 months of the SMI initial enrollment period, he or she is automatically enrolled for SMI in the month in which the application is filed.

(d) If an individual establishes entitlement to hospital insurance on the basis of an application filed after the SMI initial enrollment period but not during a general enrollment period in effect before April 1, 1981, or after September 30, 1981, he or she is automatically enrolled for SMI on the first day of the next general enrollment period.

(e) If the individual establishes entitlement to hospital insurance on the basis of an application filed during a SMI general enrollment period in effect before April 1, 1981 or after September 30, 1981, he or she is automatically enrolled on the first day of that period.

(f) If an individual established entitlement to hospital insurance on the basis of an application filed during the general enrollment period of April 1, 1981, through September 30, 1981, he or she was automatically enrolled for SMI on the first day of the month in which the application was filed.

§ 407.20 Special enrollment period related to coverage under group health plans.

(a) *Terminology*—(1) *Group health plan (GHP) and large group health plan (LGHP).* These terms have the meanings given them in § 411.101 of this chapter except that the ''former employee'' language of those definitions does not apply with respect to SEPs for the reasons specified in § 406.24(a)(3) of this chapter.

(2) *Special enrollment period (SEP).* This term has the meaning set forth in § 406.24(a)(4) of this chapter. In order to use a SEP, an individual must meet the conditions of paragraph (b) and of paragraph (c) or (d) of this section, as appropriate.

(b) *General rule.* All individuals must meet the following conditions:

(1) They are eligible to enroll for SMI on the basis of age or disability, but not on the basis of end-stage renal disease.

(2) When first eligible for SMI coverage (4th month of their initial enrollment period), they were covered under a GHP or LGHP on the basis of current employment status or, if not so covered, they enrolled in SMI during their initial enrollment period; and

(3) For all months thereafter, they maintained coverage under either SMI or a GHP or LGHP. (Generally, if an individual fails to enroll in SMI during any available SEP, he or she is not entitled to any additional SEPs. However, if an individual fails to enroll during a SEP because coverage under the same or a different GHP or LGHP was restored before the end of that particular SEP, that failure to enroll does not preclude additional SEPs.)

(c) *Special rule: Individual age 65 or over.* For an individual who is or was covered under a GHP, coverage must be by reason of the current employment status of the individual or the individual's spouse.

(d) *Special rules: Disabled individual.*[4] Individuals entitled on the basis of disability (but not on the basis of end-stage renal disease) must meet conditions that vary depending on whether they were covered under a GHP or an LGHP.

(1) For a disabled individual who is or was covered under a GHP, coverage must be on the basis of the current employment status of the individual or the individual's spouse.

(2) For a disabled individual who is or was covered under an LGHP, coverage must be as follows:

(i) Before August 10, 1993, as an ''active individual'', that is, as an employee, employer, self-employed individual (such as the employer), individual associated with the employer in a business relationship, or as a member of the family of any of those persons.

(ii) On or after August 10, 1993, by reason of current employment status of the individual or a member of the individual's family.

(e) *Effective date of coverage.* The rule set forth in § 406.24(d) for Medicare Part A applies equally to Medicare Part B.

[61 FR 40346, Aug. 2, 1996]

[4] Under the current statute, the SEP provision applicable to disabled individuals covered under an LGHP expires on September 1998. Unless Congress changes that date, the last SEP available under those provisions will begin with June 1998.

§ 407.21 Special enrollment period for volunteers outside the United States.

(a) *General rule.* A SEP, as defined in § 406.24(a)(4) of this subchapter, is provided for an individual who does not elect to enroll or to be deemed enrolled in SMI when first eligible, or who terminates SMI enrollment, if the individual meets the following requirements:

(1) The individual is serving as a volunteer outside of the United States in a program that covers at least a 12-month period.

(2) The individual is in a program that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of the Internal Revenue Code of 1986.

(3) The individual demonstrates that he or she has health insurance that covers medical services that the individual receives outside of the United States while serving in the program.

(b) *Duration of SEP.* The SEP is the 6-month period beginning on the first day of the month that includes the date that the individual no longer satisfies the provisions of paragraph (a) of this section.

(c) *Effective date of coverage.* Coverage under a SEP authorized by this section, begins on the first day of the month following the month in which the individual enrolls.

[73 FR 36468, June 27, 2008]

§ 407.22 Request for individual enrollment.

(a) A request for enrollment is required of an individual who meets the eligibility requirements of § 407.10 and desires SMI, if the individual—

(1) Is not entitled to hospital insurance;

(2) Has previously declined enrollment in SMI;

(3) Has had a previous period of SMI entitlement which terminated;

(4) Resides in Puerto Rico or outside the United States; or

(5) Is enrolling or reenrolling during a special enrollment period under § 407.20.

(b) A request for enrollment under paragraph (a) of this section must:

(1) Be signed by the individual or someone acting in his or her behalf; and

(2) Be filed with SSA or CMS during the initial enrollment period, a general enrollment period, or a special enrollment period as provided in § 407.20.

§ 407.23 Special enrollment periods for exceptional conditions.

(a) *General rule:* Beginning January 1, 2023, in accordance with the Secretary's authority in sections 1837(m) and 1838(g) of the Act, the following SEPs, as defined under § 406.24(a)(4) of this subchapter, are provided for individuals who missed a Medicare enrollment period (as specified in § 407.21, § 407.15 or § 407.20 of this subchapter) due to exceptional conditions as determined by the Secretary and established under paragraphs (b) through (f) of this section. SEPs are provided for exceptional conditions that took place on or after January 1, 2023 except as specified in paragraph (e) of this section.

(b) *Special enrollment period for individuals impacted by an emergency or disaster.* An SEP exists for individuals prevented from submitting a timely Medicare enrollment request by an emergency or disaster declared by a Federal, State, or local government entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they (or their SSA-authorized representative as defined at 42 CFR 405.910), their legal guardian, or the person who makes healthcare decisions on behalf of that individual, reside (or resided) in an area for which a Federal, State or local government entity newly declared a disaster or other emergency. The individual (or the individual's authorized representative, legal guardian, or the person who makes healthcare decisions on behalf of that individual) must demonstrate that they reside (or resided) in the area during the period covered by that declaration.

(2) *SEP duration.* The SEP begins on the earlier of the date an emergency or disaster is declared or, if different, the start date identified in such declaration. The SEP ends 6 months after the end date identified in the declaration, the end date of any extensions or the date when the declaration has been determined to have ended or has been revoked, if applicable.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(c) *Special enrollment period for individuals affected by a health plan or employer misrepresentation.* An SEP exists for individuals whose non-enrollment in SMI is unintentional, inadvertent, or erroneous and results from misrepresentation or reliance on incorrect information provided by the individual's employer or GHP, agents or brokers of health plans, or any person authorized to act on behalf of such entity.

(1) *SEP parameters.* An individual is eligible for the SEP if they can demonstrate (by documentation or written attestation) the both of the following:

(i) He or she did not enroll in SMI during another enrollment period in which they were eligible based on information received from an employer or GHP, agents or brokers of health plans, or any person authorized to act on such organization's behalf.

(ii) An employer, GHP, agent or broker of a health plan, or their representative materially misrepresented information or provided incorrect information relating to enrollment in SMI.

(2) *SEP duration.* This SEP begins the day the individual notifies SSA of the employer or GHP misrepresentation, or the incorrect information provided and ends 6 months later.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

(d) *SEP for formerly incarcerated individuals.* An SEP exists for Medicare eligible individuals who are released from the custody of penal authorities as described in § 411.4(b) of this subchapter on or after January 1, 2023.

(1) *SEP parameters.* An individual is eligible for this SEP if they demonstrate that they are eligible for Medicare and failed to enroll or reenroll in SMI due to being in custody of penal authorities, and there is a record of release either through discharge documents or data available to SSA.

(2) *SEP duration.* The SEP starts the day of the individual's release from the custody of penal authorities and ends the last day of the 12th month after the month in which the individual is released from the custody of penal authorities.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on after January 1, 2023.

(ii) *Special rule.* An individual has the option of requesting entitlement for a retroactive period of up to 6 months provided the date does not precede release from incarceration and the individual pays the monthly premiums for the period of coverage (as required under § 406.31). If the application is filed within the first 6 months of the SEP, the effective date is retroactive to the date of their release from incarceration. If the application is filed in the last 6 months of the SEP, the coverage effective date is retroactive to 6 months after the date of release from incarceration.

(e) *Special enrollment period for termination of Medicaid coverage.* An SEP exists for individuals whose Medicaid eligibility is terminated.

(1) *SEP parameters.* An individual is eligible for this SEP if they can demonstrate that—

(i) They are eligible for Part B under § 407.4(a); and

(ii) Their Medicaid eligibility is being terminated on or after January 1, 2023, or after the last day of the Coronavirus Disease 2019 public health emergency (COVID–19 PHE) as determined by the Secretary, whichever is earlier.

(2) *SEP duration.* If the termination of Medicaid eligibility occurs—

(i) After the last day of the COVID–19 PHE and before January 1, 2023, the SEP starts on January 1, 2023 and ends on June 30, 2023.

(ii) On or after January 1, 2023, the SEP starts when the individual is notified of termination of Medicaid eligibility and ends 6 months after the termination of eligibility.

(3) *Entitlement*—(i) *General rule.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is the month following the last month of the COVID–19 PHE or on or after January 1, 2023, whichever is earlier.

(ii) *Special COVID–19 PHE rule.* An individual whose Medicaid eligibility is terminated after the end of the COVD–19 PHE, but before January 1, 2023 (if applicable), has the option of requesting that entitlement begin back to the first of the month following termination of Medicaid eligibility provided the individual pays the monthly premiums for the period of coverage (as required under part 408 of this subchapter).

(iii) *Other special rule.* After January 1, 2023, an individual has the option of requesting entitlement for a retroactive period back to the date of termination from Medicaid provided the individual pays the monthly premiums for the period of coverage (as required under § 406.31 of this subchapter).

(4) *Effect on previously accrued late enrollment penalties.* Individuals who otherwise would be eligible for this SEP, but enrolled during the COVID–19 PHE prior to January 1, 2023, are eligible to have late enrollment penalties collected under § 408.22 of this subchapter reimbursed and ongoing penalties removed.

(f) *Special enrollment period for other exceptional conditions.* An SEP exists for other exceptional conditions as CMS may provide.

(1) *SEP parameters.* An individual is eligible for the SEP if both of the following apply:

(i) The individual demonstrates that they missed an enrollment period in which they were eligible because of an event or circumstance outside of the individual's control which prevented them from enrolling in SMI.

(ii) It is determined that the conditions were exceptional in nature.

(2) *SEP duration.* The SEP duration is determined on a case by case basis, but will be no less than 6 months.

(3) *Entitlement.* Entitlement begins the first day of the month following the month of enrollment, so long as the date is on or after January 1, 2023.

[87 FR 66505, Nov. 3, 2022]

§ 407.25 Beginning of entitlement: Individual enrollment.

The following apply whether an individual is self-enrolled or automatically enrolled in SMI:

(a) *Enrollment during initial enrollment period.* For individuals who first meet the eligibility requirements of § 407.10 in a month beginning—

(1) Before January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the fourth month of the initial enrollment period, entitlement begins with the following month.

(iii) If an individual enrolls during the fifth month of the initial enrollment period, entitlement begins with the second month after the month of enrollment.

(iv) If an individual enrolls in either of the last 2 months of the initial enrollment period, entitlement begins with the third month after the month of enrollment.

(v) For example, if an individual first meets the eligibility requirements for enrollment in April, then the individual's initial enrollment period is January through July. The month in which the individual enrolls determines the month that begins the period of entitlement, as follows:

TABLE 1 TO PARAGRAPH (a)(1)(v)

Enrolls in initial enrollment period	Entitlement begins on—
January	April 1 (month eligibility requirements first met).
February	April 1.
March	April 1.
April	May 1 (month following month of enrollment).
May	July 1 (second month after month of enrollment).
June	September 1 (third month after month of enrollment).
July	October 1 (third month after month of enrollment).

(2) On or after January 1, 2023, the following entitlement dates apply:

(i) If an individual enrolls during the first 3 months of the initial enrollment period, entitlement begins with the first month of eligibility.

(ii) If an individual enrolls during the last 4 months of the initial enrollment period, entitlement begins with the month following the month in which they enroll.

(b) *Enrollment on reenrollment during general enrollment period.* (1) If an individual enrolls or reenrolls during a general enrollment period before April 1, 1981, or after September 30, 1981 and before January 1, 2023, entitlement begins on July 1 of that calendar year.

(2) If an individual enrolled or reenrolled during the general enrollment period between April 1, 1981 and September 20, 1981, entitlement began with the third month after the month in which the enrollment request was filed.

(3) If an individual enrolls or reenrolls during a general enrollment period on or after January 1, 2023, entitlement begins on the first day of the month following the month in which they enroll.

(c) *Enrollment or reenrollment during a SEP.* The rules set forth in § 406.24(d) of this chapter apply.

[53 FR 47204, Nov. 22, 1988, as amended at 61 FR 40347, Aug. 2, 1996; 87 FR 66506, Nov. 3, 2022; 87 FR 80469, Dec. 30, 2022]

§ 407.27 Termination of entitlement: Individual enrollment.

An individual's entitlement will terminate for any of the following reasons:

(a) *Death.* Entitlement to SMI ends on the last day of the month in which the individual dies.

(b) *Termination of hospital insurance benefits.* If an individual's entitlement to hospital insurance ends before the month in which he or she attains age 65, entitlement to SMI will end on the same day unless it has been previously terminated in accordance with paragraph (c) or (d) of this section.

(c) *Request by individual.* An individual may at any time give CMS or SSA written notice that he or she no longer wishes to participate in SMI, and request disenrollment.

(1) Before July 1987, entitlement ended at the end of the calendar quarter after the quarter in which the individual filed the disenrollment request.

(2) For disenrollment requests filed in or after July 1987, entitlement ends at the end of the month after the month in which the individual files the disenrollment request.

(d) *Nonpayment of premiums.* If an individual fails to pay the premiums, entitlement will end as provided in the rules for SMI premiums, set forth in part 408 of this chapter.

§ 407.30 Limitations on enrollment.

(a) *Initial enrollment periods*—(1) *Individual under age 65.* An individual who has not attained age 65 may have one or more periods of entitlement to hospital insurance, based on disability. Since each period of disability entitlement entitles the individual to hospital insurance and since entitlement to hospital insurance makes the individual eligible for SMI enrollment, an individual may have an SMI initial enrollment period for each continous period of entitlement to hospital insurance.

(2) *Individuals who have attained age 65.* An individual who has attained age 65 may not have more than one initial enrollment period on the basis of age. However, if the individual develops ESRD after age 65, he or she may have another initial enrollment period based on meeting the requirements of § 406.13 of this chapter.

(b) *Number of enrollments.* There is no limitation on the number of enrollments.

(c) *Coverage under buy-in agreements.* For purposes of paragraph (a) of this section, the continued enrollment of an individual following the end of coverage under a State buy-in agreement in considered an initial enrollment.

§ 407.32 Prejudice to enrollment rights because of Federal Government misrepresentation, inaction, or error.

If an individual's enrollment or nonenrollment in SMI is unintentional, inadvertent, or erroneous because of the error, misrepresentation, on inaction of a Federal employee or any person authorized by the Federal Government to act in its behalf, the Social Security Administration or CMS may take whatever action it determines is necessary to provide appropriate relief. The action may include:

(a) Designation of a special initial or general enrollment period;

(b) Designation of an entitlement period based on that enrollment period;

(c) Adjustment of premiums;

(d) Any combination of actions under paragraphs (a) through (c) of this section; or

(e) Any other remedial action that may be necessary to correct or eliminate the effects of the error, misrepresentation, or inaction.

Subpart C—State Buy-In Agreements

§ 407.40 Enrollment under a State buy-in agreement.

(a) *Statutory basis.* (1) Section 1843 of the Act, as amended through 1969, permitted a State to enter into an agreement with the Secretary to enroll in the SMI program certain individuals who are eligible for SMI and who are members of the buy-in group specified in the agreement. A buy-in group could include certain individuals receiving Federally-aided State cash assistance (with the option of excluding individuals also entitled to social security benefits or railroad retirement benefits) or could include all individuals eligible for Medicaid. Before 1981, December 31, 1969 was the last day on which a State could request a buy-in agreement or a modification to include a coverage group broader than the one originally selected.

(2) Section 945(e) of the Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) further amended section 1843 to provide that, during calendar year 1981, a State could request a buy-in agreement if it did not already have one, or request a broader coverage group for an existing agreement.

(3) Several laws enacted during 1980–1987 had the effect of requiring that the buy-in groups available under section 1843 of the Act be expanded to include certain individuals who lose eligibility for cash assistance payments but are treated as if they were cash assistance beneficiaries for Medicaid eligibility purposes.

(4) Section 301(e)(1) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) amends section 1843 of the

Act to restore the 1981 provisions on a permanent basis, effective ''after 1988.''

(5) The same section 301, as amended by section 608(d)(14)(H) of the Family Support Act of 1988 (Pub. L. 100–485), further amended section 1843 of the Act, beginning January 1, 1989, to establish a new buy-in category consisting of Qualified Medicare Beneficiaries and to provide that a State may request a buy-in agreement if it does not already have one, or request a broader buy-in group for the existing agreement.

(6) Section 4501 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) established the Specified Low-Income Medicare Beneficiary or SLMB eligibility group effective January 1993.

(7) Section 4732 of the Balanced Budget Act of 1997 (Pub. L. 105–33) established the Qualifying Individual or QI eligibility group effective January 1998.

(8) Section 112 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) increased the resource standard for QMB, SLMB, and QI to 3 times the maximum resources available under the Supplemental Security Income program, adjusted annually by increases in the Consumer Price Index effective January 1, 2010.

(9) Title II, section 211, of the Medicare Access and CHIP Reauthorization Act (Pub. L. 114–10), effective April 16, 2015, permanently extended the QI eligibility group.

(10) Title II, section 402 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260), effective January 1, 2023, expands QMB, SLMB, and QI to cover individuals who are enrolled in Medicare Part B for coverage of immunosuppressive drugs.

(b) *Definitions.* As used in this subpart, unless the context indicates otherwise—

Buy-in group means a coverage group described in section 1843 of the Act that is identified by the State and is composed of multiple Medicaid eligibility groups specified in the buy-in agreement.

Cash assistance means any of the following kinds of monthly cash benefits, authorized by specified titles of the Act and, for convenience, represented by initials, as follows:

AABD stands for aid to the aged, blind or disabled under the first title XVI of the Act in effect until December 31, 1973.

AB stands for aid to the blind under title X of the Act.

AFDC stands for aid to families with dependent children under Part A of title IV of the Act, as it was in effect on July 16, 1996.

APTD stands for aid to the permanently and totally disabled under title XIV of the Act.

OAA stands for old-age assistance under title I of the Act.

SSI stands for supplemental security income for the aged, blind, and disabled under the second title XVI of the Act, effective January 1, 1974.

SSP stands for State supplementary payments, whether mandatory or optional, to an aged, blind, or disabled individual under the second title XVI or the Act.

Railroad retirement beneficiary means an individual entitled to receive an annuity under the Railroad Retirement Act of 1974.

1634 State means a State that has an agreement with SSA, in accordance with section 1634 of the Act, for SSA to determine Medicaid eligibility on behalf of the State for individuals residing in the State whom the SSA has determined eligible for SSI.

State means one of the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, American Samoa, or the Northern Mariana Islands, except when reference is made to ''the 50 States''.

State buy-in agreement or buy-in agreement means an agreement authorized or modified by section 1843 or 1818(g) of the Act, under which a State secures Part B or premium Part A coverage for individuals who are members of the buy-in group specified in the agreement, by enrolling them and paying the premiums on their behalf. A State's submission of a State plan amendment addressing its buy-in process, if approved by CMS, constitutes the ''buy-in agreement'' between the State and CMS for purposes of sections 1843 and 1818(g) of the Act.

(c) *Basic rules.* (1) A State that has a buy-in agreement in effect must enroll any individual who is eligible to enroll

in SMI under § 407.10 and who is a member of the buy-in group, with the State paying the premiums on the individual's behalf. Individuals enrolled in the buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

(2) Any State that does not have a buy-in agreement in effect may request buy-in for any one of the groups specified in §§ 407.42 and 407.43.

(3) Any State that does have an agreement may request a modification to cover a broader buy-in group or cancel its current agreement and request a new agreement to cover a narrower group.

(4) Any State that has a buy-in agreement in effect must participate in daily exchanges of enrollment data with CMS.

(5) In a 1634 State, CMS enrolls SSI beneficiaries in Medicare Part B, on behalf of the State, with the State paying the beneficiary's Part B premiums.

(6) Premiums paid under a State buy-in agreement are not subject to increase because of late enrollment or reenrollment.

[56 FR 38080, Aug. 12, 1991; 56 FR 50058, Oct. 3, 1991; as amended at 85 FR 25632, May 1, 2020; 87 FR 66507, Nov. 3, 2022]

§ 407.42 Buy-in groups available to the 50 States, the District of Columbia, and the Northern Mariana Islands.

(a) *Basic rule.* The 50 States, the District of Columbia, and the Northern Mariana Islands must select one of the buy-in groups described in paragraph (b) in their buy-in agreements.

(b) *Buy-in groups available*—(1) *Group 1.* Cash Assistance and Deemed Recipients of Cash Assistance: This buy-in group includes all of the following:

(i) Individuals who receive SSI or SSP or both and are covered under the State's Medicaid state plan as categorically needy.

(ii) Individuals who under the Act or any other provision of Federal Law are treated, for Medicaid eligibility purposes, as though the individual was receiving SSI or SSP and are covered under the State's Medicaid state plan as categorically needy.

(iii) At State option, individuals whom the State must consider to be recipients of AFDC. Individuals a State would be required to include in electing this option would be, but not limited to, individuals eligible for Medicaid on the basis of section 1931(b) of the Act or their receipt of adoption assistance, foster care or guardianship care under Part E of title IV of the Act, in accordance with § 435.145 of this chapter.

(2) *Group 2.* Cash Assistance and Deemed Recipients of Cash Assistance and three Medicare Savings Program eligibility groups. This buy-in group includes both of the following:

(i) Group 1.

(ii) Individuals enrolled in the—

(A) Qualified Medicare Beneficiary eligibility group described in § 435.123 of this chapter;

(B) Specified Low-Income Beneficiary eligibility group described in § 435.124 of this chapter; and

(C) Qualifying Individual eligibility group described in § 435.125 of this chapter.

(3) *Group 3.* All Medicaid Eligibility Groups: This buy-in group includes all individuals eligible for Medicaid.

[87 FR 66507, Nov. 3, 2022]

§ 407.43 Buy-in groups available to Puerto Rico, Guam, the Virgin Islands, and American Samoa.

(a) *Categories included in buy-in groups.* The buy-in groups that are available to Puerto Rico, Guam, the Virgin Islands, and American Samoa, which are not covered by the SSI program, are described in paragraph (b) of this section in terms of the following categories:

(1) *Category A:* Individuals receiving OAA, AB, APTD, or AFDC.

(2) *Category B:* Individuals who, under the Act or any other provision of Federal law, are treated, for Medicaid eligibility purposes, as though they were receiving AFDC.

(3) *Category C:* Individuals who, in accordance with § 436.112 of this chapter, are covered under the State's Medicaid plan despite the increase in social security benefits provided by Public Law 92–336.

(4) *Category D:* Individuals who are Qualified Medicare Beneficiaries.[1]

(5) *Category E:* All other individuals who are eligible for Medicaid.

(b) *Buy-in groups available.* Puerto Rico, Guam, the Virgin Islands, and American Samoa may choose any of the following coverage groups:

(1) *Group 1:* Categories A through E.

(2) *Group 2:* Categories A through D.

(3) *Group 3:* Categories A through C.

(4) *Group 4:* Individuals in category D, and individuals in categories A and B who are not social security or railroad retirement beneficiaries.

(5) *Group 5:* Individuals in categories A and B who are not social security or railroad retirement beneficiaries.

(6) *Group 6:* Individuals in category D, individuals in category A who are receiving OAA, and individuals in category C who are included in that category (in accordance with § 436.112 of this chapter) because they received OAA for August 1972 or would have been eligible to receive OAA for that month if they had applied or had not been institutionalized.

(7) *Group 7:* Individuals in category A who are receiving OAA, and individuals in category C who are included in that category (in accordance with § 436.112 of this chapter) because they received OAA for August 1972 or would have been eligible to receive OAA for that month if they had applied or had not been institutionalized.

(8) *Group 8:* Individuals in category D and individuals in category A who are receiving OAA and are not social security or railroad retirement beneficiaries.

(9) *Group 9:* Individuals in category A who are receiving OAA and are not social security or railroad retirement beneficiaries.

[56 FR 38082, Aug. 12, 1991]

§ 407.47 Beginning of coverage under a State buy-in agreement.

(a) *General rule.* The beginning of an individual's coverage period depends on two factors:

(1) The individual's meeting the SMI eligibility requirements and the requirements for being a member of the buy-in group; and

(2) The effective date of the buy-in agreement or agreement modification that covers the buy-in group to which the individual belongs, and which may not be earlier than the third month after the month in which the agreement or modification is executed. The State must apply the earliest applicable start date for the applicable buy-in group.

(b) *Application of general rule: Medicaid eligibles who are, or are treated as, cash assistance beneficiaries.* For Medicaid eligibles who are, or are treated as, cash assistance beneficiaries, coverage begins with the later of the following:

(1) The first month in which the individual—

(i) Meets the SMI eligibility requirements specified in § 407.10; and

(ii) Is, or is treated as, a cash assistance beneficiary.

(2) The month in which the buy-in agreement is effective.

(c) *Application of general rule: Qualified Medicare Beneficiaries.* For individuals who are QMBs as defined under § 435.123 of this chapter, coverage begins with the later of the following:

(1) The first month in which the individual meets the SMI eligibility requirements specified in § 407.10, and has QMB status.

(2) The month in which the buy-in agreement or agreement modification covering QMBs is effective.

(d) *Application of general rule: Other individuals eligible for Medicaid.* For individuals who are not cash assistance beneficiaries, are not treated as cash assistance beneficiaries, and are not QMBs, coverage begins with the later of the following:

(1) The second month after the month in which the individual—

(i) Meets the SMI eligibility requirements specified in § 407.10; and

(ii) Is determined to be eligible for Medicaid.

(2) The month in which the buy-in agreement or agreement modification is effective.

(e) *Coverage based on erroneous report.* If the State erroneously reports to SSA that an individual is a member of its coverage group, the rules of paragraphs

[1] Rules for buy-in for premium hospital insurance for QMBs are set forth in § 406.26 of this chapter.

(a) through (d) of this section apply, and coverage begins as though the individual were in fact a member of the group. Coverage will end only as provided in § 407.48.

(f) *Exception to the general rule: Limitations on retroactive adjustments in the case of retroactive Medicare Part A entitlement.* (1) In cases in which a Medicaid beneficiary is retroactively entitled to Medicare Part A, beginning with retroactive determinations made on or after January 1, 2024, State liability for retroactive Medicare Part B premiums for Medicaid beneficiaries under a buy-in agreement is limited to a period of no greater than 36 months prior to the date of the Medicare eligibility determination.

(2) The Secretary may grant good cause exceptions for periods of greater or less than 36 months if application of paragraph (f)(1) of the section would result in harm to a beneficiary or if the State cannot benefit from Medicare and further limiting State liability would not result in harm to the beneficiary.

(g) *Part B enrollment under a buy-in agreement.* Individuals in a buy-in group can enroll in Part B at any time of the year, without regard to Medicare enrollment periods.

[56 FR 38082, Aug. 12, 1991, as amended at 87 FR 66508, Nov. 3, 2022]

§ 407.48 Termination of coverage under a State buy-in agreement.

An individual's coverage under a buy-in agreement terminates with the earliest of the following events:

(a) *Death.* Coverage ends on the last day of the month in which the individual dies.

(b) *Loss of entitlement to hospital insurance benefits before age 65.* If an individual loses entitlement to hospital insurance benefits before attaining age 65, coverage ends on the last day of the last month for which he or she is entitled to hospital insurance.

(c) *Loss of eligibility for the buy-in group.* If an individual loses eligibility for inclusion in the buy-in group, buy-in coverage ends as follows:

(1) On the last day of the last month for which he or she is eligible for inclusion in the buy-in group, if CMS determines ineligibility or receives a State ineligibility notice by a processing cut-off date as described in paragraph (e) of this section, by the second month after the month in which the individual becomes ineligible for inclusion in the buy-in group.

(2) On the last day of the second month before the month in which CMS receives a State ineligibility notice later than the time specified in paragraph (c)(1) of this section. If CMS receives a notice after the processing cut-off date conveyed under paragraph (e) of this section, CMS considers it to have been received the following month.

(d) *Termination or modification of buy-in agreement.* If the State's buy-in agreement is terminated, or modified to substitute a narrower buy-in group, coverage ends on the last day of the last month for which the agreement was in effect, or covered the broader buy-in group.

(e) *Processing cut-off dates for each calendar month.* On a quarterly basis, CMS is to prospectively convey to States a schedule of processing cut-off dates for each calendar month.

[53 FR 47204, Nov. 22, 1988, as amended at 56 FR 38082, Aug. 12, 1991; 87 FR 66508, Nov. 3, 2022]

§ 407.50 Continuation of coverage: Individual enrollment following end of coverage under a State buy-in agreement.

(a) *Deemed enrollment.* When coverage under a buy-in agreement ends because the agreement terminates, or is modified to substitute a narrower buy-in group, or because the individual is no longer eligible for inclusion in the buy-in group, the individual—

(1) Is considered to have enrolled during his or her initial enrollment period; and

(2) Will be entitled to SMI on this basis and liable for SMI premiums beginning with the first month for which he or she is no longer covered under the buy-in agreement.

(b) *Voluntary termination.* (1) An individual may voluntarily terminate entitlement acquired under paragraph (a) of this section by filing, with SSA or CMS, a request for disenrollment.

(2) Voluntary disenrollment is effective as follows:

(i) If the individual files a request within 30 days after the date of CMS's notice that buy-in coverage has ended, the individual's entitlement ends on the last day of the last month for which the State paid the premium.

(ii) If the individual files the request more than 30 days but not more than 6 months after buy-in coverage ends, entitlement ends on the last day of the month in which the request is filed.

(iii) If the individual files the request later than the 6th month after buy-in coverage ends, entitlement ends at the end of the month after the month in which request is filed. [1]

[53 FR 47204, Nov. 22, 1988, as amended at 56 FR 38082, Aug. 12, 1991]

Subpart D—Part B Immunosuppressive Drug Benefit

SOURCE: 87 FR 66508, Nov. 3, 2022 unless otherwise noted.

§ 407.55 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll, be deemed enrolled, or reenroll in the Part B–ID benefit if their Part A entitlement ends as described in § 406.13(f)(2) of this subchapter.

(b) *Exception.* An individual is not eligible for the Part B–ID benefit if the individual is enrolled in or for any of the following:

(1) A group health plan or group or individual health insurance coverage, as such terms are defined in section 2791 of the Public Health Service Act.

(2) Coverage under the TRICARE for Life program under section 1086(d) of title 10, United States Code.

(3) A State plan (or waiver of such plan) under title XIX and is eligible to receive benefits for immunosuppressive drugs described in section 1836(b) of the Act under such plan (or such waiver).

(4) A State child health plan (or waiver of such plan) under title XXI and is eligible to receive benefits for such drugs under such plan (or such waiver).

(5) The patient enrollment system of the Department of Veterans Affairs established and operated under section 1705 of title 38, United States Code and is either of the following:

(i) Not required to enroll under section 1705 of title 38 to receive immunosuppressive drugs described in section 1836(b) of the Act.

(ii) Otherwise eligible under a provision of title 38, United States Code, other than section 1710 of such title, to receive immunosuppressive drugs described in section 1836(b) of the Act.

(c) *Appeals.* Denials for enrollment in the Part B–ID benefit will be considered an initial determination that is appealable under § 405.904(a)(1) of this subchapter.

§ 407.57 Part B–ID benefit enrollment.

(a) *Deemed enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2) of this subchapter on or after January 1, 2023, is deemed to have enrolled into the Part B–ID benefit effective the first day of the month in which the individual first satisfies § 407.55, provided he or she provides the attestation required under § 407.59 prior to the termination of their Part A benefits.

(b) *Individual enrollment.* An individual whose Part A entitlement ends in accordance with § 406.13(f)(2) of this subchapter, and who meets the requirements of § 407.55 and provides the attestation required under § 407.59, may enroll in the Part B–ID benefit under the following conditions:

(1) If the individual's entitlement ends prior to January 1, 2023, he or she may enroll in the Part B–ID benefit beginning on October 1, 2022.

(2) If individual's entitlement ends on or after January 1, 2023, the individual may enroll at any time after their entitlement ends.

(c) *Reenrollment.* An individual who had previously enrolled in the Part B–ID benefit, but terminated that benefit, can reenroll at any time, provided the individual meets the requirements of § 407.55 and provides the attestation required under § 407.59.

(d) *Attestation.* To enroll in the Part B–ID benefit, an individual must submit the required attestation as described in § 407.59.

[1] For requests filed before July 1987, entitlement ended on the last day of the calendar quarter after the quarter in which the disenrollment request was filed.

(e) *Entitlement date.* The entitlement to the Part B–ID benefit will start as follows:

(1) For enrollments provided under paragraph (a) of this section, entitlement is effective the month Part A benefits are terminated.

(2) For enrollments provided under paragraphs (b) and (c) of this section, the Part B–ID benefit is effective the month following the month in which the individual provides the attestation required in §407.59.

(3) *Exception.* Enrollments submitted October 1, 2022 through December 31, 2022, are effective January 1, 2023.

§407.59 Attestation.

As a condition of enrollment, an individual must attest to SSA in either a verbal attestation, signed paper form provided by SSA, by electronic submission, or fax, using procedures determined by SSA, that—

(a) The individual is not enrolled and does not expect to enroll in other coverage described in §407.55(b); and

(b) If the individual does enroll in other coverage described in §407.55(b), the individual will notify SSA within 60 days of enrollment in such other coverage.

§407.62 Termination of coverage.

(a) *Other coverage.* An individual who enrolls in other coverage as described in §407.55(b) will have his or her enrollment in the Part B–ID benefit terminated on either of the following bases:

(1) If the individual notifies SSA of such coverage consistent with §407.59(b), their enrollment in the Part B–ID benefit will be terminated effective the first day of the month after the month of notification unless the individual requests a different, prospective termination date that is not after the effective date of enrollment in other health insurance coverage, as described in §407.55(b).

(2) If the individual does not notify SSA of this coverage consistent with §407.59(b), their enrollment in the Part B–ID benefit will be terminated effective the first day of the month after the month in which there is a determination of the individual's enrollment in coverage described in §407.55(b).

(b) *Death.* Enrollment in the Part B–ID benefit ends on the last day of the month in which the individual dies.

(c) *Nonpayment of premiums.* If an individual fails to pay the premiums, the Part B–ID benefit enrollment will end as provided in the rules for Part B premiums set forth in part 408 of this chapter.

(d) *Request by individual.* An individual may request disenrollment at any time by notifying SSA that he or she no longer wants to be enrolled in the Part B–ID benefit. Such individual's enrollment in the Part B–ID benefit ends with the last day of the month in which the individual provides the disenrollment request, except for an individual who loses coverage under a State buy-in agreement, as described in §407.50(b)(2)(i).

(e) *Entitlement to Hospital Insurance benefits.* Enrollment in the Part B–ID benefit ends effective the last day of the month prior to the month that the individual becomes entitled to benefits under §406.5, §406.12, or §406.13 of this subchapter.

(f) *Appeals.* An involuntary termination of the Part B–ID benefit for reasons described at §407.62(a)(2), (b), or (c) of this subsection, will be considered an initial determination that is appealable under §405.904(a)(1) of this subchapter. An individual can request to continue receiving Part B–ID benefits while waiting for an appeals decision.

PART 408—PREMIUMS FOR SUPPLEMENTARY MEDICAL INSURANCE

Subpart A—General Provisions

Sec.

Subpart B—Amount of Monthly Premium

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 52 FR 48115, Dec. 18, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 408.1 Statutory basis.

(a) This part implements certain provisions of sections 1837 through 1840 and 1881(d) of the Social Security Act (the Act) and conforms to other regulations that implement section 1843 of the Act. Section 1838(b) requires regulations to establish when an individual's coverage ends because of nonpayment of premiums. It also specifies that those regulations may provide a grace period for payment of overdue premiums without loss of coverage. Section 1839 sets forth the specific procedures for determining the amount of the monthly premium and section 1840 establishes the rules for payment of premiums. Section 1843 provides that a State may enter into a buy-in agreement to secure SMI coverage for certain individuals by enrolling them in the SMI program and paying the premiums on their behalf. Section 1881(d) provides that Medicare payment, for the reasonable charges incurred in connection with a kidney donation, shall be made (without regard to deductible, premium, or coinsurance provisions of title XVIII) as prescribed in regulations.

(b) The Federal Claims Collection Act (31 U.S.C. 3711), as implemented by 4 CFR parts 101–105, provides the basic authority for recovery of debts owed the United States government and

specifies the conditions for the suspension or termination of collection action. Departmental regulations at 45 CFR part 30, updated by a final rule published on January 5, 1987 (52 FR 260) set forth procedures for the exercise of the Department's authority to collect and dispose of debts and were intended to complement rules applicable to particular programs. CMS rules are set forth at 42 CFR part 401, subpart F.

[52 FR 48115, Dec. 18, 1987; 53 FR 4158, Feb. 12, 1988, as amended at 56 FR 48112, Sept. 24, 1991]

§ 408.2 Scope and purpose.

(a) This part sets forth the policies and procedures for determining the amount of monthly supplementary medical insurance (SMI) premiums, for the payment, collection, or refund of premiums, for termination of coverage because of nonpayment of premiums, and for reinstatement of coverage if certain conditions are met. It conforms to subpart C of part 407 of this chapter, which sets forth the requirements for State buy-in agreements. These policies are intended to protect enrollee coverage to the maximum degree compatible with maintaining the integrity of the SMI program.

(b) Policies that apply to premiums that certain individuals must pay in order to become entitled to Medicare Part A hospital insurance benefits, are set forth in part 406 of this chapter.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.3 Definitions.

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

Enrollee means an individual who is enrolled in the SMI program under Medicare Part B.

Taxable year means the 12-month period (calendar or fiscal year) for which the individual files his or her income tax return.

§ 408.4 Payment obligations.

(a) *Month for which payment is due.* (1) A payment is due for each month, beginning with the first month of SMI coverage and continuing through the month of death or, if earlier, the month in which coverage terminates.

(2) A premium is due for the month of death, if SMI coverage is still in effect, even though the individual dies on the first day of the month.

(b) *Overdue premiums.* (1) Overdue premiums constitute an obligation enforceable against the enrollee or the enrollee's estate.

(2) Overdue premiums are collected—

(i) By deduction from social security or railroad retirement benefits or Federal civil service annuities;

(ii) Directly from the enrollee or the enrollee's estate; or

(iii) By offset against any SMI payments payable to the enrollee or the enrollee's estate.

(3) Interest is not charged on overdue premiums, except under a State buy-in agreement, as provided in § 408.6(c)(4).

(c) *Premiums not required for certain kidney donors.* (1) No premiums are required for SMI benefits related to the donation of a kidney if the donor is not an enrollee.

(2) A kidney donor who is an enrollee is not relieved of the obligation for premiums.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.6 Methods and priorities for payment.

(a) *Methods of payment*—(1) *General rules.* Premiums are paid by one of the following four methods:

(i) Payment by a State under a buy-in agreement.

(ii) Deduction from monthly railroad retirement of social security cash benefits or Federal civil service annuities.

(iii) Direct remittance on an individual basis, by or on behalf of the enrollee.

(iv) Direct remittance on a group basis, by an employer, union, lodge or other organization, or by an entity of State or local government.

(2) *Special situations.* (i) If the monthly social security benefit or age 72 special benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance. (This situation may arise if the individual first becomes eligible for social security benefits after December 31, 1981, and is, therefore, not eligible for the

fixed minimum, or receives age 72 special benefits that are reduced because the individual receives a government pension.)

(ii) If the monthly railroad retirement benefit or civil service annuity payment is less than the premium, the monthly payment is not withheld and the enrollee is required to pay the total premium by direct remittance.

(b) *Priorities for payment.* (1) If an enrollee is enrolled under a State buy-in agreement—

(i) SMI premiums may not be deducted from monthly cash benefits or annuities; and

(ii) The enrollee may not be required to pay by direct remittance.

(2) If an enrollee is not covered under a State buy-in agreement, but is receiving a monthly benefit or an annuity specified in paragraph (a)(1)(ii) of this section—

(i) The premiums are deducted from that benefit or annuity; or

(ii) If the monthly benefit or payment is less than the monthly premium, the rules of paragraph (a)(2) of this section apply.

(3) If an enrollee is neither covered under a State buy-in agreement, nor receiving monthly benefits or annuity payments, the premiums must be paid totally by direct remittance.

(c) *Payment by a State under a buy-in agreement.* (1) A buy-in agreement is an agreement under which a State, through enrollment and payment of SMI premiums, secures SMI benefits for individuals who are eligible for that program and also eligible for certain other cash or medical benefits. (Policies on enrollment under State buy-in agreements are contained in subpart C of part 407 of this chapter.)

(2) The State pays the premiums for each month for which an individual is covered under the agreement.

(3) If an individual's coverage under a State buy-in agreement terminates, his coverage continues on an individual enrollment basis. The premiums are then deducted from benefits, as set forth in subpart C of this part, or paid by direct remittance in accordance with subpart D or subpart E of this part.

(4) Policy on collection of premiums from buy-in States is set forth in a FEDERAL REGISTER notice published on September 30, 1985 at 50 FR 39784.

§ 408.8 Grace period and termination date.

(a) *Grace period.* (1) For all initial premium payments (monthly or quarterly), and subsequent monthly or quarterly payments, the grace period ends with the last day of the third month after the billing month.

(2) For payments required because the monthly benefit is less than the monthly premium, the grace period ends on April 30 of the year following the calendar year which the premiums are due.

(b) *Extension of grace period: Last day is nonwork day.* If the last day of the grace period is a Saturday, Sunday, legal holiday, or a day that, by statute or executive order, is a nonwork day for Federal employees, the grace period is extended to the next succeeding work day.

(c) *Termination date.* The end of the grace period is the termination date for SMI coverage if overdue premiums have not been paid by that date in accordance with § 408.68.

(d) *Extension of grace period for good cause.* (1) CMS may reinstate entitlement, without interruption of coverage, if the individual shows good cause for failure to pay within the initial grace period, and pays all overdue premiums within three calendar months after the termination date.

(2) Good cause will be found if the individual establishes, by a credible statement, that failure to pay premiums within the initial grace period was due to conditions over which he or she had no control, or which he or she could not reasonably have been expected to foresee.

[52 FR 48115, Dec. 18, 1987, as amended at 56 FR 48112, Sept. 24, 1991]

§ 408.10 Claim for monthly benefits pending concurrently with request for SMI enrollment.

(a) If it is clear that an individual who applies for social security or railroad retirement benefits and for SMI will be entitled to monthly benefits, the application for monthly benefits is processed simultaneously with the request for SMI enrollment.

(1) If monthly benefits are paid, the SMI premiums are deducted from those benefits.

(2) If monthly benefits are suspended (for instance, because the individual's earnings exceed the maximum allowed by law), the enrollee is billed for direct remittance.

(b) If it is clear that an individual will be entitled to SMI, but there is substantial question as to eligibility for monthly benefits, the request for SMI enrollment is processed separately.

(1) When SMI enrollment is approved, the enrollee is billed for direct remittance.

(2) When the application for monthly benefits is adjudicated, the following rules apply:

(i) If monthly benefits are paid, the SMI premiums are deducted from those benefits, with appropriate adjustments for any premiums already paid by direct remittance.

(ii) If the application for monthly benefits is approved but the benefits are suspended, the grace period is as set forth in § 408.8(a).

(iii) If the application for monthly benefits is denied, the grace period is as set forth in § 408.8(a)(1).

[52 FR 48115, Dec. 18, 1987, as amended at 56 FR 48112, Sept. 24, 1991]

Subpart B—Amount of Monthly Premiums

§ 408.20 Monthly premiums.

(a) *Statutory provisions.* (1) The law established a monthly premium of $3 for the initial period of the program. It also set forth criteria and procedures for the Secretary to follow each December, beginning with December 1968, to determine and promulgate the standard monthly premium for the 12–month period beginning with July of the following year.

(2) The law was amended in 1983 to require that the Secretary promulgate the standard monthly premium in September of that year, and each year thereafter, to be effective for the 12 months beginning with the following January.

(3) The standard monthly premium applies to individuals who enroll during their initial enrollment periods. In other situations, that premium may be increased or decreased as specified in this subpart.

(4) The law was further amended in 1984 to include a temporary ''hold harmless'' provision (set forth in paragraph (e) of this section), that was subsequently extended and finally made permanent in 1988.

(5) The law was further amended in 2003 to ensure that amounts payable from the Transitional Assistance Account described in § 403.822 of this chapter shall not be taken into account in computing actuarrial rates or premium amounts.

(b) *Criteria and procedures for the period from July 1976 through December 1983, the period from January 1991 through December 1995, and for periods after December 1998.* (1) For periods from July 1976 through December 1983 and after December 1998, the Secretary determines and promulgates as the standard monthly premium (for disabled as well as aged enrollees) the lower of the following:

(i) The actuarial rate for the aged.

(ii) The monthly premium promulgated the previous December for the year beginning July 1, increased by a percentage that is the same as the latest cost-of-living increase in old age insurance benefits that occurred before the current promulgation. (Because of the change in the effective dates of the premium amount (under paragraph (a)(2) of this section), there was no increase in the standard monthly premium for the period July 1983 through December 1983.)

(2) For periods after December 1998, the Secretary determines the standard monthly premium in the manner specified in paragraph (b)(1) of this section, but promulgates it in September for the following calendar year.

(3) The premiums for calendar years 1991 through 1995 are those amounts as specified by section 1839(e)(1)(B) of the Act as follows:

(i) In 1991, $29.90;

(ii) In 1992, $31.80;

(iii) In 1993, $36.60;

(iv) In 1994, $41.10; and

(v) In 1995, $46.10.

(4) In no case shall payment made for transitional assistance costs under

part 403, subpart H of this chapter be included in the formula used to calculate actuarial rates or standard monthly premiums.

(c) *Premiums for calendar years 1984 through 1990 and 1996 through 1998.* For calendar years 1984 through 1990 and 1996 through 1998, the standard monthly premium for all enrollees—

(1) Is equal to 50 percent of the actuarial rate for enrollees age 65 or over, that is, is calculated on the basis of 25 percent of program costs without regard to any cost-of-living increase in old age insurance benefits; and

(2) Is promulgated in the preceding September.

(d) *Limitation on increase of standard premium: 1987 and 1988.* If there is no cost-of-living increase in old age or disability benefits for December 1985 or December 1986, the standard monthly premiums for 1987 and 1988 (promulgated in September 1986 and September 1987, respectively) may not be increased.

(e) *Nonstandard premiums for certain cases*—(1) *Basic rule.* A nonstandard premium may be established in individual cases only if the individual is entitled to old age or disability benefits for the months of November and December, and actually receives the corresponding benefit checks in December and January.

(2) *Special rules: Calendar years 1987 and 1988.* For calendar years 1987 and 1988, the following rules apply:

(i) A nonstandard premium may be established if there is a cost-of-living increase in old age or disability benefits but, because the increase in the standard premium is greater than the cost-of-living increase, the beneficiary would receive a lower cash benefit in January than he or she received in December.

(ii) A nonstandard premium may not be established if the reduction in the individual's benefit would result, in whole or in part, from any circumstance other than the circumstance described in paragraph (e)(2)(i) of this section.

(3) *Special rule: Calendar years after 1988.* (i) Beginning with calendar year 1989, a premium increase greater than the cost-of-living increase is still a prerequisite for a nonstandard premium.

(ii) However, a nonstandard premium is not precluded solely because the cash benefit is further reduced as a result of government pension offset or workers' compensation payment.

(iii) Beginning with CY 2007, a nonstandard premium may not be applied to individuals who are required to pay an income-related monthly adjustment amount described in § 408.28 of this part.

(4) *Amount of nonstandard premium.* The nonstandard premium is the greater of the following:

(i) The premium paid for December.

(ii) The standard premium promulgated for January, reduced as necessary to compensate for—

(A) The fact that the cost-of-living increase was less than the increase in the standard premium; or

(B) The further reduction in benefit because of government pension offset or workers' compensation payments.

(5) *Effective dates of nonstandard premium.* A nonstandard premium established under this paragraph (e) continues in effect for the rest of the calendar year even if later there are retroactive adjustments in benefit payments. (The nonstandard premium could be affected by a determination that the individual had not established, or had lost, entitlement to monthly benefits for November or December, or both.)

(6) *Effect of late enrollment or reenrollment.* A nonstandard premium is subject to increase for late enrollment or reenrollment as required under other sections of this subpart. The increase is computed on the basis of the standard premium and added to the nonstandard premium.

(f) *Part B–ID premiums*—(1) *Premium amount.* Beginning in 2022, and every year thereafter, the Secretary, as mandated by section 1839(j) of the Act, will determine and promulgate a monthly premium rate in September for the succeeding calendar year for individuals enrolled only in the Part B–ID benefit. Such premium is equal to 15 percent of the monthly actuarial rate for enrollees age 65 and over for that succeeding calendar year.

(2) *Premium adjustments.* (i) The Part B–ID benefit premium is subject to adjustments specified in §§ 408.20(e), 408.27, and 408.28.

(ii) The Part B–ID benefit premium is not subject to § 408.22.

(3) *Premium collection.* Premiums for the Part B–ID benefit are collected as set out in § 408.6 and subpart C of this part.

(4) *Premium deductions.* Part B–ID premiums are to be deducted following the rules set forth in § 408.40.

[56 FR 8839, Mar. 1, 1991, as amended at 59 FR 26959, May 25, 1994; 68 FR 69927, Dec. 15, 2003; 73 FR 36468, June 27, 2008; 87 FR 66509, Nov. 3, 2022]

§ 408.21 Reduction in Medicare Part B premium as an additional benefit under Medicare + Choice plans.

(a) *Basis for reduction in Part B premium.* Beginning January 1, 2003 an M + C organization may elect to receive a reduction in its payments under § 422.250(a)(1) of this chapter if—

(1) 80 percent of the payment reduction is applied to reduce the standard Medicare Part B premiums of its Medicare enrollees.

(2) The Medicare Part B premium is reduced monthly and is offered to all Medicare enrollees in a specific plan benefit package.

(b) *Administrative requirements for the Part B premium reduction.* (1) The Medicare Part B premium reduction cannot be greater than the standard premium amount determined for the year, under section 1839(a)(3) of the Act. However, it may be less.

(2) The Medicare Part B premium reduction must be a multiple of 10 cents.

(3) The Medicare Part B premium reduction is applied regardless of who pays or collects the Part B premium on behalf of the beneficiary.

(4) The Medicare Part B premium can never be less than zero and will never result in a payment to a beneficiary for a specific month.

(c) *Beneficiary eligibility.* In order for a beneficiary to be eligible for the Medicare Part B premium reduction, the beneficiary must be enrolled in an M + C plan that offers the Medicare Part B premium reduction as an additional benefit.

(d) *Notifications.* After determining the Medicare Part B premium reduction amount for each eligible beneficiary, CMS will—

(1) Transmit this information to the Social Security Administration, Railroad Retirement Board, or the Office of Personnel Management, as appropriate, which will adjust the benefit check amounts as appropriate and notify the beneficiaries of their new benefit amount.

(2) Notify states and formal groups and direct billed beneficiaries of their reduced premium amounts in the regular monthly billing process.

[68 FR 66723, Nov. 28, 2003]

§ 408.22 Increased premiums for late enrollment and for reenrollment.

For an individual who enrolls after expiration of his or her initial enrollment period or reenrolls after termination of a coverage period, the standard monthly premium determined under § 408.20 is increased by ten percent for each full twelve months in the periods specified in §§ 408.24 and 408.25.

§ 408.24 Individuals who enrolled or reenrolled before April 1, 1981 or after September 30, 1981.

(a) *Enrollment.* For an individual who first enrolled before April 1, 1981 or after September 30, 1981 and before January 1, 2023, the period includes the number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled, and excludes the following:

(1) The three months of January through March 1968, if the individual first enrolled before April 1968.

(2) Any months before January 1973 during which the individual was precluded from enrolling or reenrolling by the 3-year limitation on enrollment or reenrollment that was in effect before October 30, 1972.

(3) Any months in or before a period of coverage under a State buy-in agreement.

(4) For an individual under age 65, any month before his or her current continuous period of entitlement to hospital insurance.

(5) For an individual age 65 or older, any month before the month he or she attained age 65.

(6) For premiums due for months beginning with September 1984 and ending with May 1986, the following:

(i) Any months after December 1982 during which the individual was—

(A) Age 65 to 69;

(B) Entitled to hospital insurance (Medicare Part A); and

(C) Covered under a group health plan (GHP) by reason of current employment status.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(7) For premiums due for months beginning with June 1986, the following:

(i) Any months after December 1982 during which the individual was:

(A) Age 65 or over; and

(B) Covered under a GHP by reason of current employment status.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(8) For premiums due for months beginning with January 1987, the following:

(i) Any months after December 1986 and before October 1998 during which the individual was:

(A) A disabled Medicare beneficiary under age 65;

(B) Not eligible for Medicare on the basis of end stage renal disease, under § 406.13 of this chapter; and

(C) Covered under an LGHP as described in § 407.20 of this chapter.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(9) For premiums due for months beginning with July 1990, the following:

(i) Any months after December 1986 during which the individual met the conditions of paragraphs (a)(8)(i)(A) and (a)(8)(i)(B) of this section, and was covered under a GHP by reason of the current employment status of the individual or the individual's spouse.

(ii) Any months of SMI coverage for which the individual enrolled during a special enrollment period as provided in § 407.20 of this chapter.

(10) For premiums due for months beginning with January 1, 2007, the following:

(i) Any months after December 2006 during which the individual met the conditions under § 407.21(a) of this chapter.

(ii) Any months of Part B (SMI) coverage for which the individual enrolled during a special enrollment period as provided in § 407.21(b) of this chapter.

(b) *Enrollment on or after January 1, 2023.* For an individual who first enrolled on or after January 1, 2023, the period *includes* the number of months elapsed between the close of the individual's initial enrollment period and the close of the month in which he or she first enrolled and *excludes*—

(1) The periods of time described in (a)(1) through (10) of this section; and

(2) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 407.23 of this subchapter provided the individual enrolls within the duration of the SEP.

(c) *Reenrollment.* For an individual who reenrolled before April 1, 1981, or after September 30, 1981, and before January 1, 2023, the period—

(1) *Includes* the following:

(i) The number of months elapsed between the close of the individual's initial enrollment period and the close of the enrollment period in which he or she first enrolled; plus

(ii) The number of months elapsed between the individual's initial period of coverage and the close of the enrollment period in which he or she reenrolled; plus

(iii) The number of months elapsed between each subsequent period of coverage and the close of the enrollment period in which he or she reenrolled.

(2) *Excludes* the following:

(i) Any of the periods specified in paragraph (a) of this section; and

(ii) Any month before April 1981 during which the individual was precluded from reenrolling by the two-enrollment limitation in effect before that date.

(d) *Reenrollment on or after January 1, 2023.* For an individual who reenrolled on or after January 1, 2023, the period—

(1) Includes the number of months specified in paragraphs (c)(1)(i) through (iii) of this section; and

(2) Excludes—

(i) The number of months specified in paragraphs (c)(2)(i) and (ii) of this section; and

(ii) Any months of non-coverage in accordance with an individual's use of an exceptional conditions SEP under § 407.23 of this subchapter provided the individual enrolls within the duration of the SEP.

[52 FR 48118, Dec. 18, 1987, as amended at 53 FR 6648, Mar. 2, 1988; 61 FR 40347, Aug. 2, 1996; 73 FR 36468, June 27, 2008; 87 FR 66509, Nov. 3, 2022]

§ 408.25 Individuals who enrolled or reenrolled between April 1 and September 30, 1981.

(a) *Basic rules.* Except as specified in paragraph (b) of this section, the rules set forth in § 408.24 apply to an individual who enrolled or reenrolled between April 1 and September 30, 1981.

(b) *Exception.* For an individual who enrolled or reenrolled between April 1 and September 30, 1981, the months to be counted ran through the month in which he or she reenrolled. (During those 6 months, continuous open enrollment was in effect and there was no 3-month ''general enrollment period''.)

§ 408.26 Examples.

Example 1. Mr. J, who became age 65 and otherwise eligible for enrollment in November 1965, first enrolls in March 1968. The months to be included in determining the amount of the increase in Mr. J's premiums begin with June 1966 (the first month after the close of his initial enrollment period) and extend through December 1967 (the period January through March of 1968 is excluded in determining the total months) for a total of 19 months. Since there is only one full 12-month period in 19 months, Mr. J's premiums will be 10 percent greater than if he had enrolled in his initial enrollment period.

Example 2. Mr. V, who enrolled in December 1965, voluntarily terminates his enrollment effective midnight December 31, 1967. He enrolls for a second time in January 1969. The months to be included in determining the amount of the increase in Mr. V's premiums are January 1968 through March 1969, a total of 15 months. Since this totals one full 12-month period. Mr. V's monthly premium, will be increased by 10 percent.

Example 3. Ms. N becomes age 65 in July 1965 and first enrolls in December 1967. She pays premiums increased by 10 percent above the regular rate, beginning July 1968, the first month of her SMI coverage. Ms. N fails to pay the premiums for the calendar quarter ending June 30, 1970, and her coverage is terminated on that date, the end of her grace period. Ms. N enrolls for a second time in January 1971. The months to be included in determining the amount of the increase in Ms. N's premiums are June 1966 through December 1967, a total of 19 months, and July 1970 through March 1971, a total of 9 months, for a grand total of 28 months. Since this totals two full 12-month periods, Ms. N's monthly premium will be increased by 20 percent.

Example 4. Mr. X attained age 65 in August 1966 and enrolled during his initial enrollment period. His coverage was terminated effective June 30, 1968, for nonpayment of premiums. He reenrolls in March 1973. For purposes of computing any applicable premium increase, he will not be charged any months between March 1971 (the end of the last general enrollment period during which he was eligible to reenroll under the law in effect before October 30, 1972) and January 1973. Therefore, he will be charged 36 months (July 1968–March 1971 plus January 1973–March 1973) and his premiums for his second period of coverage will be increased 30 percent.

Example 5. Ms. C, who attained age 65 in August 1973, had two periods of supplementary medical insurance coverage, both of which were terminated because of nonpayment of premiums: August 1973 through April 1975 and July 1977 through August 1978. She reenrolls in July 1981. The months to be included in determining the amount of premium increase are May 1975 through March 1977 (23 months) and April 1981 through July 1981 (4 months) for a total of 27 months. The 31 months from September 1978 through March 1981 may not be counted because Ms. C was prevented from reenrolling by the two-enrollment limitation in effect before April 1, 1981. For Ms. C, the standard monthly premium would be increased by 20 percent.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.27 Rounding the monthly premium.

Any monthly premium that is not a multiple of 10 cents is rounded to the nearest multiple of 10 cents, and any odd multiple of 5 cents is rounded to the next higher multiple of 10 cents.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988]

§ 408.28 Increased premiums due to the income-related monthly adjustment amount (IRMAA).

Beginning January 1, 2007, Medicare beneficiaries must pay an income-related monthly adjustment amount in addition to the Part B (SMI) standard monthly premium, plus any applicable increase for late enrollment or reenrollment, if the beneficiary's modified adjusted gross income exceeds the threshold amounts specified in 20 CFR 418.1115.

[73 FR 36469, June 27, 2008]

Subpart C—Deduction From Monthly Benefits

§ 408.40 Deduction from monthly benefits: Basic rules.

(a) *Deduction from monthly benefits.* (1) Enrollees who are receiving monthly benefits do not have the option of paying by direct remittance to avoid deduction.

(2) If the enrollee is entitled to more than one type of monthly benefit, the order of priority for deduction is as follows:

(i) Railroad retirement benefits.

(ii) Social security benefits.

(iii) Civil service annuities.

(b) *Deduction from initial or reinstated benefits.* When an enrollee receives a monthly benefit check after an initial award or after a period of suspension, that check is, if administratively feasible, reduced or increased to deduct unpaid premiums or refund premiums paid in advance by direct remittance.

(c) *Ongoing deductions.* The premium for each month is deducted from the cash benefit for the preceding month, e.g., the premium for March is deducted from the benefit for February, which is paid at the beginning of March.

§ 408.42 Deduction from railroad retirement benefits.

(a) *Responsibility for deductions.* If an enrollee is entitled to railroad retirement benefits, his or her SMI premiums are deducted from those benefits by the Railroad Retirement Board (RRB) even though he or she is also entitled to social security benefits or a civil service annuity, or both.

(b) *Action when benefits are suspended.* If the railroad retirement benefits are suspended, the RRB sends premium notices requesting direct remittance, to be made in accordance with the rules set forth in Subpart D of this part.

§ 408.43 Deduction from social security benefits.

SSA, acting as CMS's agent, deducts the premiums from the monthly social security benefits if the enrollee is not entitled to railroad retirement benefits. (If the benefit is less than the monthly premium, the benefit is withheld and the enrollee is required to pay the balance through direct remittance.)

§ 408.44 Deduction from civil service annuities.

(a) *Responsibility for deductions.* If an enrollee is not entitled to railroad retirement benefits or social security benefits, and is receiving a civil service annuity, the premiums are deducted from that annuity by the Office of Personnel Management (OPM) on the basis of a notice from SSA indicating that the annuitant is entitled to SMI.

(b) *Deduction of spouse's premiums.* If the annuitant's spouse is also enrolled for SMI and is not entitled to a civil service annuity or to social security or railroad retirement benefits, and the annuitant gives written consent, OPM also deducts the spouse's premium from the annuitant's monthly check.

(c) *Withdrawal of annuitant's consent.* (1) If an annuitant wishes to withdraw consent for deduction of the spouse's premium, he or she must send written notice of withdrawal to OPM.

(2) The withdrawal notice is effective with the third month after the month in which it is received, or with the month specified in the notice, whichever is later.

§ 408.45 Deduction from age 72 special payments.

(a) *Deduction of premiums.* SMI premiums are deducted from age 72 special payments made under section 228 of the Act or the payments are withheld under procedures that correspond to the rules set forth in §§ 408.40 and 408.43.

(b) *Collection of premiums while age 72 special payments are suspended.* If the

age 72 special payments are suspended, CMS or its agent notifies the enrollee to pay premiums by direct remittance, in accordance with the rules set forth in § 408.60.

(c) *Grace period.* The grace period ends with the last day of the third month after the billing month.

(d) *Resumption of age 72 special payments.* (1) If age 72 special payments are resumed before the end of the grace period and all premium arrears can be deducted from those special payments, SMI coverage continues and the enrollee need not pay by direct remittance.

(2) Subsequent special payments are reduced by the amount of the premium for as long as the enrollee receives special payments.

§ 408.46 Effect of suspension of social security benefits.

(a) *Benefit payments to be resumed during the taxable year.* (1) If social security benefit payments are scheduled to be resumed during the enrollee's current taxable year, the enrollee is not billed.

(2) The enrollee may, if he or she wishes, pay the premiums during suspension of benefits.

(b) *Benefit payments not to be resumed during the enrollee's current taxable year.* (1) If social security benefits are suspended for a period that will not permit collection of all premiums due from monthly benefits payable in the enrollee's current taxable year, CMS or its agents bill the enrollee and require direct remittance in accordance with subpart D of this part.

(2) The first billing is for whatever premiums are necessary to place the enrollee in a quarterly cycle.

(3) Thereafter, the billing is on a quarterly basis. (Quarters for different enrollees are staggered throughout the year.)

(4) The enrollee has the option of paying premiums for more than one quarter at the same time.

§ 408.47 [Reserved]

§ 408.50 When premiums are considered paid.

(a) *Actual deduction.* A premium is considered paid if it is actually deducted from a monthly benefit check. Therefore—

(1) The premium is ''paid'' even if SSA later finds that the benefit was paid in error; but

(2) A finding that a monthly benefit was erroneously withheld does not constitute payment of the premium for that month. Since there was no payment, there was no deduction. The enrollee is billed and continuance of coverage depends on payment of premiums before the end of the grace period or extended grace period.

(b) *Payment within the grace period.* Overdue premiums are considered paid within the grace period in the following situations:

(1) *Benefits are resumed during the grace period.* (i) Monthly cash benefit payments are payable for the last month of the initial grace period or for earlier months on the basis of a notice filed by the enrollee before the initial grace period ends; and

(ii) Those payments are sufficient to permit deduction of all overdue premiums.

(2) *Annual earnings report or other report submitted during the grace period shows a benefit is due.* (i) Before the end of the grace period, the enrollee submits a report clearly showing that monthly cash benefits, previously withheld, are payable; and

(ii) Those benefits are sufficient to permit deduction of the full amount of the overdue premiums.

(3) *Premium arrears are paid by direct remittance.* The enrollee makes a direct remittance payment of all overdue premiums before the end of the grace period.

[52 FR 48115, Dec. 18, 1987; 53 FR 4159, Feb. 12, 1988; 56 FR 48112, Sept. 24, 1991]

§ 408.52 Change from direct remittance to deduction.

If a direct remittance enrollee becomes entitled to monthly benefits—

(a) The SMI premiums are deducted from those benefits; and

(b) The enrollee is notified of the deduction and of any adjustment of the initial benefit check that is required to collect overdue premiums or refund premiums paid in advance.

§ 408.53 Change from partial direct remittance to full deduction.

If a benefit that was less than the premium (and therefore required direct remittance of the difference) is increased to an amount equal to, or greater than, the premium—

(a) The full premium is paid from the benefit; and

(b) Any amounts the enrollee had paid toward premiums not yet due are refunded.

Subpart D—Direct Remittance: Individual Payment

§ 408.60 Direct remittance: Basic rules.

(a) Premiums not deducted from monthly benefits under Subpart C of this part or paid by a State buy-in agreement must be paid by direct remittance to CMS or its agents, by or on behalf of the enrollee.

(b) Quarterly payment is preferred as more cost-effective, but monthly payment is accepted if the enrollee is unwilling or unable to make quarterly payments or is also paying hospital insurance premiums, which must be paid every month.

(c) CMS, directly or through its agents, sends quarterly or monthly premium bills and includes an addressed return envelope with the bill.

(d) The individual must—

(1) Send a check or money order that is drawn payable to ''CMS Medicare Insurance'' and show the enrollee's name and claim number as it appears on the Medicare card; and

(2) Return the bill with the check or money order in the preaddressed envelope.

§ 408.62 Initial and subsequent billings.

(a) *Monthly billing.* (1) The first premium bill is for the period from the first month of coverage (or the first month of change from deduction or State buy-in payment) through the end of the first month after the month of billing.

(2) Subsequent billings are for periods of one month.

(b) *Quarterly billing.* (1) The first premium bill is for the period from the first month of coverage (or of change from deduction or State buy-in payment) through the third month after the month of billing.

(2) Subsequent billings are for periods of three months.

§ 408.63 Billing procedures when monthly benefits are less than monthly premiums.

If monthly benefits are less than monthly premiums, the following procedures apply:

(a) *Notice of amount due.* At the beginning of SMI entitlement, and at the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of the amount of benefits payable for the rest of the year and the total premiums due for those same months; and

(2) Bills the enrollee for the difference.

(b) *Notice of amount overdue.* At the beginning of each succeeding calendar year, SSA—

(1) Notifies the enrollee of any amounts overdue for premiums for the preceding calendar year; and

(2) Indicates that if the amount still overdue on April 30 is equal to or greater than the premium for 3 months, SMI coverage will terminate on that date.

§ 408.65 Payment options.

(a) The enrollee is not asked to pay premiums at the time of enrollment but is instructed to pay them upon receipt of a premium bill from CMS or its agents.

(b) However, if the enrollee wishes, he or she may pay from one to 12 months or from one to four quarters at the time of enrollment.

§ 408.68 When premiums are considered paid.

(a) *Payment by check.* The premium is considered paid if the check is paid by the bank the first or second time it is presented for payment.

(b) *Payment within the grace period.* (1) A premium is considered paid within the grace period if it is delivered personally, or mailed on or before the last day of that period.

(2) A premium payment is considered to have been mailed 7 days before it is received by CMS.

§ 408.70 Change from quarterly to monthly payments.

If an enrollee requests change from quarterly to monthly payment—

(a) If the enrollee is paid up under the quarterly cycle, the first monthly bill is for one month.

(b) If the enrollee is not paid up under the quarter system, the first bill includes all premiums due.

§ 408.71 Change from deduction or State payment to direct remittance.

(a) *Basis for change.* An SMI enrollee is required to pay by direct remittance in any of the following circumstances:

(1) The enrollee's entitlement to social security or railroad retirement benefits ends for any reason other than death.

(2) The premiums can no longer be deducted from the civil service annuity of the enrollee or the enrollee's spouse.

(3) The enrollee no longer qualifies for coverage under a State buy-in agreement, and is not entitled to social security or railroad retirement monthly benefits.

(b) *Billing.* When any of the events specified in paragraph (a) of this section occurs (or as soon thereafter as possible), CMS or its agents bill the enrollee for direct remittance, in accordance with this subpart.

Subpart E—Direct Remittance: Group Payment

§ 408.80 Basic rules.

(a) *Sources of group payment.* An employer, a lodge, union, or other organization may pay SMI premiums on behalf of one or more enrollees.

(b) *Informal arrangement.* Enrollees may turn over their premium notices to their employer, union, lodge, or other organization and that organization may send a single payment (with the premium notices attached so that the payments can readily be identified with the appropriate enrollees) to the CMS Premium Collection Center. Prompt payment is essential since SMI coverage terminates if premiums are not paid by the end of the grace period.

(c) *Group billing arrangement.* CMS may send a single notice for the premiums due from a group of enrollees if the following conditions are met:

(1) The group payer—

(i) Uses funds other than the enrollees' to pay all or a substantial part of the premiums; or

(ii) Deducts the premiums from periodic payments it makes to the enrollees in the group.

(2) The enrollee's rights are protected and enrollees are not required to pay the costs of having their premiums paid on a group basis.

§ 408.82 Conditions for group billing.

CMS agrees to a group billing arrangement only if the following conditions are met:

(a) Conditions the group payer must meet. The group payer submits a written request for group billing—

(1) Showing that all or part of the payments are made from the payer's funds or from funds due the enrollees and in the payer's possession; and

(2) Agreeing not to charge the enrollees for the service of paying the premiums or for the administrative costs such as recordkeeping and postage.

(b) *Enrollees eligible for group payment.* (1) Group payment may be made only on behalf of individuals who are already enrolled and are being billed for direct remittance.

(2) Group payment may not be made for enrollees whose premiums are being deducted from monthly benefits in accordance with Subpart C of this part or being paid by the State under a buy-in agreement.

(c) *Protection of enrollee's rights.* The use of group billing must not jeopardize the enrollees' right—

(1) To confidentiality of personal information;

(2) To terminate enrollment;

(3) To resume individual payment of premiums if he or she wishes; and

(4) To receive notice of any action that affects the SMI benefits.

(d) *Authorization by the enrollee.* (1) To ensure maximum feasible protection of the rights specified in paragraph (c) of this section, each enrollee must give written authorization as specified in § 408.84(a)(2).

(2) A group payer that is not an entity of State or local government must

submit all enrollee authorizations to CMS.

(3) A group payer that is an entity of State or local government may retain the authorizations and certify to CMS that it has on file an authorization for each enrollee included in the group.

(4) It is on the basis of the enrollee's authorization that CMS sends the group payer information about each enrollee, as necessary to carry out the group payment function.

(e) *Size of group.* The number of enrollees must be at least 20, which is the minimum size sufficient to make group billing efficient. (Smaller groups may use the informal procedure described in § 408.80(b).)

§ 408.84 Billing and payment procedures.

(a) *Initial premium notice.* (1) CMS or its agent always sends the initial premium notice to the enrollee.

(2) An enrollee who wishes to have the premiums paid on a group basis must give the notice to the group payer, along with written authorization for sending subsequent notices to the group payer and for release of the information required for the group payment process.

(b) *Monthly billings.* Group premiums are billed on a monthly basis. However, the group payer may pay up to 12 months in advance.

(c) Group payers must make their payments within 30 days after billing, to avoid infringing on the 90-day grace period during which the premiums may be paid by the enrollee if he or she is dropped from the group.

(d) *Effect of group payment.* Payment by a group payer is considered payment by the enrollee.

§ 408.86 Responsibilities under group billing arrangement.

(a) *Enrollee responsibilities.* (1) The enrollee is still responsible for premium payments; the group payer simply acts as his agent. If the agent fails to pay, or identifies the payment incorrectly, SSA notifies both the agent and the enrollee that the enrollee's account is delinquent. If an enrollee fails to take action on that notice, entitlement is terminated for nonpayment of premiums.

(2) The enrollee must promptly notify both SSA and the group payer of any change of address.

(b) *Group payer's responsibilities.* The group payer must—

(1) Make premium payments promptly upon receipt of notices;

(2) Promptly notify both CMS and the enrollee when it drops an enrollee from the group;

(3) Make payments in a way that facilitates efficient and economical processing; and

(4) Maintain the confidentiality of the personal information obtained from CMS for the group payment process.

(c) *CMS responsibilities.* CMS—

(1) Sends the bill to the group payer upon authorization from the enrollee;

(2) Notifies both the payer and the enrollee if the payer fails to make timely payments; and

(3) Refunds excess premiums in accordance with § 408.88.

§ 408.88 Refund of group payments.

(a) *Basis for refund.* Group payments are refunded only in the following circumstances:

(1) The premium was for a month after the month in which the enrollee's SMI coverage terminated or the enrollee died.

(2) The premium was for a month after the month in which the group payer gave notice (before the 26th day of that month) that the enrollee was no longer eligible for group payment and was being dropped from the group.

(b) *Example.* F is the wife of J who is a retiree of Corporation X. That corporation pays premiums on behalf of all of its retirees and their dependents. F obtains a divorce from J on October 20 and thus disqualifies herself for further premium payments by the corporation. The corporation gives notice on November 10 that a refund is due because F has been dropped from the list of persons for whom it has agreed to pay premiums. The premium paid for December would be refunded to the group payer.

(c) *To whom refund is made.* (1) CMS ordinarily refunds to the group payer the premiums specified in paragraph (a) of this section.

(2) However, if CMS has information that clearly shows those premiums

were paid from the enrollee's funds, it sends the refund to the enrollee.

§ 408.90 Termination of group billing arrangement.

(a) A group billing arrangement may be terminated either by the group payer or by CMS upon 30 days' notice.

(b) CMS may terminate the arrangement if it finds that the group payer is not acting in the best interest of the enrollees or that, for any other reason, the arrangement has proved inconvenient for CMS.

§ 408.92 Change from group payment to deduction or individual payment.

(a) *Enrollee excluded from group payment arrangement because of entitlement to monthly benefits.* (1) When an enrollee becomes entitled to monthly benefits from which premiums can be deducted as specified in subpart C of this part, CMS notifies the group payer to discontinue payment for that enrollee.

(2) In order to maintain confidentiality, CMS does not explain to the group payer the reason for excluding the enrollee from the group payment arrangement.

(3) The enrollee's premiums are thereafter deducted from the monthly benefits, in accordance with subpart C of this part.

(b) *Enrollee no longer eligible for the group.* (1) When an enrollee is no longer eligible to be included in the group (for instance because he or she is no longer employed by the group payer or has terminated union or lodge membership), the group payer must promptly notify CMS and the enrollee.

(2) CMS or its agents resume sending individual bills to the enrollee, for direct remittance subject to the grace period and termination dates specified in § 408.8.

Subpart F—Termination and Reinstatement of Coverage

§ 408.100 Termination of coverage for nonpayment of premiums.

(a) *Effective date of termination.* Termination is effective on the last day of the grace period. The determination is not made until 15 days after that day to allow for processing of remittances mailed late in the grace period, as provided in § 408.68.

(b) *Notice of termination.* (1) SSA sends the enrollee notice of termination between 15 and 30 days after the end of the grace period and includes information regarding the enrollee's right of appeal.

(2) CMS notifies any intermediary or carrier that had previously been informed that the enrollee had met the SMI deductible for the year in which the termination is effective.

§ 408.102 Reconsideration of termination.

(a) *Basic rules.* Coverage may be reinstated without interruption of benefits if the following conditions are met:

(1) The enrollee appeals the termination by the end of the month following the month in which SSA sent the notice of termination.

(2) The enrollee alleges and it is found that the enrollee did not receive timely and adequate notice that the premiums were overdue.

(3) The enrollee pays, within 30 days after SSA's subsequent request for payment, all premiums due through the month in which he or she appealed the termination.

(b) *Basis for reinstating coverage.* Coverage may be reinstated if the evidence establishes one of the following:

(1) The enrollee acted diligently to pay the premiums or to request relief upon receiving a premium notice very late in the grace period or shortly after its end, and the delayed notice was not the enrollee's fault. (For example, if the billing notice was misaddressed or lost in the mail, it would not be the enrollee's fault; if the enrollee had moved and not notified SSA of the new address, he or she would be responsible for the delay.)

(2) On the basis of information given by SSA, the enrollee could reasonably have believed that the premiums were being paid by deduction from benefits or by some other means. (An example would be a notice indicating that premiums would be paid by a State Medicaid agency or a group payer or would be deducted from the spouse's civil service annuity.)

(c) *No basis for reinstating coverage.* Coverage may not be reinstated if the enrollee—

(1) Received timely and adequate notice but failed to pay within the grace period, for example because of insufficient income or resources; or

(2) Appealed the termination more than one month after the month in which SSA sent the termination notice.

§ 408.104 Reinstatement procedures.

(a) *Request for payment.* If the conditions of § 408.102(a) (1) and (2) are met, SSA sends written notice requesting the enrollee to pay, within 30 days, all premiums due through the month in which the enrollee appealed the termination.

(b) *Reinstatement of coverage.* If SSA receives the requested payment within 30 days, it sets aside the termination and reinstates the enrollee's coverage without interruption.

Subpart G—Collection of Unpaid Premiums; Refund of Excess Premiums After the Death of the Enrollee

§ 408.110 Collection of unpaid premiums.

(a) *Basis and scope*—(1) *Basis.* Under the Federal Claims Collection Act of 1966 (31 U.S.C. 3711), CMS is required to collect any debts due it but is authorized to suspend or terminate collection action on debts of less than $20,000 when certain conditions are met. (See 4 CFR, parts 101–105 for general rules implementing the Federal Claims Collection Act.) As indicated in § 408.4, unpaid premiums are debts owed the Federal government by the enrollee or the enrollee's estate.

(2) *Scope.* This section sets forth the methods of collection used by CMS and the circumstances under which CMS terminates or renews collection action. The regulations in this section apply to hospital insurance premiums as well as SMI premiums.

(b) *Collection of unpaid premiums.* Generally, CMS will attempt to collect unpaid premiums by one of the following methods:

(1) By billing enrollees who pay the premiums directly to CMS or to a designated agent in accordance with § 408.60.

(2) By deduction from any benefits payable to the enrollee or the estate of a deceased enrollee under Title II or XVIII of the Social Security Act, the Railroad Retirement Act or any act administered by the Office of Personnel Management in accordance with § 408.4(b) and Subpart C of this part (Deduction from Monthly Benefits); or

(3) By billing the estate of a deceased enrollee.

(c) *Termination of collection action.* CMS terminates collection action on unpaid premiums under either of the following circumstances, if the cost of collection exceeds the amount of overdue premiums:

(1) The individual is not entitled to benefits under the Acts listed in paragraph (b)(2) of this section, is not currently enrolled for SMI or premium hospital insurance, and demonstrates, to CMS's satisfaction, that he or she is unable to pay the debt within a reasonable time.

(2) The individual has been dead more than 27 months (the maximum time allowed for claiming SMI benefits), and the legal representative of his or her estate demonstrates, to CMS's satisfaction, that the estate is unable to pay the debt within a reasonable time.

(d) *Renewal of collection efforts.* CMS renews collection efforts in either of the following circumstances, if the cost of collection does not exceed the amount of the overdue premiums:

(1) The individual enrolls again for premium hospital insurance or SMI. (Payment of overdue premiums is not a prerequisite for reenrollment.)

(2) The individual becomes entitled or reentitled to social security or railroad retirement benefits or a Federal civil service annuity.

§ 408.112 Refund of excess premiums after the enrollee dies.

If CMS has received premiums for months after the enrollee's death, CMS refunds those premiums as follows:

(a) To the person or persons who paid the premiums or, if the premiums were paid by the enrollee, to the representative of the enrollee's estate, if any.

(b) If refund cannot be made under paragraph (a) of this section, CMS refunds the premiums to the enrollee's survivors in the following order of priority:

(1) 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;

(2) 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);

(3) 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);

(4) 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;

(5) 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);

(6) 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).

If none of the listed relatives survives, no refund can be made.

Subpart H—Supplementary Medical Insurance Premium Surcharge Agreements

SOURCE: 67 FR 60996, Sept. 27, 2002, unless otherwise noted.

§ 408.200 Statutory basis.

This subpart implements provisions of section 1839(e) of the Social Security Act that allow State or local government agencies to enter into an agreement with the Secretary to pay, on a quarterly or other periodic basis, a lump sum for the total of the SMI premium late enrollment surcharge amounts due for a group of eligible enrollees.

§ 408.201 Definitions.

For purposes of this subpart, the following definitions apply:

SMI premium surcharge means the amount that the standard monthly SMI premium is increased for late enrollment or for reenrollment as specified in §§ 408.22 through 408.25.

SMI premium surcharge agreement means a written arrangement between the Secretary and a State or local government agency to pay, on a quarterly, monthly, or other periodic basis, a lump sum for the SMI premium surcharge amounts due for a designated group of eligible enrollees.

§ 408.202 Conditions for participation.

(a) A State or local government agency may apply to CMS to enter into an SMI premium surcharge agreement if the following conditions are met:

(1) Each individual designated for coverage under the premium surcharge agreement must be enrolled in Medicare Part B at the time the individual is added to the premium surcharge account.

(2) Each enrollee designated for coverage under the agreement must, at the time the individual is added to the premium surcharge account, be responsible for paying the base premium and surcharge through direct remittance or benefit withholding from Social Security or Railroad Retirement benefits or a Civil Service annuity.

(3) Each enrollee designated for coverage under the agreement must, at the time the individual is added to the premium surcharge account, not have premiums paid by a State Welfare Agency under a State buy-in agreement as described in § 407.40 of this chapter or under a group billing arrangement as described in § 408.80.

(b) The State or local government agency must secure from each enrollee a signed, written statement authorizing CMS to send billing notices directly to the State or local government agency, and to release to the State or local government agency information required under the SMI premium surcharge agreement.

(c) The authorization statement for each enrollee must be retained in the State or local government agency files for as long as the enrollee is covered by the agreement. These authorization statements need not be forwarded to CMS.

(d) The State or local government agency must certify to CMS, in writing, that an authorization statement is on file for each enrollee covered under the SMI premium surcharge agreement. Only one certification is necessary for the entire group of covered enrollees.

(e) A State or local government agency must establish an automated data exchange with CMS using the Third Party Premium Collection System, in order to transmit electronically an input file that will be used to add or remove enrollees from the billing system.

§ 408.205 Application procedures.

(a) A State or local government agency must contact its CMS regional office (RO) to request application materials.

(b) If interested in entering into an agreement, the State or local government agency must return to the RO two copies of the completed application materials.

(c) CMS reviews the application materials, and, when they are approved, notifies the State or local government agency, and the RO.

§ 408.207 Billing and payment procedures.

(a) *Adding and removing enrollees.* The State or local government agency must transmit an input file containing addition and removal records electronically to CMS as follows:

(1) Input files must be transmitted at least once each calendar month, but may be transmitted as often as once a day.

(2) CMS will not add or remove enrollees retroactively, except for removals upon the death of an enrollee.

(3) The State or local government agency must pay the SMI premium surcharge for each eligible enrollee who is included in the agreement for the time period beginning with the month the enrollee is added and continuing through the month the State or local government agency informs CMS that the enrollee is to be removed, the month the enrollee's Part B coverage terminates, or the month of the enrollee's death, whichever comes first.

(b) *Payment and grace period.* Payment must be made to CMS as follows:

(1) Payment to CMS must be received by CMS by the first day of each month.

(2) There is a 10-day grace period for receipt of payment.

(3) Payment must be made to CMS via electronic funds transfer.

(c) *Late payment penalties.* CMS may assess interest for any payment it does not receive by the first day of the month as follows:

(1) Interest will be assessed at the SMI trust fund rate as computed for new investments in accordance with section 1841(c) of the Act.

(2) Interest will be waived if the full payment is received by the 10th day of the month in which it is due.

(3) Interest will be calculated and assessed in 30-day increments.

(4) Interest will be assessed on the balance of the amount billed that remains unpaid at the expiration of the grace period and unpaid balances from prior periods.

(5) Interest will continue to accrue on unpaid amounts until the balance is paid in full.

(d) *Disagreement over billing amounts or interest.* If the State or local government agency disagrees with the amount assessed in a billing statement or interest charge, it must notify CMS as follows:

(1) The State or local government agency must provide evidence suitable to CMS to substantiate its claim.

(2) The State or local government agency must continue to make full payment while CMS evaluates the evidence provided.

(3) Credit for payment amounts or interest that CMS determines to be due

to the State or local government agency will be reflected as an adjustment in subsequent bills, effective on the date the corrected amount would have been due.

§ 408.210 Termination of SMI premium surcharge agreement.

(a) *Termination by the State or local government agency.* The State or local government agency may voluntarily terminate its agreement with CMS as follows:

(1) The State or local government agency must notify CMS, in writing, at least 30 days before the effective date of the termination.

(2) The State or local government agency must pay any unpaid premium surcharge amounts and interest due within 30 days after the effective date of the termination.

(3) Interest will continue to accrue until all amounts due are paid in full.

(b) *Termination by CMS.* CMS may terminate the agreement with a State or local government agency as follows:

(1) If a State or local government agency's payments are delinquent 30 days or more, CMS may terminate the agreement with 30 days advance notice.

(2) If the State or local government agency fails to comply with the terms of the agreement or procedures promulgated by CMS, CMS may terminate the agreement with 30 days advance notice.

(3) If CMS finds that the State or local government agency is not acting in the best interest of the enrollees, or CMS, or for any reason other than those in paragraphs (b)(1) and (b)(2) of this section, CMS may terminate the agreement at any time.

(4) The State or local government agency must pay all outstanding premium surcharge and any interest amounts due within 30 days after the effective date of the termination.

(5) Interest will continue to accrue until all amounts due are paid in full.

(6) After the agreement is terminated, CMS will resume collection of the premium surcharge from the enrollees covered under the terminated agreement.

(7) If an agreement is terminated by CMS, the State or local government agency must wait 3 years from the effective date of the termination before it can request to enter into another SMI premium surcharge agreement.

PART 409—HOSPITAL INSURANCE BENEFITS

Subpart A—Hospital Insurance Benefits: General Provisions

Sec.

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

Subpart C—Posthospital SNF Care

Subpart D—Requirements for Coverage of Posthospital SNF Care

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 48 FR 12541, Mar. 25, 1983, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 409 appear at 62 FR 46037, Aug. 29, 1997.

Subpart A—Hospital Insurance Benefits: General Provisions

§ 409.1 Statutory basis.

This part is based on the identified provisions of the following sections of the Social Security Act:

(a) Sections 1812 and 1813 establish the scope of benefits of the hospital insurance program under Medicare Part A and set forth deductible and coinsurance requirements.

(b) Sections 1814 and 1815 establish conditions for, and limitations on, payment for services furnished by providers.

(c) Section 1820 establishes the critical access hospital program.

(d) Section 1861 describes the services covered under Medicare Part A, and benefit periods.

(e) Section 1862(a) specifies exclusions from coverage.

(f) Section 1881 sets forth the rules for individuals who have end-stage renal disease (ESRD), for organ donors, and for dialysis, transplantation, and other services furnished to ESRD patients.

[60 FR 50441, Sept. 29, 1995, as amended at 65 FR 62646, Oct. 19, 2000]

§ 409.2 Scope.

Subparts A through G of this part describe the benefits available under Medicare Part A and set forth the limitations on those benefits, including certain amounts of payment for which beneficiaries are responsible.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985]

§ 409.3 Definitions.

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

Arrangements means arrangements which provide that Medicare payment made to the provider that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services.

Covered refers to services for which the law and the regulations authorize Medicare payment.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge and is either a public provider, or another

provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income, and (2) requests that payment for its services be determined accordingly.

Participating refers to a hospital or other facility that meets the conditions of participation and has in effect a Medicare provider agreement.

Qualified hospital means a facility that—

(a) 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;

(b) Is not primarily engaged in providing skilled nursing care and related services for inpatients who require medical or nursing care;

(c) Provides 24-hour nursing service in accordance with Sec. 1861(e)(5) of the Act;

(d) If it is a U.S. hospital, is licensed, or approved as meeting the standards for licensing, by the State or local licensing agency; and

(e) If it is a foreign hospital, is licensed, or approved as meeting the standard for licensing, by the appropriate foreign licensing agency, and for purposes of furnishing nonemergency services to U.S. residents, is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or by a foreign program under standards that CMS finds to be equivalent to those of JCAHO.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 51 FR 41338, Nov. 14, 1986; 71 FR 48135, Aug. 18, 2006]

§ 409.5 General description of benefits.

Hospital insurance (Part A of Medicare) helps pay for inpatient hospital or inpatient CAH services and posthospital SNF care. It also pays for home health services and hospice care. There are limitations on the number of days of care that Medicare can pay for and there are deductible and coinsurance amounts for which the beneficiary is responsible. For each type of service, certain conditions must be met as specified in the pertinent sections of this subpart and in part 418 of this chapter regarding hospice care. Conditions for payment of emergency inpatient services furnished by a nonparticipating U.S. hospital and for services furnished in a foreign country are set forth in subparts G and H of part 424 of this chapter.

[71 FR 48135, Aug. 18, 2006]

Subpart B—Inpatient Hospital Services and Inpatient Critical Access Hospital Services

§ 409.10 Included services.

(a) Subject to the conditions, limitations, and exceptions set forth in this subpart, the term ''inpatient hospital or inpatient CAH services'' means the following services furnished to an inpatient of a participating hospital or of a participating CAH or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

(1) Bed and board.

(2) Nursing services and other related services.

(3) Use of hospital or CAH facilities.

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Certain other diagnostic or therapeutic services.

(7) Medical or surgical services provided by certain interns or residents-in-training.

(8) Transportation services, including transport by ambulance.

(b) *Inpatient hospital services* does not include the following types of services:

(1) Posthospital SNF care, as described in § 409.20, furnished by a hospital or a critical access hospital that has a swing-bed approval.

(2) Nursing facility services, described in § 440.155 of this chapter, that may be furnished as a Medicaid service under title XIX of the Act in a swing-bed hospital that has an approval to furnish nursing facility services.

(3) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(4) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(5) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(6) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(7) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(8) Services of an anesthetist, as defined in § 410.69

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993; 64 FR 3648, Jan. 25, 1999; 65 FR 18535, Apr. 7, 2000]

§ 409.11 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for bed and board and semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable deductible and coinsurance amounts, Medicare Part A pays in full for a private room if—

(i) The patient's condition requires him or her to be isolated;

(ii) The hospital or CAH has no semiprivate or ward accommodations; or

(iii) The hospital's or CAH's semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the hospital or CAH, respectively, for treatment of a condition that required immediate inpatient hospital or inpatient CAH care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section, Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The hospital or CAH may charge the patient the difference between its customary charge for the private room and its most prevalent charge for a semiprivate room if—

(i) None of the conditions of paragraph (b)(1) of this section is met; and

(ii) The private room was requested by the patient or a member of the family, who, at the time of the request, was informed what the hospital's or CAH's charge would be.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.12 Nursing and related services, medical social services; use of hospital or CAH facilities.

(a) Except as provided in paragraph (b) of this section, Medicare pays for nursing and related services, use of hospital or CAH facilities, and medical social services as inpatient hospital or inpatient CAH services only if those services are ordinarily furnished by the hospital or CAH, respectively, for the care and treatment of inpatients.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is a hospital or CAH employee at the time the services are furnished.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, 30667, May 26, 1993]

§ 409.13 Drugs and biologicals.

(a) Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as inpatient hospital or inpatient CAH services only if—

(1) They represent a cost to the hospital or CAH;

(2) They are ordinarily furnished by the hospital or CAH for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the hospital or CAH.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the hospital or CAH if it is medically necessary to facilitate the beneficiary's departure from the hospital and required until he or she can obtain a continuing supply.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.14 Supplies, appliances, and equipment.

(a) Except as specified in paragraph (b) of this section, Medicare pays for supplies, appliances, and equipment as inpatient hospital or inpatient CAH services only if—

(1) They are ordinarily furnished by the hospital or CAH to inpatients; and

(2) They are furnished to inpatients for use in the hospital or CAH.

(b) *Exceptions.* Medicare pays for items to be used beyond the hospital or CAH stay if—

(1) The item is one that the beneficiary must continue to use after he or she leaves the hospital or CAH, for example, heart valves or a heart pacemaker, or

(2) The item is medically necessary to permit or facilitate the beneficiary's departure from the hospital or CAH and is required until the beneficiary can obtain a continuing supply. Tracheostomy or draining tubes are examples.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.15 Services furnished by an intern or a resident-in-training.

Medical or surgical services provided by an intern or a resident-in-training are included as ''inpatient hospital or inpatient CAH services'' if they are provided—

(a) By an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association, or the Bureau of Professional Education of the American Osteopathic Association;

(b) By an intern or a resident-in-training in the field of dentistry under a teaching program approved by the Council on Dental Education of the American Dental Association; or

(c) By an intern or a resident-in-training in the field of podiatry under a teaching program approved by the Council on Podiatry Education of the American Podiatry Association.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.16 Other diagnostic or therapeutic services.

Diagnostic or therapeutic services other than those provided for in §§ 409.12, 409.13, and 409.14 are considered as inpatient hospital or inpatient CAH services if—

(a) They are furnished by the hospital or CAH, or by others under arrangements made by the hospital or CAH;

(b) Billing for those services is through the hospital or CAH; and

(c) The services are of a kind ordinarily furnished to inpatients either by the hospital or CAH or under arrangements made by the hospital or CAH.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.17 Physical therapy, occupational therapy, and speech-language pathology services.

(a) *General rules.* (1) Except as specified in this section, physical therapy, occupational therapy, or speech-language pathology services must be furnished by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, or speech-language pathologists who meet the requirements specified in part 484 of this chapter.

(2) Physical therapy, occupational therapy or speech-language pathology services must be furnished under a plan that meets the requirements of paragraphs (b) through (d) of this section, or plan requirements specific to the payment policy under which the services are rendered, if applicable.

(b) *Establishment of the plan.* The plan must be established before treatment begins by one of the following:

(1) A physician.

(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.

(3) The physical therapist furnishing the physical therapy services.

(4) A speech-language pathologist furnishing the speech-language pathology services.

(5) An occupational therapist furnishing the occupational therapy services.

(c) *Content of the plan.* The plan:

(1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and

(2) Indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan are implemented in accordance with the provider's policies and procedures.

[72 FR 66397, Nov. 27, 2007, as amended at 73 FR 69932, Nov. 19, 2008; 75 FR 73613, Nov. 29, 2010]

§ 409.18 Services related to kidney transplantations.

(a) *Kidney transplants.* Medicare pays for kidney transplantation surgery only if performed in a renal transplantation center approved under subpart U of part 405 of this chapter.

(b) *Services in connection with kidney donations.* Medicare pays for services related to the evaluation or preparation of a potential or actual donor, to the donation of the kidney, or to postoperative recovery services directly related to the kidney donation—

(1) If the kidney is intended for an individual who has ESRD and is entitled to Medicare benefits or can be expected to become so entitled within a reasonable time; and

(2) Regardless of whether the donor is entitled to Medicare.

Subpart C—Posthospital SNF Care

§ 409.20 Coverage of services.

(a) *Included services.* Subject to the conditions and limitations set forth in this subpart and subpart D of this part, ''posthospital SNF care'' means the following services furnished to an inpatient of a participating SNF, or of a participating hospital or critical access hospital (CAH) that has a swing-bed approval:

(1) Nursing care provided by or under the supervision of a registered professional nurse.

(2) Bed and board in connection with the furnishing of that nursing care.

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

(4) Medical social services.

(5) Drugs, biologicals, supplies, appliances, and equipment.

(6) Services furnished by a hospital with which the SNF has a transfer agreement in effect under § 483.70(j) of this chapter.

(7) Other services that are generally provided by (or under arrangements made by) SNFs.

(b) *Excluded services*—(1) *Services that are not considered inpatient hospital services.* No service is included as posthospital SNF care if it would not be included as an inpatient hospital service under §§ 409.11 through 409.18.

(2) *Services not generally provided by (or under arrangements made by) SNFs.* Except as specifically listed in §§ 409.21 through 409.27, only those services generally provided by (or under arrangements made by) SNFs are considered as posthospital SNF care. For example, a type of medical or surgical procedure that is ordinarily performed only on an inpatient basis in a hospital is not included as ''posthospital SNF care,'' because such procedures are not generally provided by (or under arrangements made by) SNFs.

(c) *Terminology.* In § 409.21 through § 409.36—.

(1) The terms *SNF* and *swing-bed hospital* are used when the context applies to the particular facility.

(2) The term *facility* is used to mean both SNFs and swing-bed hospitals.

(3) The term *swing-bed hospital* includes a CAH with swing-bed approval under subpart F of part 485 of this chapter.

(4) The term *post-hospital SNF care* includes SNF care that does not follow a hospital stay when the beneficiary is enrolled in a plan, as defined in § 422.4 of this chapter, offered by a Medicare + Choice (M + C) organization, that includes the benefits described in § 422.101(c) of this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30667, May 26, 1993; 63 FR 26306, May 12, 1998; 64 FR 3648, Jan. 25, 1999; 64 FR 41681, July 30, 1999; 68 FR 46070, Aug. 4, 2003; 68 FR 50854, Aug. 22, 2003; 69 FR 35529, June 25, 2004; 75 FR 73613, Nov. 29, 2010; 82 FR 32258, July 13, 2017]

§ 409.21 Nursing care.

(a) *Basic rule.* Medicare pays for nursing care as posthospital SNF care when provided by or under the supervision of a registered professional nurse.

(b) *Exception.* Medicare does not pay for the services of a private duty nurse or attendant. An individual is not considered to be a private duty nurse or attendant if he or she is an SNF employee at the time the services are furnished.

[63 FR 26306, May 12, 1998]

§ 409.22 Bed and board.

(a) *Semiprivate and ward accommodations.* Except for applicable deductible and coinsurance amounts Medicare

Part A pays in full for semiprivate (2 to 4 beds), or ward (5 or more beds) accommodations.

(b) *Private accommodations*—(1) *Conditions for payment in full.* Except for applicable coinsurance amounts, Medicare pays in full for a private room if—

(i) The patient's condition requires him to be isolated;

(ii) The SNF has no semiprivate or ward accommodations; or

(iii) The SNF semiprivate and ward accommodations are fully occupied by other patients, were so occupied at the time the patient was admitted to the SNF for treatment of a condition that required immediate inpatient SNF care, and have been so occupied during the interval.

(2) *Period of payment.* In the situations specified in paragraph (b)(1) (i) and (iii) of this section. Medicare pays for a private room until the patient's condition no longer requires isolation or until semiprivate or ward accommodations are available.

(3) *Conditions for patient's liability.* The facility may charge the patient the difference between its customary charge for the private room furnished and its most prevalent charge for a semiprivate room if:

(i) None of the conditions of paragraph (b)(1) of this section is met, and

(ii) The private room was requested by the patient or a member of the family who, at the time of request was informed what the charge would be.

§ 409.23 Physical therapy, occupational therapy, and speech-language pathology services.

Medicare pays for physical therapy, occupational therapy, or speech-language pathology services as posthospital SNF care if they are furnished—

(a) By (or under arrangements made by) the facility and billed by (or through) the facility;

(b) By qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, or speech-language pathologists as defined in part 484 of this chapter; and

(c) In accordance with a plan that meets the requirements of § 409.17(b) through (d) of this part.

[75 FR 73613, Nov. 29, 2010]

§ 409.24 Medical social services.

Medicare pays for medical social services as posthospital SNF care, including—

(a) Assessment of the social and emotional factors related to the beneficiary's illness, need for care, response to treatment, and adjustment to care in the facility;

(b) Case work services to assist in resolving social or emotional problems that may have an adverse effect on the beneficiary's ability to respond to treatment; and

(c) Assessment of the relationship of the beneficiary's medical and nursing requirements to his or her home situation, financial resources, and the community resources available upon discharge from facility care.

[63 FR 26306, May 12, 1998]

§ 409.25 Drugs, biologicals, supplies, appliances, and equipment.

(a) *Drugs and biologicals.* Except as specified in paragraph (b) of this section, Medicare pays for drugs and biologicals as posthospital SNF care only if—

(1) They represent a cost to the facility;

(2) They are ordinarily furnished by the facility for the care and treatment of inpatients; and

(3) They are furnished to an inpatient for use in the facility.

(b) *Exception.* Medicare pays for a limited supply of drugs for use outside the facility if it is medically necessary to facilitate the beneficiary's departure from the facility and required until he or she can obtain a continuing supply.

(c) *Supplies, appliances, and equipment.* Except as specified in paragraph (d) of this section, Medicare pays for supplies, appliances, and equipment as posthospital SNF care only if they are—

(1) Ordinarily furnished by the facility to inpatients; and

(2) Furnished to inpatients for use in the facility.

(d) *Exception.* Medicare pays for items to be used after the individual leaves the facility if—

(1) The item is one that the beneficiary must continue to use after leaving, such as a leg brace; or

(2) The item is necessary to permit or facilitate the beneficiary's departure from the facility and is required until he or she can obtain a continuing supply, for example, sterile dressings.

[63 FR 26307, May 12, 1998]

§ 409.26 Transfer agreement hospital services.

(a) *Services furnished by an intern or a resident-in-training.* Medicare pays for medical services that are furnished by an intern or a resident-in-training (under a hospital teaching program approved in accordance with the provisions of § 409.15) as posthospital SNF care, if the intern or resident is in—

(1) A participating hospital with which the SNF has in effect an agreement under § 483.70(j) of this chapter for the transfer of patients and exchange of medical records; or

(2) A hospital that has a swing-bed approval, and is furnishing services to an SNF-level inpatient of that hospital.

(b) *Other diagnostic or therapeutic services.* Medicare pays for other diagnostic or therapeutic services as posthospital SNF care if they are provided—

(1) By a participating hospital with which the SNF has in effect a transfer agreement as described in paragraph (a)(1) of this section; or

(2) By a hospital or a CAH that has a swing-bed approval, to its own SNF-level inpatient.

[63 FR 26307, May 12, 1998; 82 FR 32258, July 13, 2017]

§ 409.27 Other services generally provided by (or under arrangements made by) SNFs.

In addition to those services specified in §§ 409.21 through 409.26, Medicare pays as posthospital SNF care for such other diagnostic and therapeutic services as are generally provided by (or under arrangements made by) SNFs, including—

(a) Medical and other health services as described in subpart B of part 410 of this chapter, subject to any applicable limitations or exclusions contained in that subpart or in § 409.20(b);

(b) Respiratory therapy services prescribed by a physician for the assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies and abnormalities of cardiopulmonary function; and

(c) Transportation by ambulance that meets the general medical necessity requirements set forth in § 410.40(e)(1) of this chapter.

[63 FR 26307, May 12, 1998, as amended at 64 FR 41681, July 30, 1999; 84 FR 63187, Nov. 15, 2019]

Subpart D—Requirements for Coverage of Posthospital SNF Care

§ 409.30 Basic requirements.

Posthospital SNF care, including SNF-type care furnished in a hospital or CAH that has a swing-bed approval, is covered only if the beneficiary meets the requirements of this section and only for days when he or she needs and receives care of the level described in § 409.31. A beneficiary in an SNF is also considered to meet the level of care requirements of § 409.31 up to and including the assessment reference date for the initial Medicare assessment prescribed in § 413.343(b) of this chapter, when correctly assigned one of the case-mix classifiers that CMS designates for this purpose as representing the required level of care. For the purposes of this section, the assessment reference date is defined in accordance with § 483.315(d) of this chapter, and must be set for no later than the eighth day of posthospital SNF care.

(a) *Pre-admission requirements.* The beneficiary must—

(1) Have been hospitalized in a participating or qualified hospital or participating CAH, for medically necessary inpatient hospital or inpatient CAH care, for at least 3 consecutive calendar days, not counting the date of discharge; and

(2) Have been discharged from the hospital or CAH in or after the month he or she attained age 65, or in a month for which he or she was entitled to hospital insurance benefits on the basis of

disability or end-stage renal disease, in accordance with part 406 of this chapter.

(b) *Date of admission requirements.*[1] (1) Except as specified in paragraph (b)(2) of this section, the beneficiary must be in need of posthospital SNF care, be admitted to the facility, and receive the needed care within 30 calendar days after the date of discharge from a hospital or CAH.

(2) The following exceptions apply—

(i) A beneficiary for whom posthospital SNF care would not be medically appropriate within 30 days after discharge from the hospital or CAH, or a beneficiary enrolled in a Medicare + Choice (M + C) plan, may be admitted at the time it would be medically appropriate to begin an active course of treatment.

(ii) If, upon admission to the SNF, the beneficiary was enrolled in an M + C plan, as defined in § 422.4 of this chapter, offering the benefits described in § 422.101(c) of this chapter, the beneficiary will be considered to have met the requirements described in paragraphs (a) and (b) of this section, and also in § 409.31(b)(2), for the duration of the SNF stay.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41338, Nov. 14, 1986; 58 FR 30666, 30667, May 26, 1993; 62 FR 46025, Aug. 29, 1997; 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999; 68 FR 50584, Aug. 22, 2003; 72 FR 43436, Aug. 3, 2007; 82 FR 36633, Aug. 4, 2017; 84 FR 38832, Aug. 7, 2019]

§ 409.31 Level of care requirement.

(a) *Definition.* As used in this section, *skilled nursing and skilled rehabilitation services* means services that:

(1) Are ordered by a physician;

(2) Require the skills of technical or professional personnel such as registered nurses, licensed practical (vocational) nurses, physical therapists, occupational therapists, and speech pathologists or audiologists; and

(3) Are furnished directly by, or under the supervision of, such personnel.

(b) *Specific conditions for meeting level of care requirements.* (1) The beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis.

(2) Those services must be furnished for a condition—

(i) For which the beneficiary received inpatient hospital or inpatient CAH services; or

(ii) Which arose while the beneficiary was receiving care in a SNF or swing-bed hospital for a condition for which he or she received inpatient hospital or inpatient CAH services; or

(iii) For which, for an M + C enrollee described in § 409.20(c)(4), a physician has determined that a direct admission to a SNF without an inpatient hospital or inpatient CAH stay would be medically appropriate.

(3) The daily skilled services must be ones that, as a practical matter, can only be provided in a SNF, on an inpatient basis.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993; 68 FR 50854, Aug. 22, 2003; 70 FR 45055, Aug. 4, 2005]

§ 409.32 Criteria for skilled services and the need for skilled services.

(a) To be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel.

(b) A condition that does not ordinarily require skilled services may require them because of special medical complications. Under those circumstances, a service that is usually nonskilled (such as those listed in § 409.33(d)) may be considered skilled because it must be performed or supervised by skilled nursing or rehabilitation personnel. For example, a plaster cast on a leg does not usually require skilled care. However, if the patient has a preexisting acute skin condition or needs traction, skilled personnel may be needed to adjust traction or watch for complications. In situations of this type, the complications, and the

[1] Before December 5, 1980, the law required that admission and receipt of care be within 14 days after discharge from the hospital or CAH and permitted admission up to 28 days after discharge if a SNF bed was not available in the geographic area in which the patient lived, or at the time it would be medically appropriate to begin an active course of treatment, if SNF care would not be medically appropriate within 14 days after discharge.

skilled services they require, must be documented by physicians' orders and nursing or therapy notes.

(c) The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. For example, a terminal cancer patient may need some of the skilled services described in § 409.33.

[48 FR 12541, Mar. 25, 1983, as amended at 59 FR 65493, Dec. 20, 1994]

§ 409.33 Examples of skilled nursing and rehabilitation services.

(a) *Services that could qualify as either skilled nursing or skilled rehabilitation services*—(1) *Overall management and evaluation of care plan.* (i) When overall management and evaluation of care plan *constitute skilled services.* The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety. Those activities include the management of a plan involving a variety of personal care services only when, in light of the patient's condition, the aggregate of those services requires the involvement of technical or professional personnel.

(ii) *Example.* An aged patient with a history of diabetes mellitus and angina pectoris who is recovering from an open reduction of a fracture of the neck of the femur requires, among other services, careful skin care, appropriate oral medications, a diabetic diet, an exercise program to preserve muscle tone and body condition, and observation to detect signs of deterioration in his or her condition or complications resulting from restricted, but increasing, mobility. Although any of the required services could be performed by a properly instructed person, such a person would not have the ability to understand the relationship between the services and evaluate the ultimate effect of one service on the other. Since the nature of the patient's condition, age, and immobility create a high potential for serious complications, such an understanding is essential to ensure the patient's recovery and safety. Under these circumstances, the management of the plan of care would require the skills of a nurse even though the individual services are not skilled. Skilled planning and management activities are not always specifically identified in the patient's clinical record. Therefore, if the patient's overall condition supports a finding that recovery and safety can be ensured only if the total care is planned, managed, and evaluated by technical or professional personnel, it is appropriate to infer that skilled services are being provided.

(2) *Observation and assessment of the patient's changing condition*—(i) *When observation and assessment constitute skilled services.* Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.

(ii) *Examples.* A patient with congestive heart failure may require continuous close observation to detect signs of decompensation, abnormal fluid balance, or adverse effects resulting from prescribed medication(s) that serve as indicators for adjusting therapeutic measures. Similarly, surgical patients transferred from a hospital to an SNF while in the complicated, unstabilized postoperative period, for example, after hip prosthesis or cataract surgery, may need continued close skilled monitoring for postoperative complications and adverse reaction. Patients who, in addition to their physical problems, exhibit acute psychological symptoms such as depression, anxiety, or agitation, may also require skilled observation and assessment by technical or professional personnel to ensure their safety or the safety of others, that is, to observe for indications of suicidal or hostile behavior. The need for services of this type must be documented by physicians' orders or nursing or therapy notes.

(3) *Patient education services*—(i) *When patient education services constitute skilled services.* Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance.

(ii) *Examples.* A patient who has had a recent leg amputation needs skilled rehabilitation services provided by technical or professional personnel to provide gait training and to teach prosthesis care. Similarly, a patient newly diagnosed with diabetes requires instruction from technical or professional personnel to learn the self-administration of insulin or foot-care precautions.

(b) *Services that qualify as skilled nursing services.* (1) Intravenous or intramuscular injections and intravenous feeding.

(2) Enteral feeding that comprises at least 26 per cent of daily calorie requirements and provides at least 501 milliliters of fluid per day.

(3) Nasopharyngeal and tracheostomy aspiration;

(4) Insertion and sterile irrigation and replacement of suprapubic catheters;

(5) Application of dressings involving prescription medications and aseptic techniques;

(6) Treatment of extensive decubitus ulcers or other widespread skin disorder;

(7) Heat treatments which have been specifically ordered by a physician as part of active treatment and which require observation by nurses to adequately evaluate the patient's progress;

(8) Initial phases of a regimen involving administration of medical gases;

(9) Rehabilitation nursing procedures, including the related teaching and adaptive aspects of nursing, that are part of active treatment, e.g., the institution and supervision of bowel and bladder training programs.

(c) *Services which would qualify as skilled rehabilitation services.* (1) Ongoing assessment of rehabilitation needs and potential: Services concurrent with the management of a patient care plan, including tests and measurements of range of motion, strength, balance, coordination, endurance, functional ability, activities of daily living, perceptual deficits, speech and language or hearing disorders;

(2) Therapeutic exercises or activities: Therapeutic exercises or activities which, because of the type of exercises employed or the condition of the patient, must be performed by or under the supervision of a qualified physical therapist or occupational therapist to ensure the safety of the patient and the effectiveness of the treatment;

(3) Gait evaluation and training: Gait evaluation and training furnished to restore function in a patient whose ability to walk has been impaired by neurological, muscular, or skeletal abnormality;

(4) Range of motion exercises: Range of motion exercises which are part of the active treatment of a specific disease state which has resulted in a loss of, or restriction of, mobility (as evidenced by a therapist's notes showing the degree of motion lost and the degree to be restored);

(5) Maintenance therapy; Maintenance therapy, when the specialized knowledge and judgment of a qualified therapist is required to design and establish a maintenance program based on an initial evaluation and periodic reassessment of the patient's needs, and consistent with the patient's capacity and tolerance. For example, a patient with Parkinson's disease who has not been under a rehabilitation regimen may require the services of a qualified therapist to determine what type of exercises will contribute the most to the maintenance of his present level of functioning.

(6) Ultrasound, short-wave, and microwave therapy treatment by a qualified physical therapist;

(7) Hot pack, hydrocollator, infrared treatments, paraffin baths, and whirlpool; Hot pack hydrocollator, infrared treatments, paraffin baths, and whirlpool in particular cases where the patient's condition is complicated by circulatory deficiency, areas of desensitization, open wounds, fractures, or other complications, and the skills, knowledge, and judgment of a qualified physical therapist are required; and

(8) Services of a speech pathologist or audiologist when necessary for the restoration of function in speech or hearing.

(d) *Personal care services.* Personal care services which do not require the skills of qualified technical or professional personnel are not skilled services except under the circumstances specified in §409.32(b). Personal care services include, but are not limited to, the following:

(1) Administration of routine oral medications, eye drops, and ointments;

(2) General maintenance care of colostomy and ileostomy;

(3) Routine services to maintain satisfactory functioning of indwelling bladder catheters;

(4) Changes of dressings for noninfected postoperative or chronic conditions;

(5) Prophylactic and palliative skin care, including bathing and application of creams, or treatment of minor skin problems;

(6) Routine care of the incontinent patient, including use of diapers and protective sheets;

(7) General maintenance care in connection with a plaster cast;

(8) Routine care in connection with braces and similar devices;

(9) Use of heat as a palliative and comfort measure, such as whirlpool and hydrocollator;

(10) Routine administration of medical gases after a regimen of therapy has been established;

(11) Assistance in dressing, eating, and going to the toilet;

(12) Periodic turning and positioning in bed; and

(13) General supervision of exercises which have been taught to the patient; including the actual carrying out of maintenance programs, i.e., the performance of the repetitive exercises required to maintain function do not require the skills of a therapist and would not constitute skilled rehabilitation services (see paragraph (c) of this section). Similarly, repetitious exercises to improve gait, maintain strength, or endurance; passive exercises to maintain range of motion in paralyzed extremities, which are not related to a specific loss of function; and assistive walking do not constitute skilled rehabilitation services.

[48 FR 12541, Mar. 25, 1983, as amended at 63 FR 26307, May 12, 1998; 64 FR 41681, July 30, 1999]

§ 409.34 Criteria for "daily basis".

(a) To meet the daily basis requirement specified in §409.31(b)(1), the following frequency is required:

(1) Skilled nursing services or skilled rehabilitation services must be needed and provided 7 days a week; or

(2) As an exception, if skilled rehabilitation services are not available 7 days a week those services must be needed and provided at least 5 days a week.

(b) A break of one or two days in the furnishing of rehabilitation services will not preclude coverage if discharge would not be practical for the one or two days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

§ 409.35 Criteria for "practical matter".

(a) *General considerations.* In making a ''practical matter'' determination, as required by §409.31(b)(3), consideration must be given to the patient's condition and to the availability and feasibility of using more economical alternative facilities and services. However, in making that determination, the availability of Medicare payment for those services may not be a factor. For example, if a beneficiary can obtain daily physical therapy services on an outpatient basis, the unavailability of Medicare payment for those alternative services due to the beneficiary's non-enrollment in Part B may not be a basis for finding that the needed care can only be provided in a SNF.

(b) *Examples of circumstances that meet practical matter criteria*—(1) *Beneficiary's condition.* Inpatient care would be required ''as a practical matter'' if transporting the beneficiary to and from the nearest facility that furnishes the required daily skilled services would be an excessive physical hardship.

(2) *Economy and efficiency.* Even if the beneficiary's condition does not preclude transportation, inpatient care might be more efficient and less costly

if, for instance, the only alternative is daily transportation by ambulance.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 85 FR 47632, Aug. 5, 2020]

§ 409.36 Effect of discharge from posthospital SNF care.

If a beneficiary is discharged from a facility after receiving posthospital SNF care, he or she is not entitled to additional services of this kind in the same benefit period unless—

(a) He or she is readmitted to the same or another facility within 30 calendar days following the day of discharge (or, before December 5, 1980, within 14 calendar days after discharge); or

(b) He or she is again hospitalized for at least 3 consecutive calendar days.

Subpart E—Home Health Services Under Hospital Insurance

§ 409.40 Basis, purpose, and scope.

This subpart implements sections 1814(a)(2)(C), 1835(a)(2)(A), and 1861(m) of the Act with respect to the requirements that must be met for Medicare payment to be made for home health services furnished to eligible beneficiaries.

[59 FR 65493, Dec. 20, 1994]

§ 409.41 Requirement for payment.

In order for home health services to qualify for payment under the Medicare program the following requirements must be met:

(a) The services must be furnished to an eligible beneficiary by, or under arrangements with, an HHA that—

(1) Meets the conditions of participation for HHAs at part 484 of this chapter; and

(2) Has in effect a Medicare provider agreement as described in part 489, subparts A, B, C, D, and E of this chapter.

(b) The certification and recertification requirements for home health services described in § 424.22.

(c) All requirements contained in §§ 409.42 through 409.47.

[59 FR 65494, Dec. 20, 1994, as amended at 85 FR 27619, May 8, 2020]

§ 409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) *Confined to the home.* The beneficiary must be confined to the home or in an institution that is not a hospital, SNF or nursing facility as defined in section 1861(e)(1), 1819(a)(1) or 1919(a)(1) of the Act, respectively.

(b) *Under the care of a physician or allowed practitioner, as defined at § 484.2 of this chapter.* The beneficiary must be under the care of a physician or allowed practitioner, as defined at § 484.2 of this chapter who establishes the plan of care. A doctor of podiatric medicine may establish a plan of care only if that is consistent with the functions he or she is authorized to perform under State law.

(c) *In need of skilled services.* The beneficiary must need at least one of the following skilled services as certified by a physician or allowed practitioner, as defined at § 484.2 of this chapter in accordance with the certification and recertification requirements for home health services under § 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services found in § 409.32. (Also see § 409.33(a) and (b) for a description of examples of skilled nursing and rehabilitation services.) These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition. Where nursing visits are not needed to observe and assess the effects of the non-skilled services being provided

to treat the illness or injury, skilled nursing care would not be considered reasonable and necessary, and the management and evaluation of the care plan would not be considered a skilled service. In some cases, the condition of the patient may cause a service that would originally be considered unskilled to be considered a skilled nursing service. This would occur when the patient's underlying condition or complication requires that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. The registered nurse is ensuring that service is safely and effectively performed. However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

(2) Physical therapy services that meet the requirements of § 409.44(c).

(3) Speech-language pathology services that meet the requirements of § 409.44(c).

(4) Occupational therapy services in the current and subsequent certification periods (subsequent adjacent episodes) that meet the requirements of § 409.44(c) initially qualify for home health coverage as a dependent service as defined in § 409.45(d) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period. Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) are considered to be qualifying services.

(d) *Under a plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 409.43.

(e) *By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by, a participating HHA.

[59 FR 65494, Dec. 20, 1994; 60 FR 39122, Aug. 1, 1995, as amended at 74 FR 58133, Nov. 10, 2009; 76 FR 68606, Nov. 4, 2011; 85 FR 27619, May 8, 2020]

§ 409.43 Plan of care requirements.

(a) *Contents.* An individualized plan of care must be established and periodically reviewed by the certifying physician or allowed practitioner.

(1) The HHA must be acting upon a plan of care that meets the requirements of this section for HHA services to be covered.

(2) For HHA services to be covered, the individualized plan of care must specify the services necessary to meet the patient-specific needs identified in the comprehensive assessment.

(3)(i) The plan of care must include all of the following:

(A) The identification of the responsible discipline(s) and the frequency and duration of all visits as well as those items listed in § 484.60(a) of this chapter that establish the need for such services.

(B) Any provision of remote patient monitoring or other services furnished via telecommunications technology (as defined in § 409.46(e)) or audio-only technology. Such services must be tied to the patient-specific needs as identified in the comprehensive assessment, cannot substitute for a home visit ordered as part of the plan of care, and cannot be considered a home visit for the purposes of patient eligibility or payment.

(ii) All care provided must be in accordance with the plan of care.

(b) *Physician's or allowed practitioner's orders.* The physician or allowed practitioner's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished. Orders for services to be provided ''as needed'' or ''PRN'' must be accompanied by a description of the beneficiary's medical signs and symptoms that would occasion the visit and a specific limit on the number of those visits to be made under the order before an additional physician or allowed practitioner order would have to be obtained. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. If a range of visits is ordered, the upper limit of the range is considered the specific frequency.

(c) *Physician or allowed practitioner signature*—(1) *Request for Anticipated payment signature requirements.* If the physician or allowed practitioner signed plan of care is not available at the time the HHA requests an anticipated payment of the initial percentage prospective payment in accordance with § 484.205, the request for the anticipated payment must be based on—

(i) A physician or allowed practitioner's orders that—

(A) Is recorded in the plan of care;

(B) Includes a description of the patient's condition and the services to be provided by the home health agency;

(C) Includes an attestation (relating to the physician's or allowed practitioner's orders and the date received) signed and dated by the registered nurse or qualified therapist (as defined in 42 CFR 484.115) responsible for furnishing or supervising the ordered service in the plan of care; and

(D) Is copied into the plan of care and the plan of care is immediately submitted to the physician or allowed practitioner; or

(ii) A referral prescribing detailed orders for the services to be rendered that is signed and dated by a physician.

(2) *Final percentage payment signature requirements.* The plan of care must be signed and dated—

(i) By a physician or allowed practitioner as described who meets the certification and recertification requirements of § 424.22 of this chapter; and

(ii) Before the claim for each episode (for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted.

(3) *Changes to the plan of care signature requirements.* Any changes in the plan must be signed and dated by a physician or allowed practitioner.

(d) *Oral (verbal) orders.* If any services are provided based on a physician's or allowed practitioner's oral orders, the orders must be put in writing and be signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.115 of this chapter) responsible for furnishing or supervising the ordered services. Oral orders may only be accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies. The oral orders must also be countersigned and dated by the physician or allowed practitioner before the HHA bills for the care.

(e) *Frequency of review.* (1) The plan of care must be reviewed by the physician or allowed practitioner (as specified in § 409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge with goals met and/or no expectation of a return to home health care and the patient returns to home health care within 60 days.

(2) Each review of a beneficiary's plan of care must contain the signature of the physician or allowed practitioner who reviewed it and the date of review.

(f) *Termination of the plan of care.* The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 60-day period unless the physician or allowed practitioner documents that the interval without

such care is appropriate to the treatment of the beneficiary's illness or injury.

[59 FR 65494, Dec. 20, 1994, as amended at 65 FR 41210, July 3, 2000; 74 FR 58133, Nov. 10, 2009; 80 FR 68717, Nov. 5, 2015; 82 FR 4578, Jan. 13, 2017; 83 FR 56627, Nov. 13, 2018; 84 FR 60642, Nov. 8, 2019; 85 FR 19285, Apr. 6, 2020; 85 FR 27619, May 8, 2020; 85 FR 70354, Nov. 4, 2020; 86 FR 62418, Nov. 9, 2021]

§ 409.44 Skilled services requirements.

(a) *General.* The Medicare Administrative Contractor's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) *Skilled nursing care.* (1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.115 of this chapter, meet the criteria for skilled nursing services specified in § 409.32, and meet the qualifications for coverage of skilled services specified in § 409.42(c). See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.

(c) *Physical therapy, speech-language pathology services, and occupational therapy.* To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) and (2) of this section.

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen (established by the physician or allowed practitioner) after any needed consultation with the qualified therapist, that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes. To be covered by Medicare, all of the requirements apply as follows:

(i) The patient's plan of care must describe a course of therapy treatment and therapy goals which are consistent with the evaluation of the patient's function, and both must be included in the clinical record. The therapy goals

must be established by a qualified therapist in conjunction with the physician or allowed practitioner.

(ii) The patient's clinical record must include documentation describing how the course of therapy treatment for the patient's illness or injury is in accordance with accepted professional standards of clinical practice.

(iii) Therapy treatment goals described in the plan of care must be measurable, and must pertain directly to the patient's illness or injury, and the patient's resultant impairments.

(iv) The patient's clinical record must demonstrate that the method used to assess a patient's function included objective measurements of function in accordance with accepted professional standards of clinical practice enabling comparison of successive measurements to determine the effectiveness of therapy goals. Such objective measurements would be made by the qualified therapist using measurements which assess activities of daily living that may include but are not limited to eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, or using assistive devices, and mental and cognitive factors.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of professional clinical practice, to be a specific, safe, and effective treatment for the beneficiary's condition. Each of the following requirements must also be met:

(A) The patient's function must be initially assessed and periodically reassessed by a qualified therapist, of the corresponding discipline for the type of therapy being provided, using a method which would include objective measurement as described in § 409.44(c)(1)(iv). If more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must perform the assessment and periodic reassessments. The measurement results and corresponding effectiveness of the therapy, or lack thereof, must be documented in the clinical record.

(B) At least every 30 calendar days a qualified therapist (instead of an assistant) must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A). Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must provide the needed therapy service and functionally reassess the patient in accordance with § 409.44(c)(2)(i)(A) at least every 30 calendar days.

(C) As specified in paragraphs (c)(2)(i)(A) and (B) of this section, therapy visits for the therapy discipline(s) not in compliance with these policies will not be covered until the following conditions are met:

(*1*) The qualified therapist has completed the reassessment and objective measurement of the effectiveness of the therapy as it relates to the therapy goals. As long as paragraphs (c)(2)(i)(C)(*2*) and (c)(2)(i)(C)(*3*) of this section are met, therapy coverage resumes with the completed reassessment therapy visit.

(*2*) The qualified therapist has determined if goals have been achieved or require updating.

(*3*) The qualified therapist has documented measurement results and corresponding therapy effectiveness in the clinical record in accordance with paragraph (c)(2)(i)(F) of this section.

(D) If the criteria for maintenance therapy, described at § 409.44(c)(2)(iii)(B) and (C) of this section are not met, the following criteria must also be met for subsequent therapy visits to be covered:

(*1*) If the objective measurements of the reassessment do not reveal progress toward goals, the qualified therapist together with the physician or allowed practitioner must determine whether the therapy is still effective or should be discontinued.

(*2*) If therapy is to be continued in accordance with § 409.44(c)(2)(iv)(B)(*1*) of this section, the clinical record must document with a clinically supportable statement why there is an expectation that the goals are attainable in a reasonable and generally predictable period of time.

(E) Clinical notes written by therapy assistants may supplement the clinical record, and if included, must include the date written, the signature, professional designation, and objective measurements or description of changes in status (if any) relative to each goal being addressed by treatment. Assistants may not make clinical judgments about why progress was or was not made, but must report the progress or the effectiveness of the therapy (or lack thereof) objectively.

(F) Documentation by a qualified therapist must include the following:

(*1*) The therapist's assessment of the effectiveness of the therapy as it relates to the therapy goals;

(*2*) Plans for continuing or discontinuing treatment with reference to evaluation results and or treatment plan revisions;

(*3*) Changes to therapy goals or an updated plan of care that is sent to the physician or allowed practitioner for signature or discharge;

(*4*) Documentation of objective evidence or a clinically supportable statement of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy in a reasonable and generally predictable period of time; or in the case of maintenance therapy, the patient is responding to therapy and can meet the goals in a predictable period of time.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in § 484.115 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) For therapy services to be covered in the home health setting, one of the following three criteria must be met:

(A) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's or allowed practitioner's assessment of the beneficiary's restoration potential and unique medical condition.

(*1*) Material improvement requires that the clinical record demonstrate that the patient is making improvement towards goals when measured against his or her condition at the start of treatment.

(*2*) If an individual's expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to achieve such potential, therapy would not be considered reasonable and necessary, and thus would not be covered.

(*3*) When a patient suffers a transient and easily reversible loss or reduction of function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities, because the services do not require the performance or supervision of a qualified therapist, those services are not to be considered reasonable and necessary covered therapy services.

(B) The unique clinical condition of a patient may require the specialized skills, knowledge, and judgment of a qualified therapist to design or establish a safe and effective maintenance program required in connection with the patient's specific illness or injury.

(*1*) If the services are for the establishment of a maintenance program, they must include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary periodic reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical

therapist, speech-language pathologist, or occupational therapist is required.

(*2*) The maintenance program must be established by a qualified therapist (and not an assistant).

(C) The unique clinical condition of a patient may require the specialized skills of a qualified therapist or therapist assistant to perform a safe and effective maintenance program required in connection with the patient's specific illness or injury. Where the clinical condition of the patient is such that the complexity of the therapy services required—

(*1*) Involve the use of complex and sophisticated therapy procedures to be delivered by the therapist or the therapist assistant in order to maintain function or to prevent or slow further deterioration of function; or

(*2*) To maintain function or to prevent or slow further deterioration of function must be delivered by the therapist or the therapist assistant in order to ensure the patient's safety and to provide an effective maintenance program, then those reasonable and necessary services must be covered.

(iv) The amount, frequency, and duration of the services must be reasonable and necessary, as determined by a qualified therapist and/or physician or allowed practitioner, using accepted standards of clinical practice.

(A) Where factors exist that would influence the amount, frequency or duration of therapy services, such as factors that may result in providing more services than are typical for the patient's condition, those factors must be documented in the plan of care and/or functional assessment.

(B) Clinical records must include documentation using objective measures that the patient continues to progress towards goals. If progress cannot be measured, and continued progress towards goals cannot be expected, therapy services cease to be covered except when—

(*1*) Therapy progress regresses or plateaus, and the reasons for lack of progress are documented to include justification that continued therapy treatment will lead to resumption of progress toward goals; or

(*2*) Maintenance therapy as described in § 409.44(c)(2)(iii)(B) or (C) is needed.

[59 FR 65494, Dec. 20, 1994, as amended at 74 FR 58133, Nov. 10, 2009; 75 FR 70461, Nov. 17, 2010; 76 FR 68606, Nov. 4, 2011; 77 FR 67162, Nov. 8, 2012; 79 FR 66116, Nov. 6, 2014; 82 FR 4578, Jan. 13, 2017; 84 FR 60642, Nov. 8, 2019; 85 FR 27619, May 8, 2020]

§ 409.45 Dependent services requirements.

(a) *General.* Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in § 409.44(b); physical therapy or speech-language pathology services as described in § 409.44(c); or has a continuing need for occupational therapy services as described in § 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician or allowed practitioner, in need of skilled services, and under a plan of care) specified in § 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.

(b) *Home health aide services.* To be covered, home health aide services must meet each of the following requirements:

(1) The reason for the visits by the home health aide must be to provide hands-on personal care to the beneficiary or services that are needed to maintain the beneficiary's health or to facilitate treatment of the beneficiary's illness or injury. The physician or allowed practitioner's orders must indicate the frequency of the home health aide services required by

the beneficiary. These services may include but are not limited to:

(i) Personal care services such as bathing, dressing, grooming, caring for hair, nail and oral hygiene that are needed to facilitate treatment or to prevent deterioration of the beneficiary's health, changing the bed linens of an incontinent beneficiary, shaving, deodorant application, skin care with lotions and/or powder, foot care, ear care, feeding, assistance with elimination (including enemas unless the skills of a licensed nurse are required due to the beneficiary's condition, routine catheter care, and routine colostomy care), assistance with ambulation, changing position in bed, and assistance with transfers.

(ii) Simple dressing changes that do not require the skills of a licensed nurse.

(iii) Assistance with medications that are ordinarily self-administered and that do not require the skills of a licensed nurse to be provided safely and effectively.

(iv) Assistance with activities that are directly supportive of skilled therapy services but do not require the skills of a therapist to be safely and effectively performed, such as routine maintenance exercises and repetitive practice of functional communication skills to support speech-language pathology services.

(v) Routine care of prosthetic and orthotic devices.

(2) The services to be provided by the home health aide must be—

(i) Ordered by a physician or allowed practitioner in the plan of care; and

(ii) Provided by the home health aide on a part-time or intermittent basis.

(3) The services provided by the home health aide must be reasonable and necessary. To be considered reasonable and necessary, the services must—

(i) Meet the requirement for home health aide services in paragraph (b)(1) of this section;

(ii) Be of a type the beneficiary cannot perform for himself or herself; and

(iii) Be of a type that there is no able or willing caregiver to provide, or, if there is a potential caregiver, the beneficiary is unwilling to use the services of that individual.

(4) The home health aide also may perform services incidental to a visit that was for the provision of care as described in paragraphs (b)(3)(i) through (iii) of this section. For example, these incidental services may include changing bed linens, personal laundry, or preparing a light meal.

(c) *Medical social services.* Medical social services may be covered if the following requirements are met:

(1) The services are ordered by a physician or allowed practitioner and included in the plan of care.

(2)(i) The services are necessary to resolve social or emotional problems that are expected to be an impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(ii) If these services are furnished to a beneficiary's family member or caregiver, they are furnished on a short-term basis and it can be demonstrated that the service is necessary to resolve a clear and direct impediment to the effective treatment of the beneficiary's medical condition or to his or her rate of recovery.

(3) The frequency and nature of the medical social services are reasonable and necessary to the treatment of the beneficiary's condition.

(4) The medical social services are furnished by a qualified social worker or qualified social work assistant under the supervision of a social worker as defined in § 484.115 of this chapter.

(5) The services needed to resolve the problems that are impeding the beneficiary's recovery require the skills of a social worker or a social work assistant under the supervision of a social worker to be performed safely and effectively.

(d) *Occupational therapy.* Occupational therapy services that are not qualifying services under § 409.44(c) are nevertheless covered as dependent services if the requirements of § 409.44(c)(2)(i) through (iv), as to reasonableness and necessity, are met.

(e) *Durable medical equipment.* Durable medical equipment in accordance with § 410.38 of this chapter, which describes the scope and conditions of payment for durable medical equipment under Part B, may be covered under the home health benefit as either a Part A or

Part B service. Durable medical equipment furnished by an HHA as a home health service is always covered by Part A if the beneficiary is entitled to Part A.

(f) *Medical supplies.* Medical supplies (including catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care but excluding drugs and biologicals) may be covered as a home health benefit. For medical supplies to be covered as a Medicare home health benefit, the medical supplies must be needed to treat the beneficiary's illness or injury that occasioned the home health care.

(g) *Intern and resident services.* The medical services of interns and residents in training under an approved hospital teaching program are covered if the services are ordered by the physician or allowed practitioner who is responsible for the plan of care and the HHA is affiliated with or under the common control of the hospital furnishing the medical services.

Approved means—

(1) Approved by the Accreditation Council for Graduate Medical Education;

(2) In the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;

(3) In the case of an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association; or

(4) In the case of an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association.

[59 FR 65495, Dec. 20, 1994; 60 FR 39122, 39123, Aug. 1, 1995, as amended at 82 FR 4578, Jan. 13, 2017; 85 FR 27620, May 8, 2020]

§ 409.46 Allowable administrative costs.

Services that are allowable as administrative costs but are not separately billable include, but are not limited to, the following:

(a) *Registered nurse initial evaluation visits.* Initial evaluation visits by a registered nurse for the purpose of assessing a beneficiary's health needs, determining if the agency can meet those health needs, and formulating a plan of care for the beneficiary are allowable administrative costs. If a physician or allowed practitioner specifically orders that a particular skilled service be furnished during the evaluation in which the agency accepts the beneficiary for treatment and all other coverage criteria are met, the visit is billable as a skilled nursing visit. Otherwise it is considered to be an administrative cost.

(b) *Visits by registered nurses or qualified professionals for the supervision of home health aides.* Visits by registered nurses or qualified professionals for the purpose of supervising home health aides as required at § 484.80(h) of this chapter are allowable administrative costs. Only if the registered nurse or qualified professional visits the beneficiary for the purpose of furnishing care that meets the coverage criteria at § 409.44, and the supervisory visit occurs simultaneously with the provision of covered care, is the visit billable as a skilled nursing or therapist's visit.

(c) *Respiratory care services.* If a respiratory therapist is used to furnish overall training or consultative advice to an HHA's staff and incidentally provides respiratory therapy services to beneficiaries in their homes, the costs of the respiratory therapist's services are allowable as administrative costs. Visits by a respiratory therapist to a beneficiary's home are not separately billable. However, respiratory therapy services that are furnished as part of a plan of care by a skilled nurse or physical therapist and that constitute skilled care may be separately billed as skilled visits.

(d) *Dietary and nutrition personnel.* If dieticians or nutritionists are used to provide overall training or consultative advice to HHA staff and incidentally provide dietetic or nutritional services to beneficiaries in their homes, the costs of these professional services are allowable as administrative costs. Visits by a dietician or nutritionist to a beneficiary's home are not separately billable.

(e) *Telecommunications technology.* Telecommunications technology, as indicated on the plan of care, can include: remote patient monitoring, defined as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient or caregiver or both to the home health agency; teletypewriter (TTY); and 2-way audio-video telecommunications technology that allows for real-time interaction between the patient and clinician. The costs of any equipment, set-up, and service related to the technology are allowable only as administrative costs. Visits to a beneficiary's home for the sole purpose of supplying, connecting, or training the patient on the technology, without the provision of a skilled service, are not separately billable.

[59 FR 65496, Dec. 20, 1994, as amended at 82 FR 4578, Jan. 13, 2017; 83 FR 56627, Nov. 13, 2018; 85 FR 27620, May 8, 2020; 85 FR 70354, Nov. 4, 2020]

§ 409.47 Place of service requirements.

To be covered, home health services must be furnished in either the beneficiary's home or an outpatient setting as defined in this section.

(a) *Beneficiary's home.* A beneficiary's home is any place in which a beneficiary resides that is not a hospital, SNF, or nursing facility as defined in sections 1861(e)(1), 1819(a)(1), of 1919(a)(1) of the Act, respectively.

(b) *Outpatient setting.* For purposes of coverage of home health services, an outpatient setting may include a hospital, SNF or a rehabilitation center with which the HHA has an arrangement in accordance with the requirements of § 484.105(e) of this chapter and that is used by the HHA to provide services that either—

(1) Require equipment that cannot be made available at the beneficiary's home; or

(2) Are furnished while the beneficiary is at the facility to receive services requiring equipment described in paragraph (b)(1) of this section.

[59 FR 65496, Dec. 20, 1994, as amended at 82 FR 4578, Jan. 13, 2017]

§ 409.48 Visits.

(a) *Number of allowable visits under Part A.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part A for an unlimited number of covered home health visits. All Medicare home health services are covered under hospital insurance unless there is no Part A entitlement.

(b) *Number of visits under Part B.* To the extent that all coverage requirements specified in this subpart are met, payment may be made on behalf of eligible beneficiaries under Part B for an unlimited number of covered home health visits. Medicare home health services are covered under Part B only when the beneficiary is not entitled to coverage under Part A.

(c) *Definition of visit.* A visit is an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service.

(1) Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangements enters the beneficiary's home and provides a covered service to a beneficiary who meets the criteria of § 409.42 (confined to the home, under the care of a physician or allowed practitioner, in need of skilled services, and under a plan of care).

(2) If the HHA furnishes services in an outpatient facility under arrangements with the facility, one visit may be covered for each type of service provided.

(3) If two individuals are needed to provide a service, two visits may be covered. If two individuals are present, but only one is needed to provide the care, only one visit may be covered.

(4) A visit is initiated with the delivery of covered home health services and ends at the conclusion of delivery of covered home health services. In those circumstances in which all reasonable and necessary home health services cannot be provided in the course of a single visit, HHA staff or others providing services under arrangements with the HHA may remain at the beneficiary's residence between

visits (for example, to provide non-covered services). However, if all covered services could be provided in the course of one visit, only one visit may be covered.

[59 FR 65497, Dec. 20, 1994, as amended at 85 FR 27620, May 8, 2020]

§ 409.49 Excluded services.

(a) *Drugs and biologicals.* Drugs and biologicals are excluded from payment under the Medicare home health benefit.

(1) A drug is any chemical compound that may be used on or administered to humans or animals as an aid in the diagnosis, treatment or prevention of disease or other condition or for the relief of pain or suffering or to control or improve any physiological pathologic condition.

(2) A biological is any medicinal preparation made from living organisms and their products including, but not limited to, serums, vaccines, antigens, and antitoxins.

(b) *Transportation.* The transportation of beneficiaries, whether to receive covered care or for other purposes, is excluded from home health coverage. Costs of transportation of equipment, materials, supplies, or staff may be allowable as administrative costs, but no separate payment is made for them.

(c) *Services that would not be covered as inpatient services.* Services that would not be covered if furnished as inpatient hospital services are excluded from home health coverage.

(d) *Housekeeping services.* Services whose sole purpose is to enable the beneficiary to continue residing in his or her home (for example, cooking, shopping, Meals on Wheels, cleaning, laundry) are excluded from home health coverage.

(e) *Services covered under the End Stage Renal Disease (ESRD) program.* Services that are covered under the ESRD program and are contained in the composite rate reimbursement methodology, including any service furnished to a Medicare ESRD beneficiary that is directly related to that individual's dialysis, are excluded from coverage under the Medicare home health benefit.

(f) *Prosthetic devices.* Items that meet the requirements of § 410.36(a)(2) of this chapter for prosthetic devices covered under Part B are excluded from home health coverage. Catheters, catheter supplies, ostomy bags, and supplies relating to ostomy care are not considered prosthetic devices if furnished under a home health plan of care and are not subject to this exclusion from coverage.

(g) *Medical social services provided to family members.* Except as provided in § 409.45(c)(2), medical social services provided solely to members of the beneficiary's family and that are not incidental to covered medical social services being provided to the beneficiary are not covered.

(h) *Services covered under the home infusion therapy benefit.* Services that are covered under the home infusion therapy benefit as outlined at § 486.525 of this chapter, including any home infusion therapy services furnished to a Medicare beneficiary that is under a home health plan of care, are excluded from coverage under the Medicare home health benefit. Excluded home infusion therapy services pertain to the items and services for the provision of home infusion drugs, as defined at § 486.505 of this chapter. Services for the provision of drugs and biologicals not covered under this definition may continue to be provided under the Medicare home health benefit.

[59 FR 65497, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995; 85 FR 70354, Nov. 4, 2020]

§ 409.50 Coinsurance for durable medical equipment (DME) and applicable disposable devices furnished as a home health service.

The coinsurance liability of the beneficiary or other person for the following home health services is:

(a) DME—20 percent of the customary (insofar as reasonable) charge.

(b) An applicable disposable device (as defined in section 1834(s)(2) of the Act)—20 percent of the payment amount for the disposable Negative Pressure Wound Therapy (NPWT) device (as that term is defined in § 484.202 of this chapter).

[81 FR 76796, Nov. 3, 2016, as amended at 88 FR 77874, Nov. 13, 2023]

Subpart F—Scope of Hospital Insurance Benefits

§ 409.60 Benefit periods.

(a) *When benefit periods begin.* The initial benefit period begins on the day the beneficiary receives inpatient hospital, inpatient CAH, or SNF services for the first time after becoming entitled to hospital insurance. Thereafter, a new benefit period begins whenever the beneficiary receives inpatient hospital, inpatient CAH, or SNF services after he or she has ended a benefit period as described in paragraph (b) of this section.

(b) *When benefit periods end*—(1) A benefit period ends when a beneficiary has, for at least 60 consecutive days not been an inpatient in any of the following:

(i) A hospital that meets the requirements of section 1861(e)(1) of the Act.

(ii) A CAH that meets the requirements of section 1820 of the Act.

(iii) A SNF that meets the requirements of sections 1819(a)(1) or 1861(y) of the Act.

(2) For purposes of ending a benefit period, a beneficiary was an inpatient of a SNF if his or her care in the SNF met the skilled level of care requirements specified in § 409.31(b) (1) and (3).

(c) *Presumptions.* (1) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section—

(i) A beneficiary's care met the skilled level of care requirements if inpatient SNF claims were paid for those services under Medicare or Medicaid, unless:

(A) Such payments were made under § 411.400 or Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements, or

(B) A Medicare denial and a Medicaid payment are made for the same period, in which case the presumption in paragraph (c)(2)(ii) of this section applies;

(ii) A beneficiary's care met the skilled level of care requirements if a SNF claim was paid under section 1879(e) of the Social Security Act;

(iii) A beneficiary's care did not meet the skilled level of care requirements if a SNF claim was paid for the services under § 411.400;

(iv) A beneficiary's care did not meet the skilled level of care requirements if a Medicaid SNF claim was denied on the grounds that the services were not at the skilled level of care (even if paid under applicable Medicaid administratively necessary days provisions which result in payment for care not meeting the skilled level of care requirements);

(2) For purposes of determining whether a beneficiary was an inpatient of a SNF under paragraph (b)(2) of this section a beneficiary's care in a SNF is presumed—

(i) To have met the skilled level of care requirements during any period for which the beneficiary was assigned to one of the Resource Utilization Groups designated as representing the required level of care, as provided in § 409.30.

(ii) To have met the skilled level of care requirements if a Medicaid or Medicare claim was denied on grounds other than that the services were not at the skilled level of care;

(iii) Not to have met the skilled level of care requirements if a Medicare SNF claim was denied on the grounds that the services were not at the skilled level of care and payment was not made under § 411.400; or

(iv) Not to have met the skilled level of care requirements if no Medicare or Medicaid claim was submitted by the SNF.

(3) If information upon which to base a presumption is not readily available, the intermediary may, at its discretion review the beneficiary's medical records to determine whether he or she was an inpatient of a SNF as set forth under paragraph (b)(2) of this section.

(4) When the intermediary makes a benefit period determination based upon paragraph (c)(1) of this section, the beneficiary may seek to reverse the benefit period determination by timely appealing the prior Medicare SNF claim determination under part 405, subpart G of this chapter, or the prior Medicaid SNF claim under part 431, subpart E of this chapter.

(5) When the intermediary makes a benefit period determination under paragraph (c)(2) of this section, the beneficiary will be notified of the basis for the determination, and of his or her right to present evidence to rebut the

determination that the skilled level of care requirements specified in § 409.31 (b)(1) and (b)(3) were or were not met on reconsideration and appeal under 42 CFR, part 405, subpart G of this chapter.

(d) *Limitation on benefit period determinations.* When the intermediary considers the same prior SNF stay of a particular beneficiary in making benefit period determinations for more than one inpatient Medicare claim—

(1) Medicare will recognize only the initial level of care characterization for that prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal); or

(2) If part of a prior SNF stay has one level of care characterization and another part has another level of care characterization, Medicare will recognize only the initial level of care characterization for a particular part of a prior SNF stay (or if appealed under 42 CFR part 405, subpart G of this chapter, the level of care determined under appeal).

(e) *Relation of benefit period to benefit limitations.* The limitations specified in §§ 409.61 and 409.64, and the deductible and coinsurance requirements set forth in subpart G of this part apply for each benefit period. The limitations of § 409.63 apply only to the initial benefit period.

[52 FR 22645, June 15, 1987; 52 FR 28824, Aug. 4, 1987, as amended at 58 FR 30667, May 26, 1993; 63 FR 26307, May 12, 1998; 70 FR 45055, Aug. 4, 2005]

§ 409.61 General limitations on amount of benefits.

(a) *Inpatient hospital or inpatient CAH services*—(1) *Regular benefit days.* Up to 90 days are available in each benefit period, subject to the limitations on days for psychiatric hospital services set forth in §§ 409.62 and 409.63.

(i) For the first 60 days (referred to in this subpart as *full benefit days*), Medicare pays the hospital or CAH for all covered services furnished the beneficiary, except for a deductible which is the beneficiary's responsibility. (Section 409.82 specifies the requirements for the inpatient hospital deductible.)

(ii) For the next 30 days (referred to in this subpart as *coinsurance days*), Medicare pays for all covered services except for a daily coinsurance amount, which is the beneficiary's responsibility. (Section 409.83 specifies the inpatient hospital coinsurance amounts.)

(2) *Lifetime reserve days.* Each beneficiary has a non-renewable lifetime reserve of 60 days of inpatient hospital or inpatient CAH services that he may draw upon whenever he is hospitalized for more than 90 days in a benefit period. Upon exhaustion of the regular benefit days, the reserve days will be used unless the beneficiary elects not to use them, as provided in § 409.65. For lifetime reserve days, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility. (See § 409.83.)

(3) *Order of payment for inpatient hospital or inpatient CAH services.* Medicare pays for inpatient hospital services in the following order.

(i) The 60 full benefit days;

(ii) The 30 coinsurance days;

(iii) The remaining lifetime reserve days.

(b) *Posthospital SNF care furnished by a SNF, or by a hospital or a CAH with a swing-bed approval.* Up to 100 days are available in each benefit period after discharge from a hospital or CAH. For the first 20 days, Medicare pays for all covered services. For the 21st through 100th day, Medicare pays for all covered services except for a daily coinsurance amount that is the beneficiary's responsibility.

(c) *Renewal of inpatient benefits.* The beneficiary's full entitlement to the 90 inpatient hospital or inpatient CAH regular benefit days, and the 100 SNF benefit days, is renewed each time he or she begins a benefit period. However, once lifetime reserve days are used, they can never be renewed.

(d) *Home health services.* Medicare Part A pays for all covered home health services[1] with no deductible, and subject to the following limitations on payment for durable medical equipment (DME):

(1) For DME furnished by an HHA that is a nominal charge provider,

[1] Before July 1, 1981, Medicare Part A paid for not more than 100 home health visits during one year following the beneficiary's most recent discharge from a hospital or a SNF.

Medicare Part A pays 80 percent of fair compensation.

(2) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part A pays the lesser of the following:

(i) 80 percent of the reasonable cost of the service.

(ii) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

[48 FR 12541, Mar. 25, 1983, as amended at 51 FR 41339, Nov. 14, 1986; 54 FR 4027, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.62 Lifetime maximum on inpatient psychiatric care.

There is a lifetime maximum of 190 days on inpatient psychiatric hospital services available to any beneficiary. Therefore, once an individual receives benefits for 190 days of care in a psychiatric hospital, no further benefits of that type are available to that individual.

§ 409.63 Reduction of inpatient psychiatric benefit days available in the initial benefit period.

(a) *Reduction rule.* (1) If the individual was an inpatient in a psychiatric hospital on the first day of Medicare entitlement and for any of the 150 days immediately before that first day of entitlement, those days are subtracted from the 150 days (90 regular days plus 60 lifetime reserve days) which would otherwise be available in the initial benefit period for inpatient psychiatric services in a psychiatric or general hospital.

(2) Reduction is required only if the hospital was participating in Medicare as a psychiatric hospital on the individual's first day of entitlement.

(3) The reduction applies only to the beneficiary's first benefit period. For subsequent benefit periods, the 90 benefit days, plus any remaining lifetime reserve days, subject to the 190 day lifetime limit on psychiatric hospital care, are available.

(b) *Application to general hospital days.* (1) Days spent in a general hospital before entitlement are not subtracted under paragraph (a) of this section even if the stay was for diagnosis or treatment of mental illness.

(2) After entitlement, all psychiatric care days, whether in a general or a psychiatric hospital, are counted toward the number of days available in the initial benefit period.

(c) *Examples:* (1) The individual was an inpatient of a participating psychiatric hospital for 20 days before the first day of entitlement and remained there for another 6 months. Therefore, 130 days of benefits (150 minus 20) are payable. Payment could be made for: 60 full benefit days, 30 coinsurance days, and 40 lifetime reserve days.

(2) During the 150-day period preceding Medicare entitlement, an individual had been a patient of a general hospital for 60 days of inpatient psychiatric care and had spent 90 days in a psychiatric hospital, ending with the first day of entitlement. During the initial benefit period, the beneficiary spent 90 days in a general hospital and received psychiatric care there. The 60 days spent in the general hospital for psychiatric treatment before entitlement do not reduce the benefits available in the first benefit period. Only the 90 days spent in the psychiatric hospital before entitlement reduce such benefits, leaving a total of 60 available psychiatric days. However, after entitlement, the reduction applies not only to days spent in a psychiatric hospital, but also to days of psychiatric treatment in a general hospital. Thus, Medicare payment could be made only for 60 of the 90 days spent in the general hospital.

(3) An individual was admitted to a general hospital for a mental condition and, after 10 days, transferred to a participating psychiatric hospital. The individual remained in the psychiatric hospital for 78 days before becoming entitled to hospital insurance benefits and for 130 days after entitlement. The beneficiary was then transferred to a general hospital and received treatment of a medical condition for 20 days. The 10 days spent in the general hospital during the 150-day pre-entitlement period have no effect on the inpatient hospital benefit days available to the individual for psychiatric care in the first benefit period, even though the general hospital stay was for a

mental condition. Only the 78 days spent in the psychiatric hospital during the pre-entitlement period are subtracted from the 150 benefit days. Accordingly, the individual has 72 days of psychiatric care (150 days less 78 days) available in the first benefit period. Benefits could be paid for the individual's hospitalization during the first benefit period in the following manner. For the 130-day psychiatric hospital stay, 72 days (60 full benefit days and 12 coinsurance days), and for the general hospital stay, 20 days (18 coinsurance and 2 lifetime reserve days).

§ 409.64 Services that are counted toward allowable amounts.

(a) Except as provided in paragraph (b) of this section for lifetime reserve days, all covered inpatient days and home health visits are counted toward the allowable amounts specified in §§ 409.61 through 409.63 if—

(1) They are paid for by Medicare; or

(2) They would be paid for by Medicare if the following requirements had been met:

(i) A proper and timely request for payment had been filed; and

(ii) The hospital, CAH, SNF, or home health agency had submitted all necessary evidence, including physician or allowed practitioner certification of need for services when such certification was required;

(3) They could not be paid for because the total payment due was equal to, or less than, the applicable deductible and coinsurance amounts.

(b) *Exception.* Even though the requirements of paragraph (a)(2) of this section are met, lifetime reserve days are not counted toward the allowable amounts if the beneficiary elected or is deemed to have elected not to use them as set forth in § 409.65.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30667, May 26, 1993; 85 FR 70354, Nov. 4, 2020]

§ 409.65 Lifetime reserve days.

(a) *Election not to use lifetime reserve days.* (1) Whenever a beneficiary has exhausted the 90 regular benefit days, the hospital or CAH may bill Medicare for lifetime reserve days unless the beneficiary elects not to use them or, in accordance with paragraph (b) of this section, is deemed to have elected not to use them.

(2) It may be advantageous to elect not to use lifetime reserve days if the beneficiary has private insurance coverage that begins after the first 90 inpatient days in a benefit period, or if the daily charge is only slightly higher than the lifetime reserve days coinsurance amount. In such cases, the beneficiary may want to save the lifetime reserve days for future care that may be more expensive.

(3) If the beneficiary elects not to use lifetime reserve days for a particular hospital or CAH stay, they are still available for a later stay. However, once the beneficiary uses lifetime reserve days, they can never be renewed.

(4) If the beneficiary elects not to use lifetime reserve days, the hospital or CAH may require him or her to pay for any services furnished after the regular days are exhausted.

(b) *Deemed election.* A beneficiary will be deemed to have elected not to use lifetime reserve days if the average daily charges for such days is equal to or less than the applicable coinsurance amount specified in § 409.83. A beneficiary would get no benefit from using the days under those circumstances.

(c) *Who may file an election.* An election not to use reserve days may be filed by—

(1) The beneficiary; or

(2) If the beneficiary is physically or mentally unable to act, by the beneficiary's legal representative. In addition, if some other payment source is available, such as private insurance, any person authorized under § 405.1664 of this chapter to execute a request for payment for the beneficiary may file the election.

(d) *Filing the election.* (1) The beneficiary's election not to use lifetime reserve days must be filed in writing with the hospital or CAH.

(2) The election may be filed at the time of admission to the hospital or CAH or at any time thereafter up to 90 days after the beneficiary's discharge.

(3) A retroactive election (that is, one made after lifetime reserve days have been used because the regular days were exhausted), is not acceptable unless it is approved by the hospital or CAH.

(e) *Period covered by election*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, an election not to use lifetime reserve days may apply to an entire hospital or CAH stay or to a single period of consecutive days in a stay, but cannot apply to selected days in a stay. For example, a beneficiary may restrict the election to the period covered by private insurance but cannot use individual lifetime reserve days within that period. If an election not to use reserve days is effective after the first day on which reserve days are available, it must remain in effect until the end of the stay, unless it is revoked in accordance with § 409.66.

(2) *Exception.* A beneficiary election not to use lifetime reserve days for an inpatient hospital or inpatient CAH stay for which payment may be made under the prospective payment system (part 412 of this chapter) is subject to the following rules:

(i) If the beneficiary has one or more regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days will apply automatically to all days that are not outlier days. The beneficiary may also elect not to use lifetime reserve days for outlier days but this election must apply to all outlier days.

(ii) If the beneficiary has no regular benefit days (see § 409.61(a)(1) of this chapter) remaining in the benefit period upon entering the hospital or CAH, an election not to use lifetime reserve days must apply to the entire hospital or CAH stay.

[48 FR 12541, Mar. 25, 1983, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 58 FR 30666, 30667, May 26, 1993]

§ 409.66 Revocation of election not to use lifetime reserve days.

(a) Except as provided in paragraph (c) of this section, a beneficiary (or anyone authorized to execute a request for payment, if the beneficiary is incapacitated) may revoke an election not to use lifetime reserve days during hospitalization or within 90 days after discharge.

(b) The revocation must be submitted to the hospital or CAH in writing and identify the stay or stays to which it applies.

(c) *Exceptions.* A revocation of an election not to use lifetime reserve days may not be filed—

(1) After the beneficiary dies; or

(2) After the hospital or CAH has filed a claim under the supplementary medical insurance program (Medicare Part B), for medical and other health services furnished to the beneficiary on the days in question.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.68 Guarantee of payment for inpatient hospital or inpatient CAH services furnished before notification of exhaustion of benefits.

(a) *Conditions for payment.* Payment may be made for inpatient hospital or inpatient CAH services furnished a beneficiary after he or she has exhausted the available benefit days if the following conditions are met:

(1) The services were furnished before CMS or the intermediary notified the hospital or CAH that the beneficiary had exhausted the available benefit days and was not entitled to have payment made for those services.

(2) At the time the hospital or CAH furnished the services, it was unaware that the beneficiary had exhausted the available benefit days and could reasonably have assumed that he or she was entitled to have payment made for these services.

(3) Payment would be precluded solely because the beneficiary has no benefit days available for the particular hospital or CAH stay.

(4) The hospital or CAH claims reimbursement for the services and refunds any payments made for those services by the beneficiary or by another person on his or her behalf.

(b) *Limitations on payment.* (1) If all of the conditions in paragraph (a) of this section are met, Medicare payment may be made for the day of admission, and up to 6 weekdays thereafter, plus any intervening Saturdays, Sundays, and Federal holidays.

(2) Payment may not be made under this section for any day after the hospital or CAH is notified that the beneficiary has exhausted the available benefit days.

(c) *Recovery from the beneficiary.* Any payment made to a hospital or CAH under this section is considered an overpayment to the beneficiary and may be recovered from him or her under the provisions set forth elsewhere in this chapter.

[48 FR 12541, Mar. 25, 1983, as amended at 50 FR 33033, Aug. 16, 1985; 58 FR 30666, May 26, 1993]

Subpart G—Hospital Insurance Deductibles and Coinsurance

§ 409.80 Inpatient deductible and coinsurance: General provisions.

(a) *What they are.* (1) The inpatient deductible and coinsurance amounts are portions of the cost of covered hospital or CAH or SNF services that Medicare does not pay.

(2) The hospital or CAH or SNF may charge these amounts to the beneficiary or someone on his or her behalf.

(b) *Changes in the inpatient deductible and coinsurance amounts.* (1) The law requires the Secretary to adjust the inpatient hospital deductible each year to reflect changes in the average cost of hospital care. In adjusting the deductible, the Secretary must use a formula specified in section 1813(b)(2) of the Act. Under that formula, the inpatient hospital deductible is increased each year by about the same percentage as the increase in the average Medicare daily hospital costs. The result of the deductible increase is that the beneficiary continues to pay about the same proportion of the hospital bill.

(2) Since the coinsurance amounts are, by statute, specific fractions of the deductible, they change when the deductible changes.

[48 FR 12541, Mar. 25, 1983, as amended at 58 FR 30666, May 26, 1993]

§ 409.82 Inpatient hospital deductible.

(a) *General provisions*—(1) The inpatient hospital deductible is a fixed amount chargeable to the beneficiary when he or she receives covered services in a hospital or a CAH for the first time in a benefit period.

(2) Although the beneficiary may be hospitalized several times during a benefit period, the deductible is charged only once during that period. If the beneficiary begins more than one benefit period in the same year, a deductible is charged for each of those periods.

(3) For services furnished before January 1, 1982, the applicable deductible is the one in effect when the benefit period began.

(4) For services furnished after December 31, 1981, the applicable deductible is the one in effect during the calendar year in which the services were furnished.

(b) *Specific deductible amounts.* The specific deductible amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the total hospital or CAH charge is less than the deductible amount applicable for the calendar year in which the services were furnished, the amount of the charge is the deductible for the year.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.83 Inpatient hospital coinsurance.

(a) *General provisions*—(1) Inpatient hospital coinsurance is the amount chargeable to a beneficiary for each day after the first 60 days of inpatient hospital care or inpatient CAH care or both in a benefit period.

(2) For each day from the 61st to the 90th day, the coinsurance amount is ¼ of the applicable deductible.

(3) For each day from the 91st to the 150th day (lifetime reserve days), the coinsurance amount is ½ of the applicable deductible.

(4) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the calendar year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(5) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which

the services were furnished. For example, if an individual starts a benefit period by being admitted to a hospital in 1981 and remains in the hospital long enough to use coinsurance days in 1982, the coinsurance amount charged for those days is based on the 1982 inpatient hospital deductible.

(b) *Specific coinsurance amounts.* The specific coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exceptions to published amounts.* (1) If the actual charge to the patient for the 61st through the 90th day of inpatient hospital or inpatient CAH services is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance amount.

(2) If the actual charge to the patient for the 91st through the 150th day (lifetime reserve days) is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the beneficiary is deemed to have elected not to use the days because he or she would not benefit from using them.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989; 58 FR 30666, 30667, May 26, 1993]

§ 409.85 Skilled nursing facility (SNF) care coinsurance.

(a) *General provisions.* (1) SNF care coinsurance is the amount chargeable to a beneficiary after the first 20 days of SNF care in a benefit period.

(2) For each day from the 21st through the 100th day, the coinsurance is ⅛ of the applicable inpatient hospital deductible.

(3) For coinsurance days before January 1, 1982, the coinsurance amount is based on the deductible applicable for the year in which the benefit period began. The coinsurance amounts do not change during a beneficiary's benefit period even though the coinsurance days may fall in a subsequent year for which a higher deductible amount has been determined.

(4) For coinsurance days after December 31, 1981, the coinsurance amount is based on the deductible applicable for the calendar year in which the services were furnished.

(b) *Specific coinsurance amounts.* The specific SNF coinsurance amounts for each calendar year are published in the FEDERAL REGISTER no later than October 1 of the preceding year.

(c) *Exception to published amounts.* If the actual charge to the patient is less than the coinsurance amount applicable for the calendar year in which the services were furnished, the actual charge per day is the daily coinsurance.

[48 FR 12541, Mar. 25, 1983, as amended at 54 FR 4026, Jan. 27, 1989]

§ 409.87 Blood deductible.

(a) *General provisions.* (1) As used in this section, packed red cells means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that a beneficiary receives, during a calendar year, as an inpatient of a hospital or CAH or SNF, or on an outpatient basis under Medicare Part B.

(4) The deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin, and serum albumin, or to the cost of processing, storing, and administering blood.

(5) The blood deductible is in addition to the inpatient hospital deductible and daily coinsurance.

(6) The Part A blood deductible is reduced to the extent that the Part B blood deductible has been applied. For example, if a beneficiary had received one unit under Medicare Part B, and later in the same benefit period received three units under Medicare Part A, Medicare Part A would pay for the third of the latter units. (As specified in § 410.161 of this chapter, the Part B blood deductible is reduced to the extent a blood deductible has been applied under Medicare Part A.)

(b) *Beneficiary's responsibility for the first 3 units of whole blood or packed red cells*—(1) *Basic rule.* Except as specified in paragraph (b)(2) of this section, the beneficiary is responsible for the first 3

units of whole blood or packed red cells. He or she has the option of paying the hospital's or CAH's charges for the blood or packed red cells or arranging for it to be replaced.

(2) *Exception.* The beneficiary is not responsible for the first 3 units of whole blood or packed red cells if the provider obtained that blood or red cells at no charge other than a processing or service charge. In that case, the blood or red cells is deemed to have been replaced.

(c) *Provider's right to charge for the first 3 units of whole blood or packed red cells*—(1) *Basic rule.* Except as specified in paragraph (c)(2) of this section, a provider may charge a beneficiary its customary charge for any of the first 3 units of whole blood or packed red cells.

(2) *Exception.* A provider may not charge the beneficiary for the first 3 units of whole blood or packed red cells in any of the following circumstances:

(i) The blood or packed red cells has been replaced.

(ii) The provider (or its blood supplier) receives, from an individual or a blood bank, a replacement offer that meets the criteria specified in paragraph (d) of this section. The provider is precluded from charging even if it or its blood supplier rejects the replacement offer.

(iii) The provider obtained the blood or packed red cells at no charge other than a processing or service charge and it is therefore deemed to have been replaced.

(d) *Criteria for replacement of blood.* A blood replacement offer made by a beneficiary, or an individual or a blood bank on behalf of a beneficiary, discharges the beneficiary's obligation to pay for deductible blood or packed red cells if the replacement blood meets the applicable criteria specified in Food and Drug Administration regulations under 21 CFR part 640, i.e.—

(1) The replacement blood would not endanger the health of a beneficiary; and

(2) The prospective donor's health would not be endangered by making a blood donation.

[48 FR 12541, Mar. 25, 1983, as amended at 56 FR 8840, Mar. 1, 1991; 57 FR 36014, Aug. 12, 1992; 58 FR 30666, 30667, May 26, 1993]

§ 409.89 Exemption of kidney donors from deductible and coinsurance requirements.

The deductible and coinsurance requirements set forth in this subpart do not apply to any services furnished to an individual in connection with the donation of a kidney for transplant surgery.

Subpart H—Payment of Hospital Insurance Benefits

SOURCE: 53 FR 6633, Mar. 2, 1988, unless otherwise noted.

§ 409.100 To whom payment is made.

(a) *Basic rule.* Except as provided in paragraph (b) of this section—

(1) Medicare pays hospital insurance benefits only to a participating provider.

(2) For home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA, payment is made to the HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

(b) *Exceptions.* Medicare may pay hospital insurance benefits as follows:

(1) For emergency services furnished by a nonparticipating hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart G of part 424 of this chapter.

(2) For services furnished by a Canadian or Mexican hospital, to the hospital or to the beneficiary, under the conditions prescribed in subpart H of part 424 of this chapter.

[53 FR 6633, Mar. 2, 1988, as amended at 65 FR 41211, July 3, 2000]

§ 409.102 Amounts of payment.

(a) The amounts Medicare pays for hospital insurance benefits are generally determined in accordance with part 412 or part 413 of this chapter.

(b) Except as provided in §§ 409.61(d) and 409.89, hospital insurance benefits

are subject to the deductible and coinsurance requirements set forth in subpart G of this part.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart A—General Provisions

Subpart B—Medical and Other Health Services

AUTHORITY: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 410 appear at 62 FR 46037, Aug. 29, 1997.

Subpart A—General Provisions

§410.1 Basis and scope.

(a) *Statutory basis.* This part is based on the indicated provisions of the following sections of the Act:

(1) Section 1832—Scope of benefits furnished under the Medicare Part B supplementary medical insurance (SMI) program.

(2) Section 1833 through 1835 and 1862—Amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage.

(3) Section 1861(qq)—Definition of the kinds of services that may be covered.

(4) Section 1865(b)—Permission for CMS to approve and recognize a national accreditation organization for the purpose of deeming entities accredited by the organization to meet program requirements.

(5) Section 1881—Medicare coverage for end-stage renal disease beneficiaries.

(6) Section 1842(o)—Payment for drugs and biologicals not paid on a cost or prospective payment basis.

(b) *Scope of part.* This part sets forth the benefits available under Medicare

Part B, the conditions for payment and the limitations on services, the percentage of incurred expenses that Medicare Part B pays, and the deductible and copayment amounts for which the beneficiary is responsible. (Exclusions applicable to these services are set forth in subpart C of part 405 of this chapter. General conditions for Medicare payment are set forth in part 424 of this chapter.)

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 55 FR 53521, Dec. 31, 1990; 59 FR 63462, Dec. 8, 1994; 63 FR 58905, Nov. 2, 1998; 65 FR 83148, Dec. 29, 2000; 69 FR 66420, Nov. 15, 2004]

§ 410.2 Definitions.

As used in this part—

Brace means a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Community mental health center (CMHC) means an entity that—

(1) Provides outpatient services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and residents of its mental health service area who have been discharged from inpatient treatment at a mental health facility;

(2) Provides 24-hour-a-day emergency care services;

(3) Provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services;

(4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission;

(5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and

(6) Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Social Security Act.

Custom fitted gradient compression garment means a garment that is uniquely sized and shaped to fit the exact dimensions of the affected extremity or part of the body, of an individual to provide accurate gradient compression to treat lymphedema.

Encounter means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

Gradient compression means the ability to apply a higher level of compression or pressure to the distal (farther) end of the limb or body part affected by lymphedema with lower, decreasing compression or pressure at the proximal (closer) end of the limb or body part affected by lymphedema.

Intensive outpatient services mean a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

Lymphedema compression treatment item means standard and custom fitted gradient compression garments and other items specified under § 410.36(a)(4) that are—

(1) Furnished on or after January 1, 2024, to an individual with a diagnosis of lymphedema for treatment of such condition;

(2) Primarily and customarily used to serve a medical purpose and for the treatment of lymphedema; and

(3) Prescribed by a physician (or a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5) of the Act)) to the extent authorized under State law.

Nominal charge provider means a provider that furnishes services free of charge or at a nominal charge, and is either a public provider or another provider that (1) demonstrates to CMS's satisfaction that a significant portion of its patients are low-income; and (2) requests that payment for its services be determined accordingly.

Outpatient means a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.

Partial hospitalization services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.43.

Participating refers to a hospital, critical access hospital (CAH), skilled nursing facility (SNF), home health agencies (HHA), comprehensive outpatient rehabilitation facility (CORF), or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services and intensive outpatient services, and nonparticipating refers to a hospital, CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

Preventive services means all of the following:

(1) The specific services listed in section 1861(ww)(2) of the Act, with the explicit exclusion of electrocardiograms;

(2) The Initial Preventive Physical Examination (IPPE) (as specified by section 1861(ww)(1) of the Act); and

(3) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS) (as specified by section 1861(hhh)(1) of the Act).

[59 FR 6577, Feb. 11, 1994, as amended at 62 FR 46025, Aug. 29, 1997; 65 FR 18536, Apr. 7, 2000; 75 FR 72259, Nov. 24, 2010; 75 FR 73613, Nov. 29, 2010; 88 FR 77874, Nov. 13, 2023; 88 FR 82177, Nov. 22, 2023]

§ 410.3 Scope of benefits.

(a) *Covered services.* The SMI program helps pay for the following:

(1) Medical and other health services such as physicians' services, outpatient services furnished by a hospital or a CAH, diagnostic tests, outpatient physical therapy and speech pathology services, rural health clinic services, Federally qualified health center services, IHS, Indian tribe, or tribal organization facility services, and outpatient renal dialysis services.

(2) Services furnished by ambulatory surgical centers (ASCs), HHAs, CORFs, and partial hospitalization services and intensive outpatient services provided by CMHCs.

(3) Other medicial services, equipment, and supplies that are not covered under Medicare Part A hospital insurance.

(b) *Limitations on amount of payment.* (1) Medicare Part B does not pay the full reasonable costs or charges for all covered services. The beneficiary is responsible for an annual deductible and a blood deductible and, after the annual deductible has been satisfied, for coinsurance amounts specified for most of the services.

(2) Specific rules on payment are set forth in subpart I of this part.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 66 FR 55328, Nov. 1, 2001; 75 FR 73613, Nov. 29, 2010; 88 FR 82177, Nov. 22, 2023]

§ 410.5 Other applicable rules.

The following other rules of this chapter set forth additional policies and procedures applicable to four of the kinds of services covered under the SMI program:

(a) Part 494: End-Stage Renal Disease Facilities.

(b) Part 405, Subpart X: Rural Health Clinic and Federally Qualified Health Center services.

(c) Part 416: Ambulatory Surgical Center services.

(d) Part 493: Laboratory Services.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 7134, Feb. 28, 1992; 57 FR 24981, June 12, 1992; 73 FR 20474, Apr. 15, 2008]

Subpart B—Medical and Other Health Services

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, ''medical and other health services'' includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional

services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services and intensive outpatient services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or a CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal, influenza, and COVID–19 vaccines (or monoclonal antibodies used for preexposure prophylaxis of COVID–19) and their administration.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine and its administration, as defined in § 410.63(a) of this subchapter.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin, including items and services, administered in the home for the treatment of primary immune deficiency diseases.

(z) Marriage and Family Therapist services, as provided in § 410.53.

(aa) Mental Health Counselor services, as provided in § 410.54.

[51 FR 41339, Nov. 14, 1986, as amended at 52 FR 27765, July 23, 1987; 55 FR 22790, June 4, 1990; 55 FR 53522, Dec. 31, 1990; 56 FR 8841, Mar. 1, 1991; 56 FR 43709, Sept. 4, 1991; 57 FR 24981, June 12, 1992; 57 FR 33896, July 31, 1992; 58 FR 30668, May 26, 1993; 59 FR 26959, May 25, 1994; 59 FR 49833, Sept. 30, 1994; 60 FR 8955, Feb. 16, 1995; 63 FR 20128, Apr. 23, 1998; 66 FR 55328, Nov. 1, 2001; 69 FR 66420, Nov. 15, 2004; 87 FR 70223, Nov. 18, 2022; 88 FR 77874, Nov. 13, 2023; 88 FR 79525, Nov. 16, 2023; 88 FR 82177, Nov. 22, 2023]

§ 410.12 Medical and other health services: Basic conditions and limitations.

(a) *Basic conditions.* The medical and other health services specified in § 410.10 are covered by Medicare Part B only if they are not excluded under subpart A of part 411 of this chapter, and if they meet the following conditions:

(1) *When the services must be furnished.* The services must be furnished while the individual is in a period of entitlement. (The rules on entitlement are set forth in part 406 of this chapter.)

(2) *By whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.69.

(3) *Physician certification and recertification requirements.* If the services are

subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with subpart B of part 424 of this chapter.

(b) *Limitations on payment.* Payment for medical and other health services is subject to limitations on the amounts of payment as specified in §§ 410.152 and 410.155 and to the annual and blood deductibles as set forth in §§ 410.160 and 410.161.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 33896, July 31, 1992]

§ 410.14 Special requirements for services furnished outside the United States.

Medicare part B pays for physicians' services and ambulance services furnished outside the United States if the services meet the applicable conditions of § 410.12 and are furnished in connection with covered inpatient hospital services that meet the specific requirements and conditions set forth in subpart H of part 424 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) *Definitions.* For purposes of this section—

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

Detection of any cognitive impairment means assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers or others.

Eligible beneficiary means an individual who is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and who has not received either an initial preventive physical examination or an annual wellness visit providing a personalized prevention plan within the past 12 months.

Establishment of, or an update to the individual's medical and family history means, at minimum, the collection and documentation of the following:

(i) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries and treatments.

(ii) Use or exposure to medications and supplements, including calcium and vitamins.

(iii) Medical events in the beneficiary's parents and any siblings and children, including diseases that may be hereditary or place the individual at increased risk.

First annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of, a health risk assessment, as those terms are defined in this section:

(i) Review (and administration if needed) of a health risk assessment (as defined in this section).

(ii) Establishment of an individual's medical and family history.

(iii) Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

(iv) Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.

(v) Detection of any cognitive impairment that the individual may have, as that term is defined in this section.

(vi) Review of the individual's potential (risk factors) for depression, including current or past experiences

with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

(vii) Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in this section may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(viii) Establishment of the following:

(A) A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in this section), health status, screening history, and age-appropriate preventive services covered by Medicare.

(B) A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under § 410.16 of this subpart), and a list of treatment options and their associated risks and benefits.

(ix) Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

(x) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(xi) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(xii) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xiii) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

(xiv) Any other element determined appropriate through the national coverage determination process.

Health professional means—

(i) A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act); or

(ii) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or

(iii) A medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in § 410.32(b)(3)(ii)) of a physician as defined in paragraph (i) of this definition.

Health risk assessment means, for the purposes of this section, an evaluation tool that meets the following criteria:

(i) Collects self-reported information about the beneficiary.

(ii) Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.

(iii) Is appropriately tailored to and takes into account the communication

needs of underserved populations, persons with limited English proficiency, and persons with health literacy needs.

(iv) Takes no more than 20 minutes to complete.

(v) Addresses, at a minimum, the following topics:

(A) Demographic data, including but not limited to age, gender, race, and ethnicity.

(B) Self assessment of health status, frailty, and physical functioning.

(C) Psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue.

(D) Behavioral risks, including but not limited to, tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.

(E) Activities of daily living (ADLs), including but not limited to, dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.

(F) Instrumental activities of daily living (IADLs), including but not limited to, shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

Review of the individual's functional ability and level of safety means, at minimum, assessment of the following topics:

(i) Hearing impairment.

(ii) Ability to successfully perform activities of daily living.

(iii) Fall risk.

(iv) Home safety.

Subsequent annual wellness visit providing personalized prevention plan services means the following services furnished to an eligible beneficiary by a health professional that include, and take into account the results of an updated health risk assessment, as those terms are defined in this section:

(i) Review (and administration, if needed) of an updated health risk assessment (as defined in this section).

(ii) An update of the individual's medical and family history.

(iii) An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(iv) Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

(v) Detection of any cognitive impairment that the individual may have, as that term is defined in this section.

(vi) An update to the following:

(A) The written screening schedule for the individual as that schedule is defined in paragraph (a) of this section for the first annual wellness visit providing personalized prevention plan services.

(B) The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first annual wellness visit providing personalized prevention plan services or the previous subsequent annual wellness visit providing personalized prevention plan services.

(vii) Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of this section.

(viii) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(ix) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(x) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xi) At the discretion of the health professional and beneficiary, furnish a Social Determinants of Health Risk

Assessment that is standardized, evidence-based, and furnished in a manner that all communication with the patient is appropriate for the beneficiary's educational, developmental, and health literacy level, and is culturally and linguistically appropriate.

(xii) Any other element determined appropriate through the national coverage determination process.

(b) *Conditions for coverage of annual wellness visits providing personalized prevention plan services.* Medicare Part B pays for first and subsequent annual wellness visits providing personalized prevention plan services that are furnished to an eligible beneficiary, as described in this section, if they are furnished by a health professional, as defined in this section.

(c) *Limitations on coverage of an annual wellness visit providing personalized prevention plan services.* Payment may not be made for either a first or a subsequent annual wellness visit providing personalized prevention plan services that is performed for an individual who is—

(1) Not an eligible beneficiary as described in this section.

(2) An eligible beneficiary as described in this section and who has had either an initial preventive physical examination as specified in §410.16 of this subpart or either a first or a subsequent annual wellness visit providing personalized prevention plan services performed within the past 12 months.

(d) *Effective date.* Coverage for an annual wellness visit providing personalized prevention plan services is effective for services furnished on or after January 1, 2011.

[75 FR 73613, Nov. 29, 2010, as amended at 76 FR 1367, Jan. 10, 2011; 76 FR 73470, Nov. 28, 2011; 80 FR 71372, Nov. 16, 2015; 85 FR 85025, Dec. 28, 2020; 88 FR 79525, Nov. 16, 2023]

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

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

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

Eligible beneficiary means, for the purposes of this section, an individual who receives his or her initial preventive examination not more than 1 year after the effective date of his or her first Medicare Part B coverage period.

End-of-life planning means, for purposes of this section, verbal or written information regarding the following areas:

(1) An individual's ability to prepare an advance directive in the case where an injury or illness causes the individual to be unable to make health care decisions.

(2) Whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

Initial preventive physical examination means all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner with the goal of health promotion and disease detection:

(1) Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in this section.

(2) Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified nonphysician practitioner may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.

(3) Review of the beneficiary's functional ability, and level of safety as those terms are defined in this section, as described in paragraph (4) of this

definition, based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified nonphysician practitioner may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

(4) An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.

(5) End-of-life planning as that term is defined in this section upon agreement with the individual.

(6) A review of any current opioid prescriptions as defined in this section.

(7) Screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(8) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(9) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

Medical history is defined to include, at a minimum, the following:

(1) Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

(2) Current medications and supplements, including calcium and vitamins.

(3) Family history, including a review of medical events in the beneficiary's family, including diseases that may be hereditary or place the individual at risk.

A *physician* for purposes of this section means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

A qualified nonphysician practitioner for purposes of this section means a physician assistant, nurse practitioner, or clinical nurse specialist (as authorized under section 1861(s)(2)(K)(i) and section 1861(s)(2)(K)(ii) of the Act and defined in section 1861(aa)(5) of the Act, or in §§ 410.74, 410.75, and 410.76).

Review of the beneficiary's functional ability and level of safety must include, at a minimum, a review of the following areas:

(1) Hearing impairment.

(2) Activities of daily living.

(3) Falls risk.

(4) Home safety

Social history is defined to include, at a minimum, the following:

(1) History of alcohol, tobacco, and illicit drug use.

(2) Diet.

(3) Physical activities.

(b) *Condition for coverage of an initial preventive physical examination.* Medicare Part B pays for an initial preventive physical examination provided to an eligible beneficiary, as described in this section, if it is furnished by a physician or other qualified nonphysician practitioner, as defined in this section.

(c) *Limitations on coverage of initial preventive physical examinations.* Payment may not be made for an initial preventive physical preventive examination that is performed for an individual who is not an eligible beneficiary as described in this section.

[69 FR 66420, Nov. 15, 2004, as amended at 71 FR 69783, Dec. 1, 2006; 73 FR 69932, Nov. 19, 2008; 85 FR 85025, Dec. 28, 2020]

§ 410.17 Cardiovascular disease screening tests.

(a) *Definition.* For purposes of this subpart, the following definition apply:

Cardiovascular screening blood test means:

(1) A lipid panel consisting of a total cholesterol, HDL cholesterol, and triglyceride. The test is performed after a 12-hour fasting period.

(2) Other blood tests, previously recommended by the U.S. Preventive Services Task Force (USPSTF), as determined by the Secretary through a national coverage determination process.

(3) Other non-invasive tests, for indications that have a blood test recommended by the USPSTF, as determined by the Secretary through a national coverage determination process.

(b) *General conditions of coverage.* Medicare Part B covers cardiovascular disease screening tests when ordered by the physician who is treating the beneficiary (see § 410.32(a)) for the purpose of early detection of cardiovascular disease in individuals without apparent signs or symptoms of cardiovascular disease.

(c) *Limitation on coverage of cardiovascular screening tests.* Payment may be made for cardiovascular screening tests performed for an asymptomatic individual only if the individual has not had the screening tests paid for by Medicare during the preceding 59 months following the month in which the last cardiovascular screening tests were performed.

[69 FR 66421, Nov. 15, 2004]

§ 410.18 Diabetes screening tests.

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

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism.

(b) *General conditions of coverage.* Medicare Part B covers diabetes screening tests after a referral from a physician or qualified nonphysician practitioner to an individual at risk for diabetes for the purpose of early detection of diabetes.

(c) *Types of tests covered.* The following tests are covered if all other conditions of this subpart are met:

(1) Fasting blood glucose test.

(2) Post-glucose challenges including, but not limited to, an oral glucose tolerance test with a glucose challenge of 75 grams of glucose for non-pregnant adults, a 2-hour post glucose challenge test alone.

(3) Hemoglobin A1C test.

(4) Other tests as determined by the Secretary through a national coverage determination.

(d) *Amount of testing covered.* Medicare covers two tests within the 12-month period following the date of the most recent diabetes screening test of that individual.

(e) *Eligible risk factors.* Individuals with the following risk factors are eligible to receive the benefit:

(1) Hypertension.

(2) Dyslipidemia.

(3) Obesity, defined as a body mass index greater than or equal to 30 kg/m^2.

(4) Prior identification of impaired fasting glucose or glucose intolerance.

(5) Any two of the following characteristics:

(i) Overweight, defined as body mass index greater than 25, but less than 30 kg/m^2.

(ii) A family history of diabetes.

(iii) 65 years of age or older.

(iv) A history of gestational diabetes mellitus or delivery of a baby weighing more than 9 pounds.

[69 FR 66421, Nov. 15, 2004, as amended at 88 FR 79525, Nov. 16, 2023]

§ 410.19 Ultrasound screening for abdominal aortic aneurysms: Condition for and limitation on coverage.

(a) *Definitions:* As used in this section, the following definitions apply:

Eligible beneficiary means an individual who—

(1) Has not been previously furnished an ultrasound screening for an abdominal aortic aneurysm under Medicare program; and

(2) Is included in at least one of the following risk categories:

(i) Has a family history of an abdominal aortic aneurysm.

(ii) Is a man age 65 to 75 who has smoked at least 100 cigarettes in his lifetime.

(iii) Is an individual who manifests other risk factors in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms, as specified by the Secretary through a national coverage determination process.

Ultrasound screening for abdominal aortic aneurysms means the following services furnished to an asymptomatic individual for the early detection of an abdominal aortic aneurysm:

(1) A procedure using soundwaves (or other procedures using alternative technologies of commensurate accuracy and cost, as specified by the Secretary through a national coverage determination process) provided for the

early detection of abdominal aortic aneurysms.

(2) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage of an ultrasound screening for abdominal aortic aneurysms.* Medicare Part B pays for one ultrasound screening for an abdominal aortic aneurysm provided to eligible beneficiaries, as described in this section, after a referral from a physician or a qualified nonphysician practitioner as defined in § 410.16(a), when the test is performed by a provider or supplier that is authorized to provide covered ultrasound diagnostic services.

(c) *Limitation on coverage of ultrasound screening for abdominal aortic aneurysms.* Payment may not be made for an ultrasound screening for an abdominal aortic aneurysm that is performed for an individual that does not meet the definition of ''eligible beneficiary'' specified in this section.

[71 FR 69783, Dec. 1, 2006, as amended at 78 FR 74810, Dec. 10, 2013]

§ 410.20 Physicians' services.

(a) *Included services.* Medicare Part B pays for physicians' services, including diagnosis, therapy, surgery, consultations, and home, office, and institutional calls.

(b) *By whom services must be furnished.* Medicare Part B pays for the services specified in paragraph (a) of this section if they are furnished by one of the following professionals who is legally authorized to practice by the State in which he or she performs the functions or actions, and who is acting within the scope of his or her license.

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized in section 1101(a)(7) of the Act.

(2) A doctor of dental surgery or dental medicine.

(3) A doctor of podiatric medicine.

(4) A doctor of optometry.

(5) A chiropractor who meets the qualifications specified in § 410.22

(c) *Limitations on services.* The Services specified in paragraph (a) of this section may be covered under Medicare Part B if they are furnished within the limitations specified in §§ 410.22 through 410.25.

(d) *Prior determination of medical necessity for physicians' services*—(1) *Definitions.* (i) A ''Prior Determination of Medical Necessity'' means an individual decision by a Medicare contractor, before a physician's service is furnished, as to whether or not the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(ii) An ''eligible requester'' includes the following:

(A) A participating physician (or a physician that accepts assignment), but only with respect to physicians' services to be furnished to an individual who is entitled to receive benefits under this part and who has consented to the physician making the request under this section for those physicians' services.

(B) An individual entitled to benefits under this part, but only with respect to physicians' services for which the individual receives, from a physician, an advance beneficiary notice under section 1879(a) of the Act.

(2) *General rule.* Each Medicare contractor will, through the procedures established in CMS manual instructions, allow requests for prior determinations of medical necessity from eligible requesters under its respective jurisdiction for those services identified by CMS (updated annually in conjunction with the update to the MPFS and posted on that specific Medicare contractor's Web site by the Healthcare Common Procedure Coding System procedure code and code description). Only those services listed on that Medicare contractor's Web site on the date the request for a prior determination is made are subject to prior determination. Each contractor's list will consist of the following:

(i) The national list, provided by CMS, of the most expensive physicians' services (as defined in section 1848(j)(3) of the Act) included in the MPFS which are performed at least 50 times annually.

(ii) The national list, provided by CMS, of plastic and dental surgeries that may be covered by Medicare and that have an amount of at least $1,000 on the MPFS (not including the adjustment for location by the GPCI).

(3) *Services with local coverage determinations (LCDs) or national coverage determinations (NCDs).* In instances where an LCD or an NCD exists that has sufficiently specific reasonable and necessary criteria addressing the particular clinical indication for the procedure for which the prior determination is requested, the contractor will send a copy of the LCD or NCD to the requestor along with an explanation that the LCD or NCD serves as the prior determination and that no further determination will be made.

(4) *Identification of eligible services.* CMS will identify the number of services that are eligible for a prior determination through manual instructions consistent with the criteria established in the regulation.

(5) *Statutory procedures.* Under sections 1869(h)(3) through (h)(6) of the Act, the following procedures apply:

(i) *Request for prior determination*—(A) *In general.* An eligible requester may submit to the contractor a request for a determination, before the furnishing of a physician's service, as to whether the physician's service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) of the Act (relating to medical necessity).

(B) *Accompanying documentation.* CMS may require that the request be accompanied by a description of the physician's service, supporting documentation relating to the medical necessity of the physician's service, and other appropriate documentation. In the case of a request submitted by an eligible requester who is described in section 1869(h)(1)(B)(ii) of the Act, the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(ii) *Response to request*—(A) *General rule.* The contractor will provide the eligible requester with written notice of a determination as to whether—

(*1*) The physician's service is covered (the physician's service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(*2*) The physician's service is not covered (the physician's service is not covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity); or

(*3*) The contractor lacks sufficient information to make a coverage determination with respect to the physician's service.

(B) *Contents of notice for certain determinations*—(*1*) *Coverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(1) of this section, the contractor will indicate in the prior determination notice that the physician service is covered consistent with the requirements of section 1862(a)(1)(A) of the Act relating to medical necessity.

(*2*) *Noncoverage.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(*2*) of this section, the contractor will include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under section 1869(a) of the Act.

(*3*) *Insufficient information.* If the contractor makes the determination described in paragraph (d)(5)(ii)(A)(*3*) of this section, the contractor will include in the notice a description of the additional information required to make the coverage determination.

(C) *Deadline to respond.* The notice described in paragraphs (d)(5)(ii)(A)(1) through (d)(5)(ii)(A)(3) of this section will be provided by the contractor within 45 days of the date the request for a prior determination is received by the contractor.

(D) *Informing beneficiary in case of physician request.* In the case of a request by a participating physician or a physician accepting assignment, the process will provide that the individual to whom the physician's service is to be furnished will be informed of any determination described in paragraph (d)(5)(ii)(A)(*2*) of this section (relating to a determination of non-coverage). The beneficiary will also be notified that, notwithstanding the determination of non-coverage, the beneficiary has the right to obtain the physician's service in question and have a claim submitted for the physician's service.

(iii) *Binding nature of positive determination.* If the contractor makes the

determination described in paragraph (d)(5)(ii)(A)(*1*) of this section, that determination will be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(iv) *Limitation on further review*—(A) *General rule.* Contractor determinations described in paragraph (d)(5)(ii)(A)(*2*) of this section or paragraph (d)(5)(ii)(A)(*3*) of this section (relating to pre-service claims) are not subject to administrative appeal or judicial review.

(B) *Decision not to seek prior determination or negative determination does not impact the right to obtain services, seek reimbursement, or appeal rights.* Nothing in this paragraph will be construed as affecting the right of an individual who—

(*1*) Decides not to seek a prior determination under this paragraph with respect to physicians' services; or

(*2*) Seeks such a determination and has received a determination described in paragraph (d)(5)(ii)(A)(*2*) of this section, from receiving (and submitting a claim for) those physicians' services and from obtaining administrative or judicial review respecting that claim under the other applicable provisions of this part 405 subpart I of this chapter. Failure to seek a prior determination under this paragraph with respect to physicians' services will not be taken into account in that administrative or judicial review.

(C) *No prior determination after receipt of services.* Once an individual is provided physicians' services, there will be no prior determination under this paragraph with respect to those physicians' services.

(e) *Medical record documentation.* The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

[51 FR 41339, Nov. 14, 1986, as amended at 73 FR 9678, Feb. 22, 2008; 84 FR 63187, Nov. 15, 2019]

§ 410.21 Limitations on services of a chiropractor.

(a) *Qualifications for chiropractors.* (1) A chiropractor licensed or authorized to practice before July 1, 1974, and an individual who began studies in a chiropractic college before that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Graduated from a college of chiropractic approved by the State's chiropractic examiners after completing a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous attendance and covering adequate courses of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing and adjusting; and

(iii) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(1)(ii) of this section.

(2) A chiropractor first licensed or authorized to practice after June 30, 1974, and an individual who begins studies in a chiropractic college after that date, must have—

(i) Had preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

(ii) Satisfactorily completed 2 years of pre-chiropractic study at the college level;

(iii) Satisfactorily completed a 4-year course of 8 months each year offered by a college or school of chiropractic approved by the State's chiropractic examiners and including at least 4,000 hours in courses in anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, principles and practice of chiropractic, and clinical instruction in vertebral palpation, nerve tracing and adjusting, plus courses in the use and effect of X-ray and chiropractic analysis;

(iv) Passed an examination prescribed by the State's chiropractic examiners covering the subjects specified in paragraph (a)(2)(iii) of this section; and

(v) Attained 21 years of age.

(b) *Limitations on services.* (1) Medicare Part B pays only for a chiropractor's manual manipulation of the spine to correct a subluxation if the subluxation has resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment.

(2) Medicare Part B does not pay for X-rays or other diagnostic or therapeutic services furnished or ordered by a chiropractor.

[51 FR 41339, Nov. 14, 1986, as amended at 64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

§ 410.22 Limitations on services of an optometrist.

Medicare Part B pays for the services of a doctor of optometry, which he or she is legally authorized to perform in the State in which he or she performs them, if the services are among those described in section 1861(s) of the Act and § 410.10 of this part.

[64 FR 59439, Nov. 2, 1999. Redesignated at 66 FR 55328, Nov. 1, 2001]

§ 410.23 Screening for glaucoma: Conditions for and limitations on coverage.

(a) *Definitions*: As used in this section, the following definitions apply:

(1) *Direct supervision in the office setting* means the optometrist or the ophthalmologist must be present in the office suite and be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean the physician must be present in the room when the procedure is performed.

(2) *Eligible beneficiary* means individuals in the following high risk categories:

(i) Individual with diabetes mellitus.

(ii) Individual with a family history of glaucoma.

(iii) African-Americans age 50 and over.

(iv) Hispanic-Americans age 65 and over.

(3) *Screening for glaucoma* means the following procedures furnished to an individual for the early detection of glaucoma:

(i) A dilated eye examination with an intraocular pressure measurement.

(ii) A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

(b) *Condition for coverage of screening for glaucoma.* Medicare Part B pays for glaucoma screening examinations provided to eligible beneficiaries as described in paragraph (a)(2) of this section if they are furnished by or under the direct supervision in the office setting of an optometrist or ophthalmologist who is legally authorized to perform these services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or incident to a physician's professional service.

(c) *Limitations on coverage of glaucoma screening examinations.* (1) Payment may not be made for a glaucoma screening examination that is performed for an individual who is not an eligible beneficiary as described in paragraph (a)(2) of this section.

(2) Payment may be made for a glaucoma screening examination that is performed on an individual who is an eligible beneficiary as described in paragraph (a)(2) of this section, after at least 11 months have passed following the month in which the last glaucoma screening examination was performed.

[66 FR 55328, Nov. 1, 2001, as amended at 70 FR 70330, Nov. 21, 2005]

§ 410.24 Limitations on services of a doctor of dental surgery or dental medicine.

Medicare Part B pays for services furnished by a doctor of dental surgery or dental medicine within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.[1]

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8852, Mar. 1, 1991]

[1] For services furnished before July 1, 1981, Medicare Part B paid only for the following

§ 410.25 Limitations on services of a podiatrist.

Medicare Part B pays for the services of a doctor of podiatric medicine, acting within the scope of his or her license, if the services would be covered as physicians' services when performed by a doctor of medicine or osteopathy.

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

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

(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

(2) *Direct supervision* means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii).

(3) *General supervision* means the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service.

(4) *Independent contractor* means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or the entity that has hired such an individual) receives an IRS–1099 form.

(5) *Leased employment* means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(6) *Noninstitutional setting* means all settings other than a hospital or skilled nursing facility.

(7) *Practitioner* means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(8) *Services and supplies* means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Designated care management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided incident to the services of a physician (or other practitioner). Behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or other practitioner). The physician (or other practitioner) supervising the auxiliary

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services of a doctor of dental surgery or dental medicine;

Surgery on the jaw or any adjoining structure; and

Reduction of a fracture of the jaw or other facial bone.

personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

(7) Services and supplies must be furnished in accordance with applicable State law.

(8) A physician (or other practitioner) may be an employee or an independent contractor.

(9) Claims for drugs payable administered by a physician as defined in section 1861(r) of the Social Security Act to refill an implanted item of DME may only be paid under Part B to the physician as a drug incident to a physician's service under section 1861(s)(2)(A). These drugs are not payable to a pharmacy/supplier as DME under section 1861(s)(6) of the Act.

(c) *Limitations.* (1) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in §§ 410.59(a)(3)(iii), 410.60(a)(3)(iii), and 410.62(a)(3)(ii).

[51 FR 41339, Nov. 14, 1986, as amended at 66 FR 55328, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002; 69 FR 66421, Nov. 15, 2004; 77 FR 69361, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 14870, Mar. 20, 2015; 80 FR 71372, Nov. 16, 2015; 81 FR 80552, Nov. 15, 2016; 87 FR 70223, Nov. 18, 2022]

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) They are furnished—

(i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident as provided in § 411.15(p) of this subchapter;

(ii) As an integral although incidental part of a physician's or nonphysician practitioner's services;

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in § 413.65 of this subchapter, except for mental health services furnished to beneficiaries in their homes through the use of communication technology;

(iv) Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, or through the use of communication technology for mental health services, general supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure.

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision.

(*1*) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2024, the presence of the physician or nonphysician

practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

(*2*) Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

(C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77; and

(v) In accordance with applicable State law.

(2) In the case of partial hospitalization services or intensive outpatient services, also meet the conditions of paragraph (e) of this section.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.129.

(c) Rules on emergency services furnished to outpatients by nonparticipating hospitals are specified in subpart G of Part 424 of this chapter.

(d) Rules on emergency services furnished to outpatients in a foreign country are specified in subpart H of Part 424 of this chapter.

(e) Medicare Part B pays for partial hospitalization services and intensive outpatient services if they are—

(1) Prescribed by a physician who certifies and recertifies the need for the services in accordance with subpart B of part 424 of this chapter; and

(2) Furnished under a plan of treatment as required under subpart B of part 424 of this chapter.

(f) Services furnished by an entity other than the hospital are subject to the limitations specified in § 410.42(a).

(g) For purposes of this section, *nonphysician practitioner* means a clinical psychologist, licensed clinical social worker, marriage and family therapist, mental health counselor, physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse-midwife.

[76 FR 74580, Nov. 30, 2011, as amended at 78 FR 75196, Dec. 10, 2013; 84 FR 61490, Nov. 12, 2019; 85 FR 8476, Feb. 14, 2020; 85 FR 19285, Apr. 6, 2020; 85 FR 86299, Dec. 29, 2020; 87 FR 72284, Nov. 23, 2022; 88 FR 82177, Nov. 22, 2023]

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

(a) Medicare Part B pays for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

(1) They are furnished by or under arrangements made by a participating hospital or participating CAH, except in the case of an SNF resident as provided in § 411.15(p) of this chapter.

(2) They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.

(3) They would be covered as inpatient hospital services if furnished to an inpatient.

(b) Drugs and biologicals are also subject to the limitations specified in § 410.29(b) and (c).

(c) Diagnostic services furnished by an entity other than the hospital or CAH are subject to the limitations specified in § 410.42(a).

(d) Rules on emergency services furnished to outpatients by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(e) Medicare Part B makes payment under section 1833(t) of the Act for diagnostic services furnished by or under arrangements made by the participating hospital only when the diagnostic services are furnished under one of the three levels of supervision (as defined in paragraphs (e)(1) through (3) of this section) specified by CMS for the particular service by a physician or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nonphysician practitioner (physician assistant, nurse practitioner, clinical

nurse specialist, certified nurse-midwife or certified registered nurse anesthetist).

(1) *General supervision.* General supervision means the procedure is furnished under the physician's or nonphysician practitioner's overall direction and control, but the physician's or nonphysician practitioner's presence is not required during the performance of the procedure. Under general supervision at a facility accorded provider-based status, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

(2) *Direct supervision.* (i) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, ''direct supervision'' means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room where the procedure is performed.

(ii) For services furnished under arrangement in nonhospital locations, ''direct supervision'' means the physician or nonphysician practitioner must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.

(iii) Through December 31, 2024, the presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(3) Personal supervision. Personal supervision means the physician or nonphysician practitioner must be in attendance in the room during the performance of the procedure.

(f) The rules for clinical diagnostic laboratory tests set forth in §§ 410.32(a) and (d)(2) through (d)(4) of this subpart are applicable to those tests when furnished in hospitals and CAHs.

[51 FR 41339, Nov. 14, 1986, as amended at 58 FR 30668, May 26, 1993; 63 FR 26307, May 12, 1998; 65 FR 18536, Apr. 7, 2000; 66 FR 58809, Nov. 23, 2001; 74 FR 60680, Nov. 20, 2009; 75 FR 72259, Nov. 24, 2010; 85 FR 19286, Apr. 6, 2020; 87 FR 72285, Nov. 23, 2022; 88 FR 82177, Nov. 22, 2023]

§ 410.29 Limitations on drugs and biologicals.

Medicare part B does not pay for the following:

(a) Except as provided in § 410.28(a) for outpatient diagnostic services and § 410.63(b) for blood clotting factors, and except for EPO, any drug or biological which is usually self-administered by the patient.

(b) Any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program, that there is a compelling justification of the drug product's medical need. (21 CFR 310.6 contains an explanation of the efficacy review program.)

(c) Any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (b) of this section.

[51 FR 41339, Nov. 14, 1986, as amended at 55 FR 22790, June 4, 1990; 56 FR 43709, Sept. 4, 1991; 80 FR 70602, Nov. 13, 2015]

§ 410.30 Prescription drugs used in immunosuppressive therapy.

(a) *Scope.* Payment may be made for prescription drugs used in immunosuppressive therapy that have been approved for marketing by the FDA and that meet one of the following conditions:

(1) The approved labeling includes the indication for preventing or treating the rejection of a transplanted organ or tissue.

(2) The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.

(3) Have been determined by a carrier (in accordance with part 421, subpart C of this chapter), in processing a Medicare claim, to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue. (In making these determinations, the carriers may consider factors such as authoritative drug compendia, current medical literature, recognized standards of medical practice, and professional medical publications.)

(b) *Eligibility.* For drugs furnished on or after December 21, 2000, coverage is available only for prescription drugs used in immunosuppressive therapy, furnished to an individual who received an organ or tissue transplant for which Medicare payment is made, provided the individual is eligible to receive Medicare Part B benefits, including, beginning January 1, 2023, an individual who meets the requirements specified in § 407.55 of this subchapter.

(c) *Coverage.* Drugs are covered under this provision irrespective of whether they can be self-administered.

[60 FR 8955, Feb. 16, 1995. Redesignated at 63 FR 34327, June 24, 1998; 74 FR 62002, Nov. 25, 2009; 87 FR 66510, Nov. 3, 2022]

§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) *Definition.* As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage.* (1) Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(i) Following an evaluation of the beneficiary's need for the measurement, including a determination as to the medically appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in § 410.32(a)) treating the beneficiary.

(ii) It is performed under the appropriate level of supervision of a physician (as set forth in § 410.32(b)).

(iii) It is reasonable and necessary for diagnosing and treating the Condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(2) Medicare covers a medically necessary bone mass measurement for an individual defined under paragraph (d)(5) of this section if the conditions under paragraph (b)(1) of this section are met and the monitoring is performed by the use of a dual energy x-ray absorptiometry system (axial skeleton).

(3) Medicare covers a medically necessary confirmatory baseline bone mass measurement for an individual defined under paragraph (d) of this section, if the conditions under paragraph (b)(1) of this section are met and the confirmatory baseline bone mass measurement is performed by a dual energy x-ray absorptiometry system (axial skeleton) and the initial measurement was not performed by a dual energy x-

ray absorptiometry system (axial skeleton).

(c) *Standards on frequency of coverage*—(1) *General rule.* Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception.* If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline measurement to permit monitoring of beneficiaries in the future if the requirements of paragraph (b)(3) of this section are met.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary.* If CMS determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act and §411.15(k) of this chapter.

(f) *Use of the National Coverage Determination Process.* For the purposes of paragraphs (b)(2) and (b)(3) of this section, CMS may determine through the National Coverage Determination process that additional bone mass measurement systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline bone mass measurements.

[71 FR 69783, Dec. 1, 2006]

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

(a) *Ordering diagnostic tests.* Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see §411.15(k)(1) of this chapter).

(1) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in §410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(2) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, marriage and family therapists, mental health counselors, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the

scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.

(3) *Public Health Emergency exceptions.* During the Public Health Emergency for COVID–19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID–19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID–19 diagnosis when performed in conjunction with COVID–19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID–19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID–19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID–19, as defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID–19 infection or suspected current or suspected prior COVID–19 infection.

(4) *Application to audiologists.* Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a modifier CMS designates for this purpose.

(b) *Diagnostic x-ray and other diagnostic tests*— (1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) *Exceptions.* The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological and neuropsychological testing services when—

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under applicable State laws.

(viii) During the COVID–19 Public Health Emergency as defined in § 400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) *Levels of supervision.* Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.

(i) *General supervision* means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Through December 31, 2024, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

(iii) *Personal supervision* means a physician must be in attendance in the room during the performance of the procedure.

(4) *Supervision requirement for RRA or RPA.* Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

(c) *Portable x-ray services.* Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

(1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.

(2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.

(3) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.

(4) The procedures are limited to—

(i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;

(ii) Chest or abdominal films that do not involve the use of contrast media; and

(iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public

Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) *Diagnostic laboratory tests*—(1) *Who may furnish services.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(i) A participating hospital or participating RPCH.

(ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.

(iv) An RHC.

(v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

(vi) An FQHC.

(vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.

(2) *Documentation and recordkeeping requirements*—

(i) *Ordering the service.* Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.

(ii) *Submitting the claim.* Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:

(A) The documentation that it receives from the ordering physician or nonphysician practitioner.

(B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

(iii) *Requesting additional information.* The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) *Claims review.*

(i) *Documentation requirements.* Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:

(A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).

(B) Documentation showing accurate processing of the order and submission of the claim.

(C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD–9–CM code or narrative description supplied.

(ii) *Services that are not reasonable and necessary.* If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

(A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.

(B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.

(C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician

or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) *Diagnostic laboratory tests furnished in hospitals and CAHs.* The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020; 85 FR 85026, Dec. 28, 2020; 87 FR 70223, Nov. 18, 2022; 88 FR 79525, Nov. 16, 2023]

§ 410.33 Independent diagnostic testing facility.

(a) *General rule.* (1) Effective for diagnostic procedures performed on or after March 15, 1999, carriers will pay for diagnostic procedures under the physician fee schedule only when performed by a physician, a group practice of physicians, an approved supplier of portable x-ray services, a nurse practitioner, or a clinical nurse specialist when he or she performs a test he or she is authorized by the State to perform, or an independent diagnostic testing facility (IDTF). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. It is independent of a physician's office or hospital; however, these rules apply when an IDTF furnishes diagnostic procedures in a physician's office.

(2) *Exceptions.* The following diagnostic tests that are payable under the physician fee schedule and furnished by a nonhospital testing entity are not required to be furnished in accordance with the criteria set forth in paragraphs (b) through (e) and (g) and (h) of this section.

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services personally furnished by a clinical psychologist or a qualified independent psychologist as defined in program instructions.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(b) *Supervising physician.* (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests.

(2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF. The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. In the case of a procedure requiring the direct or personal supervision of a physician as set forth in § 410.32(b)(3)(ii) or (b)(3)(iii), the IDTF's supervising physician must personally furnish this level of supervision whether the procedure is performed in the IDTF or, in the case of mobile services,

at the remote location. The IDTF must maintain documentation of sufficient physician resources during all hours of operations to assure that the required physician supervision is furnished. In the case of procedures requiring direct supervision, the supervising physician may oversee concurrent procedures.

(c) *Nonphysician personnel.* (1) Except as otherwise stated in paragraph (c)(2) of this section, any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met.

(2) For services that do not require direct or in-person beneficiary interaction, treatment, or testing, any nonphysician personnel used by the IDTF to perform the tests must meet all applicable State licensure requirements for doing so. If there are any applicable State licensure requirements, the IDTF must maintain documentation available for review that these requirements are met.

(d) *Ordering of tests.* All procedures performed by the IDTF must be specifically ordered in writing by the physician who is treating the beneficiary, that is, the physician who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. (Nonphysician practitioners may order tests as set forth in § 410.32(a)(3).) The order must specify the diagnosis or other basis for the testing. The supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF's supervising physician is in fact the beneficiary's treating physician. That is, the physician in question had a relationship with the beneficiary prior to the performance of the testing and is treating the beneficiary for a specific medical problem. The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.

(e) *Multi-State entities.* (1) An IDTF that operates across State boundaries must—

(i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and

(ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

(2) The point of the actual delivery of service means the place of service on the claim form. When the IDTF performs or administers an entire diagnostic test at the beneficiary's location, the beneficiary's location is the place of service. When one or more aspects of the diagnostic testing are performed at the IDTF, the IDTF is the place of service.

(f) *Applicability of State law.* An IDTF must comply with the applicable laws of any State in which it operates.

(g) *Application certification standards.* The IDTF must certify in its enrollment application that it meets the following standards and related requirements:

(1) Operates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients.

(2) Provides complete and accurate information on its enrollment application. Changes in ownership, changes of location (including additions and deletions of locations), changes in general supervision, and adverse legal actions must be reported to the Medicare fee-for-service contractor on the Medicare enrollment application within 30 calendar days of the change. All other changes to the enrollment application must be reported within 90 days.

(3) Maintain a physical facility on an appropriate site. For the purposes of this standard, a post office box, commercial mailbox, hotel, or motel is not considered an appropriate site.

(i) The physical facility, including mobile units, must contain space for equipment appropriate to the services

designated on the enrollment application, facilities for hand washing, adequate patient privacy accommodations, and the storage of both business records and current medical records within the office setting of the IDTF, or IDTF home office, not within the actual mobile unit.

(ii) IDTF suppliers that provide services remotely and do not see beneficiaries at their practice location are exempt from providing hand washing and adequate patient privacy accommodations.

(4) Has all applicable diagnostic testing equipment available at the physical site excluding portable diagnostic testing equipment. The IDTF must—

(i) Maintain a catalog of portable diagnostic equipment, including diagnostic testing equipment serial numbers at the physical site;

(ii) Make portable diagnostic testing equipment available for inspection within 2 business days of a CMS inspection request.

(iii) Maintain a current inventory of the diagnostic testing equipment, including serial and registration numbers and provide this information to the designated fee-for-service contractor upon request, and notify the contractor of any changes in equipment within 90 days.

(5) Maintain a primary business phone under the name of the designated business. The IDTF must have its—

(i) Primary business phone located at the designated site of the business or within the home office of the mobile IDTF units.

(ii) Telephone or toll free telephone numbers available in a local directory and through directory assistance.

(6) Have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(i) Except as otherwise stated in paragraph (g)(6)(ii) of this section, have a comprehensive liability insurance policy of at least $300,000 per location that covers both the place of business and all customers and employees of the IDTF. The policy must be carried by a nonrelative-owned company. Failure to maintain required insurance at all times will result in revocation of the IDTF's billing privileges retroactive to the date the insurance lapsed. IDTF suppliers are responsible for providing the contact information for the issuing insurance agent and the underwriter. In addition, the IDTF must—

(A) Ensure that the insurance policy must remain in force at all times and provide coverage of at least $300,000 per incident; and

(B) Notify the CMS designated contractor in writing of any policy changes or cancellations.

(ii) Paragraph (g)(6)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(7) Agree not to directly solicit patients, which include, but is not limited to, a prohibition on telephone, computer, or in-person contacts. The IDTF must accept only those patients referred for diagnostic testing by an attending physician, who is furnishing a consultation or treating a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Nonphysician practitioners may order tests as set forth in §410.32(a)(3).

(8) Answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(i) Except as otherwise stated in paragraph (g)(8)(ii) of this section, answer, document, and maintain documentation of a beneficiary's written clinical complaint at the physical site of the IDTF. (For mobile IDTFs, this documentation would be stored at their home office.) This includes, but is not limited to, the following:

(A) The name, address, telephone number, and health insurance claim number of the beneficiary.

(B) The date the complaint was received; the name of the person receiving the complaint; and a summary of actions taken to resolve the complaint.

(C) If an investigation was not conducted, the name of the person making the decision and the reason for the decision.

(ii) Paragraph (g)(8)(i) of this section does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.

(9) Openly post these standards for review by patients and the public. (This requirement does not apply to IDTFs that only perform services that do not require direct or in-person beneficiary interaction, treatment, or testing.)

(10) Disclose to the government any person having ownership, financial, or control interest or any other legal interest in the supplier at the time of enrollment or within 30 days of a change.

(11) Have its testing equipment calibrated and maintained per equipment instructions and in compliance with applicable manufacturers suggested maintenance and calibration standards.

(12) Have technical staff on duty with the appropriate credentials to perform tests. The IDTF must be able to produce the applicable Federal or State licenses or certifications of the individuals performing these services.

(13) Have proper medical record storage and be able to retrieve medical records upon request from CMS or its fee-for-service contractor within 2 business days.

(14) Permit CMS, including its agents, or its designated fee-for-service contractors, to conduct unannounced, on-site inspections to confirm the IDTF's compliance with these standards. The IDTF must—

(i) Be accessible during regular business hours to CMS and beneficiaries; and

(ii) Maintain a visible sign posting its normal business hours.

(15) With the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from the following:

(i) Sharing a practice location with another Medicare-enrolled individual or organization;

(ii) Leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or

(iii) Sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

(16) Enrolls for any diagnostic testing services that it furnishes to a Medicare beneficiary, regardless of whether the service is furnished in a mobile or fixed base location.

(17) Bills for all mobile diagnostic services that are furnished to a Medicare beneficiary, unless the mobile diagnostic service is part of a service provided under arrangement as described in section 1861(w)(1) of the Act.

(h) *Failure to meet standards.* If an IDTF fails to meet one or more of the standards in paragraph (g) of this section at the time of enrollment, its enrollment will be denied. CMS will revoke a supplier's billing privileges if and IDTF is found not to meet the standards in paragraph (g) or (b)(1) of this section.

(i) *Effective date of billing privileges.* The filing date of the Medicare enrollment application is the date that the Medicare contractor receives a signed provider enrollment application that it is able to process to approval. The effective date of billing privileges for a newly enrolled IDTF is the later of the following:

(1) The filing date of the Medicare enrollment application that was subsequently approved by a Medicare fee-for-service contractor; or

(2) The date the IDTF first started furnishing services at its new practice location.

[62 FR 59099, Oct. 31, 1997, as amended at 64 FR 59440, Nov. 2, 1999; 71 FR 69784, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 72 FR 66398, Nov. 27, 2007; 73 FR 2432, Jan. 15, 2008; 73 FR 69933, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 86 FR 65662, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 410.34 Mammography services: Conditions for and limitations on coverage.

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

(1) *Diagnostic mammography* means a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer, or a personal history of biopsy-proven benign breast disease, and includes a physician's interpretation of the results of the procedure.

(2) *Screening mammography* means a radiologic procedure furnished to a woman without signs or symptoms of breast disease, for the purpose of early detection of breast cancer, and includes a physician's interpretation of the results of the procedure.

(3) *Supplier of diagnostic mammography* means a facility that is certified and responsible for ensuring that all diagnostic mammography services furnished to Medicare beneficiaries meet the conditions for coverage of diagnostic mammography services as specified in paragraph (b) of this section.

(4) *Supplier of screening mammography* means a facility that is certified and responsible for ensuring that all screening mammography services furnished to Medicare beneficiaries meet the conditions and limitations for coverage of screening mammography services as specified in paragraphs (c) and (d) of this section.

(5) *Certificate* means the certificate described in 21 CFR 900.2(b) that may be issued to, or renewed for, a facility that meets the requirements for conducting an examination or procedure involving mammography.

(6) *Provisional certificate* means the provisional certificate described in 21 CFR 900.2(m) that may be issued to a facility to enable the facility to qualify to meet the requirements for conducting an examination or procedure involving mammography.

(7) The term *meets the certification requirements of section 354 of the Public Health Service (PHS) Act* means that in order to qualify for coverage of its services under the Medicare program, a supplier of diagnostic or screening mammography services must meet the following requirements:

(i) Must have a valid provisional certificate, or a valid certificate, that has been issued by FDA indicating that the supplier meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(ii) Has not been issued a written notification by FDA that states that the supplier must cease conducting mammography examinations because the supplier is not in compliance with certain critical certification requirements of section 354 of the PHS Act, implemented by 21 CFR part 900, subpart B.

(iii) Must not employ for provision of the professional component of mammography services a physician or physicians for whom the facility has received written notification by FDA that the physician (or physicians) is (or are) in violation of the certification requirements set forth in section 354 of the PHS Act, as implemented by 21 CFR 900.12(a)(1)(i).

(b) *Conditions for coverage of diagnostic mammography services.* Medicare Part B pays for diagnostic mammography services if they meet the following conditions:

(1) They are ordered by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(2) They are furnished by a supplier of diagnostic mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(c) *Conditions for coverage of screening mammography services.* Medicare Part B pays for screening mammography services if they are furnished by a supplier of screening mammography services that meets the certification requirements of section 354 of the PHS Act, as implemented by 21 CFR part 900, subpart B.

(d) *Limitations on coverage of screening mammography services.* The following limitations apply to coverage of screening mammography services as described in paragraphs (c) and (d) of this section:

(1) The service must be, at a minimum a two-view exposure (that is, a cranio-caudal and a medial lateral oblique view) of each breast.

(2) Payment may not be made for screening mammography performed on a woman under age 35.

(3) Payment may be made for only 1 screening mammography performed on a woman over age 34, but under age 40.

(4) For an asymptomatic woman over 39 years of age, payment may be made for a screening mammography performed after at least 11 months have passed following the month in which the last screening mammography was performed.

[59 FR 49833, Sept. 30, 1994, as amended at 60 FR 14224, Mar. 16, 1995; 60 FR 63176, Dec. 8, 1995; 62 FR 59100, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998]

§ 410.35 X-ray therapy and other radiation therapy services: Scope.

Medicare Part B pays for X-ray therapy and other radiation therapy services, including radium therapy and radioactive isotope therapy, and materials and the services of technicians administering the treatment.

[51 FR 41339, Nov. 14, 1986. Redesignated at 55 FR 53522, Dec. 31, 1990]

§ 410.36 Medical supplies, appliances, and devices: Scope.

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3)(i) Leg, arm, back, and neck braces.

(A) A leg brace may include a shoe if it is an integral part of the brace (necessary for the leg brace to function properly) and its expense is included as part of the cost of the brace.

(ii) Artificial legs, arms, and eyes; and

(iii) Replacements for the devices specified in paragraphs (a)(3)(i) and (ii) if required because of a change in the individual's physical condition.

(4) Lymphedema compression treatment items, including the following:

(i) Standard and custom fitted gradient compression garments.

(ii) Gradient compression wraps with adjustable straps.

(iii) Compression bandaging systems.

(iv) Other items determined to be lymphedema compression treatment items under the process established under § 414.1670.

(v) For the purposes of paragraphs (i) and (ii) of this paragraph, the scope of the benefit for lymphedema compression treatment items includes accessories such as zippers in garments, liners worn under garments or wraps with adjustable straps, and padding or fillers that are necessary for the effective use of a gradient compression garment or wrap with adjustable straps.

(b) The conditions of payment described in § 410.38(d) also apply to medical supplies, appliances, and devices.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 36014, Aug. 12, 1992; 57 FR 57688, Dec. 7, 1992; 84 FR 60801, Nov. 8, 2019; 88 FR 77874, Nov. 13, 2023]

§ 410.37 Colorectal cancer screening tests: Conditions for and limitations on coverage.

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

(1) *Colorectal cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(i) Screening fecal-occult blood tests.

(ii) Screening flexible sigmoidoscopies.

(iii) Screening colonoscopies, including anesthesia furnished in conjunction with the service.

(iv) Screening barium enemas.

(v) Other tests or procedures established by a national coverage determination, and modifications to tests under this paragraph, with such frequency and payment limits as CMS determines appropriate, in consultation with appropriate organizations

(2) *Screening fecal-occult blood test* means—

(i) A guaiac-based test for peroxidase activity, testing two samples from each of three consecutive stools, or,

(ii) Other tests as determined by the Secretary through a national coverage determination.

(3) An *individual at high risk for colorectal cancer* means an individual with—

(i) A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;

(ii) A family history of familial adenomatous polyposis;

(iii) A family history of hereditary nonpolyposis colorectal cancer;

(iv) A personal history of adenomatous polyps; or

(v) A personal history of colorectal cancer; or

(vi) Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

(4) *Screening barium enema* means—

(i) A screening double contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure); or

(ii) In the case of an individual whose attending physician decides that he or she cannot tolerate a screening double contrast barium enema, a screening single contrast barium enema of the entire colorectum (including a physician's interpretation of the results of the procedure).

(5) An *attending physician for purposes of this provision* is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible using the results of any examination performed in the overall management of the beneficiary's specific medical problem.

(b) *Condition for coverage of screening fecal-occult blood tests.* Medicare Part B pays for a screening fecal-occult blood test if it is ordered in writing by the beneficiary's attending physician, physician assistant, nurse practitioner, or clinical nurse specialist.

(c) *Limitations on coverage of screening fecal-occult blood tests.* (1) Payment may not be made for a screening fecal-occult blood test performed for an individual under age 45.

(2) For an individual 45 years of age or over, payment may be made for a screening fecal-occult blood test performed after at least 11 months have passed following the month in which the last screening fecal-occult blood test was performed.

(d) *Condition for coverage of flexible sigmoidoscopy screening.* Medicare Part B pays for a flexible sigmoidoscopy screening service if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and §§ 410.74, 410.75, and 410.76) who is authorized under State law to perform the examination.

(e) *Limitations on coverage of screening flexible sigmoidoscopies.* (1) Payment may not be made for a screening flexible sigmoidoscopy performed for an individual under age 45.

(2) For an individual 45 years of age or over, except as described in paragraph (e)(3) of this section, payment may be made for screening flexible sigmoidoscopy after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening colonoscopy performed, payment may be made for a screening flexible sigmoidosocopy only after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(f) *Condition for coverage of screening colonoscopies.* Medicare Part B pays for a screening colonoscopy if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

(g) *Limitations on coverage of screening colonoscopies.* (1) Effective for services furnished on or after July 1, 2001, except as described in paragraph (g)(3) of this section, payment may be made for a screening colonoscopy performed for an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section, after at least 119 months have passed following the month in which the last screening colonoscopy was performed.

(2) Payment may be made for a screening colonoscopy performed for an individual who is at high risk for

colorectal cancer as described in paragraph (a)(3) of this section, after at least 23 months have passed following the month in which the last screening colonoscopy was performed, or, as provided in paragraphs (h) and (i) of this section, the last screening barium enema was performed.

(3) In the case of an individual who is not at high risk for colorectal cancer as described in paragraph (a)(3) of this section but who has had a screening flexible sigmoidoscopy performed, payment may be made for a screening colonoscopy only after at least 47 months have passed following the month in which the last screening flexible sigmoidoscopy was performed.

(h) *Conditions for coverage of screening barium enemas.* Medicare Part B pays for a screening barium enema if it is ordered in writing by the beneficiary's attending physician.

(i) *Limitations on coverage of screening barium enemas.* (1) In the case of an individual age 45 or over who is not at high risk of colorectal cancer, payment may be made for a screening barium enema examination performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed.

(2) In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed.

(j) *Expansion of coverage of colorectal cancer screening tests.* Effective January 1, 2022, colorectal cancer screening tests include a planned screening flexible sigmoidoscopy or screening colonoscopy that involves the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

(k) *A complete colorectal cancer screening.* Effective January 1, 2023, colorectal cancer screening tests include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based colorectal cancer screening test returns a positive result. The frequency limitations described for screening colonoscopy in paragraph (g) of this section shall not apply in the instance of a follow-on screening colonoscopy test described in this paragraph.

[62 FR 59100, Oct. 31, 1997, as amended at 66 FR 55329, Nov. 1, 2001; 67 FR 80040, Dec. 31, 2002; 77 FR 69362, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 86 FR 65662, Nov. 19, 2021; 87 FR 70223, Nov. 18, 2022]

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

(a) *General scope.* Medicare Part B pays for durable medical equipment, including ventilators, oxygen equipment, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home.

(b) *Institutions that may not qualify as the patient's home.* An institution that is used as a home may not be a hospital or a CAH or a SNF as defined in sections 1861(e)(1), 1861(mm)(1) and 1819(a)(1) of the Act, respectively.

(c) *Definitions.* As used in this section:

(1) *Physician* has the same meaning as in section 1861(r)(1) of the Act.

(2) *Treating practitioner* means physician as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

(3) *DMEPOS supplier* means an entity with a valid Medicare supplier number, including an entity that furnishes items through the mail.

(4) *Written Order/Prescription* is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS.

(5) *Face-to-face encounter* is an in-person or telehealth encounter between the treating practitioner and the beneficiary.

(6) *Power mobility device (PMD)* means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled

motorized scooter that is operated by a tiller) that a beneficiary uses in the home.

(7) *Master List of DMEPOS items Potentially Subject to Face-To-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements, also referred to as ''Master List,''* are items of DMEPOS that CMS has identified in accordance with sections 1834(a)(11)(B) and 1834(a)(15) of the Act. The criteria for this list are specified in § 414.234 of this chapter. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on Required Face-to-Face Encounter and Written Order Prior to Delivery List and/or the Required Prior Authorization List.

(8) *Required Face-to-Face Encounter and Written Order Prior to Delivery List* is a list of DMEPOS items selected from the Master List and subject to the requirements of a Face-to-Face Encounter and Written Order Prior to Delivery. The list of items is published in the FEDERAL REGISTER and posted on the CMS website. The list is effective no less than 60 days following its publication. When selecting items from the Master List, CMS may consider factors such as operational limitations, item utilization, cost-benefit analysis, emerging trends, vulnerabilities identified in official agency reports, or other analysis.

(d) *Conditions of Payment*. The requirements described in this paragraph (d) are conditions of payment applicable to DMEPOS items.

(1) *Written Order/Prescription*. All DMEPOS items require a written order/prescription for Medicare payment. Medicare Contractors shall consider the totality of the medical records when reviewing for compliance with standardized written order/prescription elements.

(i) *Elements*. A written order/prescription must include the following elements:

(A) Beneficiary Name or Medicare Beneficiary Identifier (MBI).

(B) General Description of the item.

(C) Quantity to be dispensed, if applicable.

(D) Order Date.

(E) Treating Practitioner Name or National Provider Identifier (NPI).

(F) Treating Practitioner Signature.

(ii) *Timing of the Written Order/Prescription*.

(A) For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the written order/prescription must be communicated to the supplier prior to delivery.

(B) For all other DMEPOS, the written order/prescription must be communicated to the supplier prior to claim submission.

(2) *Items Requiring a Face-to-Face Encounter*. For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

(i) The encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

(ii) If it is a telehealth encounter, the requirements of §§ 410.78 and 414.65 of this chapter must be met.

(3) *Documentation:* A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its agents upon request.

(i) Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the DMEPOS item.

(ii) The face-to-face encounter must be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a

clinical condition for which the DMEPOS is ordered.

(4) *Refills*—(i) *Definitions.* As used in this paragraph (d):

Date of service (for refilled items) means either—

(*1*) The date of delivery for the DMEPOS item; or

(*2*) For items rendered via delivery or shipping service, the shipping date.

Refills mean DMEPOS products that are provided on a recurring basis secondary to a medically necessary DMEPOS order.

Shipping date means—

(*1*) The date the delivery/shipping service label is created; or

(*2*) The date that the item is retrieved for delivery. These dates must not demonstrate significant variation.

(ii) *Documentation.* The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include both of the following:

(A) Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. Contact and affirmative response must be within 30 calendar days from the expected end of the current supply.

(B)(*1*) For shipped items, the beneficiary name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product; or

(*2*) For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.

(iii) *Delivery of DMEPOS items provided on a recurring basis.* The date of service for DMEPOS items provided on a recurring basis must be no earlier than 10 calendar days before the expected end of the current supply.

(e) *Suspension of face-to-face encounter and written order prior to delivery requirements.* CMS may suspend face-to-face encounter and written order prior to delivery requirements generally or for a particular item or items at any time and without undertaking rule-making, except those items for which inclusion on the Master List was statutorily imposed.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 57688, Dec. 7, 1992; 58 FR 30668, May 26, 1993; 70 FR 50946, Aug. 26, 2005; 71 FR 17030, Apr. 5, 2006; 77 FR 69362, Nov. 16, 2012; 84 FR 60802, Nov. 8, 2019; 88 FR 77875, Nov. 13, 2023]

§ 410.39 Prostate cancer screening tests: Conditions for and limitations on coverage.

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

(1) *Prostate cancer screening tests* means any of the following procedures furnished to an individual for the purpose of early detection of prostate cancer:

(i) A screening digital rectal examination.

(ii) A screening prostate-specific antigen blood test.

(iii) For years beginning after 2002, other procedures CMS finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and other factors CMS considers appropriate.

(2) *A screening digital rectal examination* means a clinical examination of an individual's prostate for nodules or other abnormalities of the prostate.

(3) *A screening prostate-specific antigen blood test* means a test that measures the level of prostate-specific antigen in an individual's blood.

(4) A physician for purposes of this provision means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(5) A physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife for purposes of this provision means a physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife (as defined in sections 1861(aa) and 1861(gg) of the Act) who is fully knowledgeable about the beneficiary, and who would be responsible for explaining the results of the screening examination or test.

(b) *Condition for coverage of screening digital rectal examinations.* Medicare Part B pays for a screening digital rectal examination if it is performed by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to perform this service under State law.

(c) *Limitation on coverage of screening digital rectal examinations.* (1) Payment may not be made for a screening digital rectal examination performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening digital rectal examination only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening digital rectal examination was performed.

(d) *Condition for coverage of screening prostate-specific antigen blood tests.* Medicare Part B pays for a screening prostate-specific antigen blood test if it is ordered by the beneficiary's physician, or by the beneficiary's physician assistant, nurse practitioner, clinical nurse specialist, or certified nurse midwife as defined in paragraphs (a)(4) or (a)(5) of this section who is authorized to order this test under State law.

(e) *Limitation on coverage of screening prostate-specific antigen blood test.* (1) Payment may not be made for a screening prostate-specific antigen blood test performed for a man age 50 or younger.

(2) For an individual over 50 years of age, payment may be made for a screening prostate-specific antigen blood test only if the man has not had such an examination paid for by Medicare during the preceding 11 months following the month in which his last Medicare-covered screening prostate-specific antigen blood test was performed.

[64 FR 59440, Nov. 2, 1999, as amended at 65 FR 19331, Apr. 11, 2000]

§ 410.40 Coverage of ambulance services.

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

Non-physician certification statement means a statement signed and dated by an individual which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met and who meets all of the criteria in paragraphs (i) through (iii) of this definition. The statement need not be a stand-alone document and no specific format or title is required.

(i) Has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished;

(ii) Who must be employed:

(A) By the beneficiary's attending physician; or

(B) By the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported;

(iii) Is among the following individuals, with respect to whom all Medicare regulations and all applicable State licensure laws apply:

(A) Physician assistant (PA).

(B) Nurse practitioner (NP).

(C) Clinical nurse specialist (CNS).

(D) Registered nurse (RN).

(E) Licensed practical nurse (LPN).

(F) Social worker.

(G) Case manager.

(H) Discharge planner.

Physician certification statement means a statement signed and dated by the beneficiary's attending physician which certifies that the medical necessity provisions of paragraph (e)(1) of this section are met. The statement need not be a stand-alone document and no specific format or title is required.

(b) *Basic rules.* Medicare Part B covers ambulance services if the following conditions are met:

(1) The supplier meets the applicable vehicle, staff, and billing and reporting requirements of § 410.41 and the service meets the medical necessity and origin and destination requirements of paragraphs (e) and (f) of this section.

(2) Medicare Part A payment is not made directly or indirectly for the services.

(c) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

(1) Basic life support (BLS) (emergency and nonemergency).

(2) Advanced life support, level 1 (ALS1) (emergency and nonemergency).

(3) Advanced life support, level 2 (ALS2).

(4) Paramedic ALS intercept (PI).

(5) Specialty care transport (SCT).

(6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

(d) *Paramedic ALS intercept services.* Paramedic ALS intercept services must meet the following requirements:

(1) Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features.)

(2) Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

(i) Are certified to furnish ambulance services as required under §410.41.

(ii) Furnish services only at the BLS level.

(iii) Be prohibited by State law from billing for any service.

(3) Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

(i) Is certified to furnish ALS services as required in §410.41(b)(2).

(ii) Bills all the beneficiaries who receive ALS intercept services from the entity, regardless of whether or not those beneficiaries are Medicare beneficiaries.

(e) *Medical necessity requirements*—(1) *General rule.* Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) *Special rule for nonemergency, scheduled, repetitive ambulance services.* (i) Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a physician certification statement dated no earlier than 60 days before the date the service is furnished.

(ii) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to CMS. The ambulance service must meet all program coverage criteria including vehicle and staffing requirements. While a signed physician certification statement (PCS), does not alone demonstrate that transportation by ground ambulance was medically necessary, the PCS and additional documentation from the beneficiary's medical record may be used to support a claim that transportation by ground ambulance is medically necessary. The PCS and additional documentation must provide detailed explanations, that are consistent with the beneficiary's current medical condition, that explains the beneficiary's need for transport by an ambulance, as described at §410.41(a), that includes observation or other services rendered by qualified ambulance personnel, as described in §410.41(b).

(3) *Special rule for nonemergency ambulance services that are either unscheduled*

or that are scheduled on a nonrepetitive basis. Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a physician certification statement within 48 hours after the transport.

(ii) For a beneficiary residing at home or in a facility who is not under the direct care of a physician. A physician certification is not required.

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a non-physician certification statement must be obtained.

(iv) If the ambulance provider or supplier is unable to obtain the required physician or non-physician certification statement within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (e)(3)(iii) of this section.

(v) In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the physician or non-physician certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

(f) *Origin and destination requirements.* Medicare covers the following ambulance transportation:

(1) From any point of origin to the nearest hospital, CAH, rural emergency hospital (REH), or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH or REH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, REH, or SNF to the beneficiary's home.

(3) From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable state or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital, REH (effective January 1, 2023), or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

(g) *Specific limits on coverage of ambulance services outside the United States.* If services are furnished outside the United States, Medicare Part B covers ambulance transportation to a foreign hospital only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

[64 FR 3648, Jan. 25, 1999, as amended at 65 FR 13914, Mar. 15, 2000; 67 FR 9132, Feb. 27, 2002; 77 FR 69362, Nov. 16, 2012; 84 FR 63187, Nov. 15, 2019; 85 FR 19286, Apr. 6, 2020; 87 FR 70223, Nov. 18, 2022; 87 FR 72285, Nov. 23, 2022]

§ 410.41 Requirements for ambulance providers and suppliers.

(a) *Vehicle.* A vehicle used as an ambulance must meet the following requirements:

(1) Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

(2) Be equipped with emergency warning lights and sirens, as required by State or local laws.

(3) Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

(4) Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

(c) *Billing and reporting requirements.* An ambulance supplier must comply with the following requirements:

(1) Bill for ambulance services using CMS-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification statement or non-physician certification statement is on file, if required.

(2) Upon a carrier's request, complete and return the ambulance supplier form designated by CMS and provide the Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws.

(3) Upon a carrier's request, provide additional information and documentation as required.

[64 FR 3648, Jan. 25, 1999, as amended at 80 FR 71373, Nov. 16, 2015; 84 FR 63188, Nov. 15, 2019]

§ 410.42 Limitations on coverage of certain services furnished to hospital outpatients.

(a) *General rule.* Except as provided in paragraph (b) of this section, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient (as defined in § 410.2) during an encounter (as defined in § 410.2) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to its patients. As used in this paragraph, the term ''hospital'' includes a CAH.

(b) *Exception.* The limitations stated in paragraph (a) of this section do not apply to the following services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69.

(7) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

[65 FR 18536, Apr. 7, 2000]

§ 410.43 Partial hospitalization services: Conditions and exclusions.

(a) Partial hospitalization services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals (including substance use disorder professionals) to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients (including patients with substance use disorder).

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as partial hospitalization services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Partial hospitalization programs are intended for patients who—

(1) Require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health or substance use disorder diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the partial hospitalization program.

[59 FR 6577, Feb. 11, 1994, as amended at 65 FR 18536, Apr. 7, 2000; 72 FR 66399, Nov. 27, 2007; 73 FR 68811, Nov. 18, 2008; 88 FR 82177, Nov. 22, 2023]

§ 410.44 Intensive outpatient services: Conditions and exclusions.

(a) Intensive outpatient services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(d) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals (including substance use disorder professionals) to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric

patients (including patients with substance use disorder).

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as intensive outpatient services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Intensive outpatient programs are intended for patients who—

(1) Require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health or substance use disorder diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

[88 FR 82177, Nov. 22, 2023]

§ 410.45 Rural health clinic services: Scope and conditions.

(a) Medicare Part B pays for the following rural health clinic services, if they are furnished in accordance with the requirements and conditions specified in part 405, subpart X, and part 491 of this chapter:

(1) Physicians' services.

(2) Services and supplies furnished as an incident to physicians' professional services.

(3) Nurse practitioner and physician assistant services.

(4) Services and supplies furnished as an incident to nurse practitioners' or physician assistants' services.

(5) Visiting nurse services.

(b) Medicare pays for rural health clinic services when they are furnished at the clinic, at a hospital or other medical facility, or at the beneficiary's place of residence.

§ 410.46 Physician and other practitioner services furnished in or at the direction of an IHS or Indian tribal hospital or clinic: Scope and conditions.

(a) Medicare Part B pays, in accordance with the physician fee schedule, for services furnished in or at the direction of a hospital or outpatient clinic (provider-based or free-standing) that is operated by the Indian Health Service (IHS) or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act). These services are subject to the same situations, terms, and conditions that would apply if the services were furnished in or at the direction of a hospital or clinic that is not operated by IHS or by an Indian tribe or tribal organization. Payments include health professional shortage areas incentive payments when the requirements for these incentive payments in § 414.42 of this chapter are met.

(b) Payment is not made under this section to the extent that Medicare otherwise pays for the same services under other provisions.

(c) Payment is made under these provisions for the following services:

(1) Services for which payment is made under the physician fee schedule

in accordance with part 414 of this chapter.

(2) Services furnished by non-physician practitioners for which payment under Part B is made under the physician fee schedule.

(3) Services furnished by a physical therapist or occupational therapist, for which payment under Part B is made under the physician fee schedule.

(d) Payments under these provisions will be paid to the IHS or tribal hospital or clinic.

[66 FR 55329, Nov. 1, 2001]

§ 410.47 Pulmonary rehabilitation program: Conditions for coverage.

(a) *Definitions.* As used in this section:

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Medical director means the physician who oversees the pulmonary rehabilitation program at a particular site.

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes the following:

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of exercise performance and self-reported measures of shortness of breath and behavior.

Physician means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as conditioning, breathing retraining, step, and strengthening) as determined to be appropriate for individual patients by a physician.

Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

Pulmonary rehabilitation means a physician or nonphysician practitioner supervised program for COPD and certain other chronic respiratory diseases designed to optimize physical and social performance and autonomy.

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under pulmonary rehabilitation programs.

(b) *General rule*—(1) *Covered conditions.* Medicare Part B covers pulmonary rehabilitation for beneficiaries:

(i) With moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease;

(ii) Who have had confirmed or suspected COVID–19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks;

(iii) Additional medical indications for coverage for pulmonary rehabilitation may be established through a national coverage determination (NCD).

(2) *Components.* Pulmonary rehabilitation must include all of the following:

(i) Physician-prescribed exercise during each pulmonary rehabilitation session.

(ii) Education or training that is closely and clearly related to the individual's care and treatment which is tailored to the individual's needs and

assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.* (i) Medicare Part B pays for pulmonary rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have the following:

(A) A physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

(B) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease.

(c) *Medical director standards.* The physician responsible for a pulmonary rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the pulmonary rehabilitation program is offered.

(d) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

(1) Expertise in the management of individuals with respiratory pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(e) *Limitations on coverage:* The number of pulmonary rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

(f) *Effective date.* Coverage for pulmonary rehabilitation program services is effective January 1, 2010.

[74 FR 62002, Nov. 25, 2009, as amended at 86 FR 65662, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 410.48 Kidney disease education services.

(a) *Definitions.* As used in this section:

Kidney disease patient education services means face-to-face educational services provided to patients with Stage IV chronic kidney disease.

Physician means a physician as defined in section 1861(r)(1) of the Act.

Qualified person means either of the following healthcare entities that meets the qualifications and requirements specified in this section to provide kidney disease patient education services—

(i) One of the following healthcare professionals who furnishes services for which payment may be made under the physician fee schedule:

(A) Physician (as defined in section 1861(r)(1) of the Act).

(B) Physician assistant as defined in section 1861(aa)(5) of the Act and § 410.74 of this subpart).

(C) Nurse practitioner as defined in section 1861(aa)(5) of the Act and § 410.75 of this subpart).

(D) Clinical nurse specialist (as defined in section 1861(aa)(5) of the Act and § 410.76 of this subpart),

(ii)(A) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice that is located in a rural area as defined in § 412.64(b)(ii)(C) of this chapter; or

(B) A hospital or critical access hospital that is treated as being rural under § 412.103 of this chapter.

Renal dialysis facility means a unit, which is approved to furnish dialysis service(s) directly to end-stage renal disease (ESRD) patients, as defined in § 405.2102 of this chapter.

Stage IV chronic kidney disease means kidney damage with a severe decrease in glomerular filtration rate (GFR) quantitatively defined by a GFR value of 15–29 ml/min/1.73m^2, using the Modification of Diet in Renal Disease (MDRD) Study formula.

(b) *Covered beneficiaries.* Medicare Part B covers outpatient kidney disease patient education services if the beneficiary meets all of the conditions and requirements of this subpart, including all of the following:

(1) Is diagnosed with Stage IV chronic kidney disease.

(2) Obtains a referral from the physician (as defined in section 1861(r)(1) of the Act) managing the beneficiary's kidney condition.

(c) *Qualified person.* (1) Medicare Part B covers outpatient kidney disease patient education services provided by a qualified person as defined in paragraph (a) of this section and must be able to properly receive Medicare payment under part 424 of this chapter.

(2) A qualified person does not include either of the following:

(i) A hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency or hospice if kidney disease patient education services are provided outside of a rural area as defined in § 412.64(b)(ii)(C) of this chapter unless the services are furnished in a hospital or critical access hospital that is treated as being in a rural area under § 412.103 of this chapter.

(ii) A renal dialysis facility, as defined in § 405.2102 of this chapter.

(d) *Standards for content of kidney disease patient education services.* The content of the kidney disease patient education services includes the following:

(1) The management of comorbidities including for the purpose of delaying the need for dialysis which includes, but not limited to, the following topics:

(i) Prevention and treatment of cardiovascular disease.

(ii) Prevention and treatment of diabetes.

(iii) Hypertension management.

(iv) Anemia management.

(v) Bone disease and disorders of calcium and phosphorus metabolism management.

(vi) Symptomatic neuropathy management.

(vii) Impairments in functioning and well-being.

(2) The prevention of uremic complications which includes, but not limited to, the following topics:

(i) Information on how the kidneys work and what happens when the kidneys fail.

(ii) Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival.

(iii) Diet and fluid restrictions.

(iv) Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision-making if the patient decides not to take a specific drug.

(3) Therapeutic options, treatment modalities, and settings, including a discussion of the advantages and disadvantages of each treatment option and how the treatments replace the kidney, which includes, but not limited to, the following topics:

(i) Hemodialysis, both at home and in-facility.

(ii) Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility.

(iii) All dialysis access options for hemodialysis and peritoneal dialysis.

(iv) Transplantation.

(4) Opportunities for beneficiaries to actively participate in the choice of therapy and be tailored to meet the needs of the individual beneficiary involved which includes, but not limited to, the following topics:

(i) Physical symptoms.

(ii) Impact on family and social life.

(iii) Exercise.

(iv) The right to refuse treatment.

(v) Impact on work and finances.

(vi) The meaning of test results.

(vii) Psychological impact.

(5) Qualified persons must develop outcomes assessments designed to measure beneficiary knowledge about chronic kidney disease and its treatment.

(i) The outcomes assessments serve to assess program effectiveness of preparing the beneficiary to make informed decisions about their healthcare options related to chronic kidney disease.

(ii) The outcomes assessments serve to assess the program's effectiveness in meeting the communication needs of underserved populations, including persons with disabilities, persons with limited English proficiency, and persons with health literacy needs.

(iii) The assessment must be administered to the beneficiary during a kidney disease education session.

(iv) The outcomes assessments must be made available to CMS upon request.

(e) *Limitations for coverage of kidney disease education services.* (1) Medicare Part B makes payment for up to 6 sessions of kidney disease patient education services.

(2) A session is 1 hour long and may be provided individually or in group settings of 2 to 20 individuals who need not all be Medicare beneficiaries.

(f) *Effective date.* Medicare Part B covers kidney disease patient education services for dates of service on or after January 1, 2010.

[74 FR 62003, Nov. 25, 2009]

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) *Definitions.* As used in this section:

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

Intensive cardiac rehabilitation site means a hospital outpatient setting or physician's office that is providing intensive cardiac rehabilitation utilizing an approved ICR program.

Medical director means the physician who oversees the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Act.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes all of the following:

(i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.

(ii) Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.

Physician means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as strengthening and stretching) as determined to be appropriate for individual patients by a physician.

Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

Supervising practitioner means a physician or nonphysician practitioner that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) *General rule*—(1) *Covered conditions.* Medicare Part B covers cardiac rehabilitation and intensive cardiac rehabilitation for beneficiaries who have experienced one or more of the following:

(i) An acute myocardial infarction within the preceding 12 months;

(ii) A coronary artery bypass surgery;

(iii) Current stable angina pectoris;

(iv) Heart valve repair or replacement;

(v) Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;

(vi) A heart or heart-lung transplant.

(vii) Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014 for cardiac rehabilitation and on or after February 9, 2018 for intensive cardiac rehabilitation; or

(viii) Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

(2) *Components.* Cardiac rehabilitation and intensive cardiac rehabilitation must include all of the following:

(i) Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.

(ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.*—(i) Medicare Part B pays for cardiac rehabilitation and intensive cardiac rehabilitation in the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at § 410.26 of this subpart; and for hospital outpatient services at § 410.27 of this subpart.

(c) *Standards for an intensive cardiac rehabilitation program.* (1) To be approved as an intensive cardiac rehabilitation program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

(i) Positively affected the progression of coronary heart disease.

(ii) Reduced the need for coronary bypass surgery.

(iii) Reduced the need for percutaneous coronary interventions;

(2) An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or

more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

(i) Low density lipoprotein.

(ii) Triglycerides.

(iii) Body mass index.

(iv) Systolic blood pressure.

(v) Diastolic blood pressure.

(vi) The need for cholesterol, blood pressure, and diabetes medications.

(3) A list of approved intensive cardiac rehabilitation programs, identified through the national coverage determination process, will be posted to the CMS Web site and listed in the FEDERAL REGISTER.

(4) All prospective intensive cardiac rehabilitation sites must apply to enroll as an intensive cardiac rehabilitation program site using the designated forms as specified at § 424.510 of this chapter. For purposes of appealing an adverse determination concerning site approval, an intensive cardiac rehabilitation site is considered a supplier (or prospective supplier) as defined in § 498.2 of this chapter.

(d) *Medical director standards.* The physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation program is identified as the medical director. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the cardiac rehabilitation program is offered.

(e) *Supervising practitioner standards.* Physicians or nonphysician practitioners acting as the supervising practitioner must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(f) *Limitations on coverage*—(1) *Cardiac rehabilitation.* The number of cardiac rehabilitation sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor.

(2) *Intensive cardiac rehabilitation.* Intensive cardiac rehabilitation sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

[74 FR 62003, Nov. 25, 2009, as amended at 84 FR 63188, Nov. 15, 2019; 86 FR 65663, Nov. 19, 2021; 88 FR 79526, Nov. 16, 2023]

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 494.130 of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in part 494 of this chapter.

(c) Routine diagnostic tests.

(d) Epoetin (EPO) and its administration.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994; 73 FR 20474, Apr. 15, 2008; 75 FR 49197, Aug. 12, 2010]

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and

reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(4) On or after July 1, 1991, erythropoeisis-stimulating agents for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with § 494.90(a)(4) of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 494.90 of this chapter contains details on patient plans of care).

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994; 73 FR 20474, Apr. 15, 2008]

§ 410.53 Marriage and family therapist services.

(a) *Definition: marriage and family therapist.* For purposes of this part, a marriage and family therapist is defined as an individual who -

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services defined as marriage and family therapist services;

(2) After obtaining such degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in marriage and family therapy in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a marriage and family therapist by the State in which the services are performed.

(b) *Covered marriage and family therapist services.* Medicare Part B covers marriage and family therapist services.

(1) *Definition: marriage and family therapist services* means services furnished by a marriage and family therapist (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not marriage and family therapist services for purposes of billing Medicare Part B under the MFT and MHC statutory benefit category:

(i) Services furnished by a marriage and family therapist to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A marriage and family therapist may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A marriage and family therapist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

[88 FR 79526, Nov. 16, 2023]

§ 410.54 Mental health counselor services.

(a) *Definition: mental health counselor.* For purposes of this part, a *mental*

health counselor is defined as an individual who—

(1) Possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, professional counselor under the State law of the State in which such individual furnishes the services defined as mental health counselor services;

(2) After obtaining such a degree, has performed at least 2 years or 3,000 hours of post master's degree clinical supervised experience in mental health counseling in an appropriate setting such as a hospital, SNF, private practice, or clinic; and

(3) Is licensed or certified as a mental health counselor, clinical professional counselor, professional counselor by the State in which the services are performed.

(b) *Covered mental health counselor services.* Medicare Part B covers mental health counselor services.

(1) *Definition: Mental health counselor services* means services furnished by a mental health counselor (as defined in paragraph (a) of this section) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital), which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are furnished. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not mental health counselor services for purposes of billing Medicare Part B:

(i) Services furnished by a mental health counselor to an inpatient of a Medicare-participating hospital.

(ii) [Reserved]

(c) *Prohibited billing.* (1) A mental health counselor may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A mental health counselor or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph(b)(2) of this section.

[88 FR 79527, Nov. 16, 2023]

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

(a) If the kidney is intended for an individual who has end-stage renal disease and is entitled to Medicare benefits; and

(b) Regardless of whether the donor is entitled to Medicare.

§ 410.56 Screening pelvic examinations.

(a) *Conditions for screening pelvic examinations.* Medicare Part B pays for a screening pelvic examination (including a clinical breast examination) if it is performed by a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act), or by a certified nurse midwife (as defined in section 1861(gg) of the Act), or a physician assistant, nurse practitioner, or clinic nurse specialist (as defined in section 1861(aa) of the Act) who is authorized under State law to perform the examination.

(b) *Limits on coverage of screening pelvic examinations.* The following limitations apply to coverage of screening pelvic examination services:

(1) *General rule.* Except as specified in paragraphs (b)(2) and (b)(3) of this section, payment may be made for a pelvic examination performed on an asymptomatic woman only if the individual has not had a pelvic examination paid for by Medicare during the preceding 23 months following the month in which her last Medicare-covered screening pelvic examination was performed.

(2) *More frequent screening based on high-risk factors.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner specified in paragraph (a) of this section, and there is evidence that the woman is at high risk (on the basis of her medical history or other findings)

of developing cervical cancer or vaginal cancer, as determined in accordance with the following risk factors:

(i) High risk factors for cervical cancer:

(A) Early onset of sexual activity (under 16 years of age).

(B) Multiple sexual partners (five or more in a lifetime).

(C) History of a sexually transmitted disease (including HIV infection).

(D) Absence of three negative or any Pap smears within the previous 7 years.

(ii) High risk factor for vaginal cancer: DES (diethylstilbestrol)-exposed daughters of women who took DES during pregnancy.

(3) *More frequent screening for women of childbearing age.* Subject to the limitation as specified in paragraph (b)(4) of this section, payment may be made for a screening pelvic examination performed more frequently than once every 24 months if the test is performed by a physician or other practitioner as specified in paragraph (a) of this section for a woman of childbearing age who has had an examination that indicated the presence of cervical or vaginal cancer or other abnormality during any of the preceding 3 years. The term ''woman of childbearing age'' means a woman who is premenopausal, and has been determined by a physician, or a qualified practitioner, as specified in paragraph (a) of this section, to be of childbearing age, based on her medical history or other findings.

(4) *Limitation applicable to women at high risk and those of childbearing age.* Payment is not made for a screening pelvic examination for women considered to be at high risk (under any of the criteria described in paragraph (b)(2) of this section), or who qualify for coverage under the childbearing provision (under the criteria described in paragraph (b)(3) of this section) more frequently than once every 11 months after the month that the last screening pelvic examination covered by Medicare was performed.

[62 FR 59101, Oct. 31, 1997; 63 FR 4596, Jan. 30, 1998, as amended at 66 FR 55329, Nov. 1, 2001]

§ 410.57 Preventive vaccines.

(a) Medicare Part B pays for the pneumococcal vaccine and its administration.

(b) Medicare Part B pays for the influenza virus vaccine and its administration.

(c) Medicare Part B pays for the COVID–19 vaccine (or monoclonal antibodies used for pre-exposure prophylaxis of COVID–19) and its administration.

(d) Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a).

[63 FR 35066, June 26, 1998, as amended at 85 FR 71197, Nov. 6, 2020; 87 FR 70223, Nov. 18, 2022; 88 FR 79527, Nov. 16, 2023]

§ 410.58 Additional services to HMO and CMP enrollees.

Services not usually covered under Medicare Part B may be covered as medical and other health services if they are furnished to an enrollee of an HMO or a CMP and the following conditions are met:

(a) The services are—

(1) Furnished by a physician assistant or nurse practitioner as defined in § 491.2 of this chapter, or are incident to services furnished by such a practitioner; or

(2) Furnished by a clinical psychologist as defined in § 417.416 of this chapter to an enrollee of an HMO or CMP that participates in Medicare under a risk-sharing contract, or are incident to those services.

(b) The services are services that would be covered under Medicare Part B if they were furnished by a physician or as incident to a physician's professional services.

§ 410.59 Outpatient occupational therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient occupational therapy services only if they are furnished by an individual meeting the qualifications in part 484 of this chapter for an occupational therapist or an appropriately supervised occupational therapy assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision (or as specified otherwise) of, an occupational therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform occupational therapy services within the scope of State law. When an occupational therapy service is provided incident to the service of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to occupational therapy and occupational therapists, except that a license to practice occupational therapy in the State is not required.

(4) Effective for dates of service on and after January 1, 2020, for occupational therapy services described in paragraph (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by an occupational therapy assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the occupational therapy assistant either:

(A) Furnishes all the minutes of a service exclusive of the occupational therapist; or

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the occupational therapist such that the minutes for that portion of a service (or unit of a service) furnished by the occupational therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the occupational therapy assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the occupational therapist and occupational therapy assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes and no more than 28 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the occupational therapist.

(b) *Conditions for coverage of outpatient therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient occupational therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by occupational therapists in private practice*—(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient occupational therapy services, each individual occupational therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of occupational therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of occupational therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, an CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of occupational therapy services.* Except as otherwise provided in this paragraph, occupational therapy services are performed by, or under the direct supervision of, an occupational therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by an occupational therapy assistant under the general supervision of the occupational therapist in private practice; services performed by an unenrolled occupational therapist must be under the direct supervision of the occupational therapist.

(d) *Excluded services.* No service is included as an outpatient occupational therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses.* (1) Amount of limitation. (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient occupational therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation is determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(iv) Outpatient occupational therapy services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is no longer applied as a limitation on incurred expenses for outpatient occupational therapy services, but, is instead applied as a threshold above which claims for occupational therapy services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient occupational therapy includes:

(i) Outpatient occupational therapy services furnished under this section;

(ii) Outpatient occupational therapy services furnished by a comprehensive outpatient rehabilitation facility;

(iii) Outpatient occupational therapy services furnished by a physician or incident to a physician's service;

(iv) Outpatient occupational therapy services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(v) Outpatient occupational therapy services furnished by a CAH directly or

under arrangements, included in the amount of annual incurred expenses as if such services were furnished under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for outpatient occupational therapy services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process applies when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 in 2027) by the increase in the Medicare Economic Index for the current year.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002; 69 FR 66421, Nov. 15, 2004; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 83 FR 60073, Nov. 23, 2018; 84 FR 63188, Nov. 15, 2019; 86 FR 65664, Nov. 19, 2021; 88 FR 79527, Nov. 16, 2023]

§ 410.60 Outpatient physical therapy services: Conditions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(iii) of this section, Medicare Part B pays for outpatient physical therapy services only if they are furnished by an individual meeting the qualifications in part 484 of this chapter for a physical therapist or an appropriately supervised physical therapist assistant but only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine, osteopathy, or podiatric medicine.

(2) They are furnished under a written plan of treatment that meets the requirements of § 410.61.

(3) They are furnished—

(i) By a provider as defined in § 489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider; or

(ii) By, or under the direct supervision (or as specified otherwise) of, a physical therapist in private practice as described in paragraph (c) of this section; or

(iii) By, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law. When a physical therapy service is provided incident to the service of a physician, physician's assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists, except that a license to practice physical therapy in the State is not required.

(4) Effective for dates of service on and after January 1, 2020, for physical therapy services described in paragraphs (a)(3)(i) or (ii) of this section, as applicable—

(i) Claims for services furnished in whole or in part by a physical therapist assistant must include the prescribed modifier; and

(ii) Effective for dates of service on or after January 1, 2022, claims for such services that include the modifier and for which payment is made under sections 1848 or 1834(k) of the Act are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service.

(iii) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant either:

(A) Furnishes all the minutes of a service exclusive of the physical therapist; or

(B) Except as provided in paragraph (a)(4)(iv) of this section, furnishes a portion of a service, or in the case of a

15-minute (or other time interval) timed code, a portion of a unit of service separately from the part furnished by the physical therapist such that the minutes for that portion of a service (or unit of a service) furnished by the physical therapist assistant exceed 10 percent of the total minutes for that service (or unit of a service).

(iv) Paragraph (a)(4)(iii)(B) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day, when the physical therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant.

(v) Where there are two remaining 15-minute units to bill of the same service, and the physical therapist and physical therapist assistant each provided between 9 and 14 minutes of the service with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist.

(b) *Condition for coverage of outpatient physical therapy services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient physical therapy services furnished to an inpatient of a hospital, CAH, or SNF who requires them but who has exhausted or is otherwise + ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by physical therapists in private practice*—(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient physical therapy services, each individual physical therapist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to engage in the private practice of physical therapy by the State in which he or she practices, and practice only within the scope of his or her license, certification, or registration.

(ii) Engage in the private practice of physical therapy on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in his or her private practice office space, or in the patient's home. A therapist's private practice office space refers to the location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in practice at that location. When services are furnished in private practice office space, that space must be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. A patient's home does not include any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(2) *Supervision of physical therapy services.* Except as otherwise provided in this paragraph, physical therapy services are performed by, or under the direct supervision of, a physical therapist in private practice. All services not performed personally by the therapist must be performed by employees of the practice, directly supervised by the therapist, and included in the fee for the therapist's services. Remote therapeutic monitoring services may be performed by a physical therapist assistant under the general supervision of the physical therapist in private practice; services performed by an unenrolled physical therapist must be under the direct supervision of the physical therapist.

(d) *Excluded services.* No service is included as an outpatient physical therapy service if it would not be included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

(e) *Annual limitation on incurred expenses*—(1) *Amount of limitation.* (i) In 1999, 2000, and 2001, no more than $1,500 of allowable charges incurred in a calendar year for outpatient physical therapy services are recognized incurred expenses.

(ii) In 2002 and thereafter, the limitation shall be determined by increasing the limitation in effect in the previous calendar year by the increase in the Medicare Economic Index for the current year.

(iii) The limitation is not applied for services furnished from December 8, 2003 through December 31, 2005.

(iv) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements must be counted towards the annual limitation on incurred expenses as if such services were paid under section 1834(k)(1)(b) of the Act.

(v) Beginning in 2018 and for each successive calendar year, the amount described in paragraph (e)(1)(ii) of this section is not applied as a limitation on incurred expenses for outpatient physical therapy and outpatient speech-language pathology services, but is instead applied as a threshold above which claims for physical therapy and speech-language pathology services must include the KX modifier (the KX modifier threshold) to indicate that the service is medically necessary and justified by appropriate documentation in the medical record; and claims for services above the KX modifier threshold that do not include the KX modifier are denied.

(2) For purposes of applying the KX modifier threshold, outpatient physical therapy includes:

(i) Outpatient physical therapy services furnished under this section;

(ii) Outpatient speech-language pathology services furnished under § 410.62;

(iii) Outpatient physical therapy and speech-language pathology services furnished by a comprehensive outpatient rehabilitation facility;

(iv) Outpatient physical therapy and speech-language pathology services furnished by a physician or incident to a physician's service;

(v) Outpatient physical therapy and speech-language pathology services furnished by a nurse practitioner, clinical nurse specialist, or physician assistant or incident to their services; and

(vi) Outpatient physical therapy and speech-language pathology services furnished by a CAH directly or under arrangements, included in the amount of annual incurred expenses as if such services were furnished and paid under section 1834(k)(1)(B) of the Act.

(3) A process for medical review of claims for physical therapy and speech-language pathology services applies as follows:

(i) For 2012 through 2017, medical review applies to claims for services at or in excess of $3,700 of recognized incurred expenses as described in paragraph (e)(1)(i) of this section.

(A) For 2012, 2013, and 2014 all claims at and above the $3,700 medical review threshold are subject to medical review; and

(B) For 2015, 2016, and 2017 claims at and above the $3,700 medical review threshold are subject to a targeted medical review process.

(ii) For 2018 and subsequent years, a targeted medical review process when the accrued annual incurred expenses reach the following medical review threshold amounts:

(A) Beginning with 2018 and before 2028, $3,000;

(B) For 2028 and each year thereafter, the applicable medical review threshold is determined by increasing the medical review threshold in effect for the previous year (starting with $3,000 for 2017) by the increase in the Medicare Economic Index for the current year.

[63 FR 58906, Nov. 2, 1998, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66422, Nov. 15, 2004; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 83 FR 60073, Nov. 23, 2018; 84 FR 63188, Nov. 15, 2019; 86 FR 65664, Nov. 19, 2021; 88 FR 79527, Nov. 16, 2023]

§ 410.61 Plan of treatment requirements for outpatient rehabilitation services.

(a) *Basic requirement.* Outpatient rehabilitation services (including services furnished by a qualified physical or occupational therapist in private practice), must be furnished under a written plan of treatment that meets the requirements of paragraphs (b) through (e) of this section.

(b) *Establishment of the plan.* The plan is established before treatment is begun by one of the following:

(1) A physician.

(2) A physical therapist who furnishes the physical therapy services.

(3) A speech-language pathologist who furnishes the speech-language pathology services.

(4) An occupational therapist who furnishes the occupational therapy services.

(5) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(c) *Content of the plan.* The plan prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual, and indicates the diagnosis and anticipated goals.

(d) *Changes in the plan.* Any changes in the plan—

(1) Are made in writing and signed by one of the following:

(i) The physician.

(ii) The physical therapist who furnishes the physical therapy services.

(iii) The occupational therapist that furnishes the occupational therapy services.

(iv) The speech-language pathologist who furnishes the speech-language pathology services.

(v) A registered professional nurse or a staff physician, in accordance with oral orders from the physician, physical therapist, occupational therapist, or speech-language pathologist who furnishes the services.

(vi) A nurse practitioner, a clinical nurse specialist, or a physician assistant.

(2) The changes are incorporated in the plan immediately.

[53 FR 6638, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988, as amended at 54 FR 38680, Sept. 20, 1989; 54 FR 46614, Nov. 6, 1989. Redesignated at 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 63 FR 58907, Nov. 2, 1998; 67 FR 80040, Dec. 31, 2002; 72 FR 66399, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018]

§ 410.62 Outpatient speech-language pathology services: Conditions and exclusions.

(a) *Basic rule.* Except as specified in paragraph (a)(3)(ii) of this section, Medicare Part B pays for outpatient speech-language pathology services only if they are furnished by an individual who meets the qualifications for a speech-language pathologist in §484.115 of this chapter and only under the following conditions:

(1) They are furnished to a beneficiary while he or she is under the care of a physician who is a doctor of medicine or osteopathy.

(2) They are furnished under a written plan of treatment that meets the requirements of §410.61.

(3) They are furnished by one of the following:

(i) A provider as defined in §489.2 of this chapter, or by others under arrangements with, and under the supervision of, a provider.

(ii) A speech-language pathologist in private practice as described in paragraph (c) of this section.

(iii) Incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform speech-language pathology services under State law. When a speech-language pathology service is provided incident to the services of a physician, physician assistant, clinical nurse specialist, or nurse practitioner, by anyone other than a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the service and the person who furnishes the service must meet the standards and conditions that apply to speech-language pathology and speech-language pathologists, except that a license to practice speech-language pathology services in the State is not required.

(b) *Condition for coverage of outpatient speech-language pathology services furnished to certain inpatients of a hospital or a CAH or SNF.* Medicare Part B pays for outpatient speech-language pathology services furnished to an inpatient of a hospital, CAH, or SNF who requires the services but has exhausted or is otherwise ineligible for benefit days under Medicare Part A.

(c) *Special provisions for services furnished by speech-language pathologists in private practice*—(1) *Basic qualifications.* In order to qualify under Medicare as a supplier of outpatient speech-language pathology services, each individual speech-language pathologist in private practice must meet the following requirements:

(i) Be legally authorized (if applicable, licensed, certified, or registered) to

engage in the private practice of speech-language pathology by the State in which he or she practices, and practice only within the scope of his or her license and/or certification.

(ii) Engage in the private practice of speech-language pathology on a regular basis as an individual, in one of the following practice types: a solo practice, partnership, or group practice; or as an employee of one of these.

(iii) Bill Medicare only for services furnished in one of the following:

(A) A speech-language pathologist's private practice office space that meets all of the following:

(*1*) The location(s) where the practice is operated, in the State(s) where the therapist (and practice, if applicable) is legally authorized to furnish services and during the hours that the therapist engages in practice at that location.

(*2*) The space must be owned, leased, or rented by the practice, and used for the exclusive purpose of operating the practice.

(B) A patient's home not including any institution that is a hospital, a CAH, or a SNF.

(iv) Treat individuals who are patients of the practice and for whom the practice collects fees for the services furnished.

(d) *Excluded services.* No service is included as an outpatient speech-language pathology service if it is not included as an inpatient hospital service if furnished to a hospital or CAH inpatient.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 58 FR 30668, May 26, 1993; 63 FR 58907, Nov. 2, 1998; 69 FR 66422, Nov. 15, 2004; 73 FR 69933, Nov. 19, 2008; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 79 FR 68002, Nov. 13, 2014; 82 FR 4578, Jan. 13, 2017; 83 FR 60073, Nov. 23, 2018]

§ 410.63 Hepatitis B vaccine and blood clotting factors: Conditions.

Notwithstanding the exclusion from coverage of vaccines (see § 411.15 of this chapter) and self-administered drugs (see § 410.29), the following services are included as medical and other health services covered under § 410.10, subject to the specified conditions:

(a) *Hepatitis B vaccine: Conditions.* Effective September 1, 1984, hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals who are at high or intermediate risk of contracting hepatitis B as listed below:

(1) *High risk groups.* (i) End-Stage Renal Disease (ESRD) patients;

(ii) Hemophiliacs who receive Factor VIII or IX concentrates;

(iii) Clients of institutions for individuals with intellectual disabilities;

(iv) Persons who live in the same household as a hepatitis B carrier;

(v) Homosexual men;

(vi) Illicit injectable drug abusers;

(vii) Pacific Islanders (that is, those Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii); and

(viii) Persons diagnosed with diabetes mellitus.

(2) *Intermediate risk groups.* (i) Staff in institutions for individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities;

(ii) Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work (including workers who work outside of a hospital and have frequent contact with blood or other infectious secretions); and

(iii) Heterosexually active persons with multiple sexual partners (that is, those Medicare beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years).

(3) *Exception.* Individuals described in paragraphs (a) (1) and (2) of this section are not considered at high or intermediate risk of contracting hepatitis B if they have undergone a prevaccination screening and have been found to be currently positive for antibodies to hepatitis B.

(b) *Blood clotting factors: Conditions.* Effective July 18, 1984, blood clotting factors to control bleeding for hemophilia patients competent to use these factors without medical or other supervision, and items related to the administration of those factors. The amount of clotting factors covered under this provision is determined by the carrier based on the historical utilization pattern or profile developed by the carrier

for each patient, and based on consideration of the need for a reasonable reserve supply to be kept in the home in the event of emergency or unforeseen circumstance.

(c) *Blood clotting factors: Furnishing Fee.* (1) Effective January 1, 2005, a furnishing fee of $0.14 per unit of clotting factor is paid to entities that furnish blood clotting factors unless the costs associated with furnishing the clotting factor are paid through another payment system, for example, hospitals that furnish clotting factor to patients during a Part A covered inpatient hospital stay.

(2) The furnishing fee for blood clotting factors furnished in 2006 or a subsequent year is be equal to the furnishing fee paid the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

[55 FR 22790, June 4, 1990; 55 FR 31186, Aug. 1, 1990, as amended at 69 FR 66422, Nov. 15, 2004; 77 FR 69363, Nov. 16, 2012; 87 FR 70223, Nov. 18, 2022]

§ 410.64 Additional preventive services.

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of ''preventive services'' under § 410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force.

(3) Appropriate for individuals entitled to benefits under part A or enrolled under Part B.

(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.

[73 FR 69933, Nov. 19, 2008, as amended at 75 FR 73615, Nov. 29, 2010]

§ 410.66 Emergency outpatient services furnished by a nonparticipating hospital and services furnished in a foreign country.

Conditions for payment of emergency inpatient services furnished by a nonparticipating U.S. hospital and for services furnished in a foreign country are set forth in subparts G and H of part 424 of this chapter.

[71 FR 48136, Aug. 18, 2006]

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

(a) *Basis and scope—* (1) *Basis.* This section implements sections 1861(jjj), 1861(s)(2)(HH), 1833(a)(1)(CC) and 1834(w) of the Act which provide for coverage of opioid use disorder treatment services furnished by an opioid treatment program and the payment of a bundled payment under Part B to an opioid treatment program for opioid use disorder treatment services that are furnished to a beneficiary during an episode of care beginning on or after January 1, 2020.

(2) *Scope.* This section sets forth the criteria for an opioid treatment program, the scope of opioid use disorder treatment services, and the methodology for determining the bundled payments to opioid treatment programs for furnishing opioid use disorder treatment services.

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

Episode of care means a one-week (contiguous 7-day) period.

Opioid treatment program means an entity that is an opioid treatment program (as defined in § 8.2 of this title, or any successor regulation) that meets the requirements described in paragraph (c) of this section.

Opioid use disorder treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid

treatment program that meets the requirements described in paragraph (c) of this section.

(i) Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug, and Cosmetic Act for use in treatment of opioid use disorder.

(ii) Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

(iii) Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(iv) Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During a Public Health Emergency, as defined in § 400.200 of this chapter, or for services furnished after the end of such emergency, in cases where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(v) Toxicology testing.

(vi) Intake activities, including initial medical examination services required under § 8.12(f)(2) of this title and initial assessment services required under § 8.12(f)(4) of this title. Services to initiate treatment with buprenorphine may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. In cases where audio-video communications technology is not available to the beneficiary, services to initiate treatment with buprenorphine may be furnished using audio-only telephone calls if all other applicable requirements are met.

(vii) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, and through the end of CY 2024, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(viii) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

(ix) Opioid treatment program (OTP) intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of opioid use disorder (OUD) and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician or nonphysician practitioner (as defined in section 1842(b)(18)(C) of the Act) certification and plan of care, as permitted by State law and scope of practice requirements, in which a physician or

non-physician practitioner must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

(c) *Requirements for opioid treatment programs.* To participate in the Medicare program and receive payment, an opioid treatment program must meet all of the following:

(1) Be enrolled in the Medicare program.

(2) Have in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the opioid treatment program.

(3) Be accredited by an accrediting body approved by the SAMHSA.

(4) Have in effect a provider agreement under part 489 of this title.

(5) OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care and any reference to a physician requirement in § 424.24(d)(1) through (3) may also be performed by a non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act, as permitted by state law and scope of practice requirements.

(d) *Bundled payments for opioid use disorder treatment services furnished by opioid treatment programs.* (1) CMS will establish categories of bundled payments for opioid treatment programs for an episode of care as follows:

(i) Categories for each type of opioid agonist and antagonist treatment medication;

(ii) A category for medication not otherwise specified, which will be used for new FDA-approved opioid agonist or antagonist treatment medications for which CMS has not established a category; and

(iii) A category for episodes of care in which no medication is provided.

(2) The bundled payment for episodes of care in which a medication is provided consists of payment for a drug component, reflecting payment for the applicable FDA-approved opioid agonist or antagonist medication in the patient's treatment plan, and a non-drug component, reflecting payment for all other opioid use disorder treatment services reflected in the patient's treatment plan (including dispensing/administration of the medication, if applicable). The payments for the drug component and non-drug component are added together to create the bundled payment amount. The bundled payment for episodes of care in which no medication is provided consists of a single payment amount for all opioid use disorder treatment services reflected in the patient's treatment plan (excluding medication and dispensing/administration of medication).

(i) *Drug component.* The payment for the drug component for an episode of care will be determined as follows, using the most recent data available at time of ratesetting for the applicable calendar year:

(A) *Implantable and injectable medications.* For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

(B) *For oral medications.* (*1*) Except as provided under paragraph (d)(2)(i)(B)(*2*) of this section, if ASP data are available, the payment amount is 100 percent of ASP, which will be determined based on ASP data that have been calculated consistent with the provisions in part 414, subpart J of this chapter and voluntarily submitted by drug manufacturers. If ASP data are not available, the payment amount for methadone will be based on the TRICARE rate and for buprenorphine will be calculated using the National Average Drug Acquisition Cost.

(*2*) For CY 2022, the payment amount for methadone is the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021. For CY 2023 and subsequent years, the payment amount for methadone will be based on the payment amount determined under paragraph (d)(2)(i)(B)(*1*) of this section for methadone in CY 2021 and updated by the PPI for Pharmaceuticals for Human Use (Prescription).

(C) *Exception.* For the drug component of bundled payments in the medication not otherwise specified category under paragraph (d)(1)(iii) of this section, the payment amount is be based on the applicable methodology under paragraphs (d)(2)(i)(A) and (B) of this section (applying the most recent available data for such new medication), or invoice pricing until the necessary data become available.

(ii) *Non-drug component.* The payment for CY 2020 for the non-drug component of the bundled payment for an episode of care is the sum of:

(A) The CY 2019 Medicare physician fee schedule non-facility rates for the following items and services:

(*1*) Psychotherapy, 30 minutes with patient

(*2*) Group psychotherapy

(*3*) Alcohol and/or substance (other than tobacco) abuse structured assessment and brief intervention at the nonphysician practitioner rate.

(*4*) For administration of an injectable medication, if applicable, drug administration (Therapeutic, prophylactic).

(*5*) For the insertion, removal, or insertion and removal of the implantable medication, if applicable, the applicable rate.

(B) For dispensing oral medication, if applicable, an approximation of the average dispensing fees under state Medicaid programs.

(C) One fourth of the sum of the CY 2019 Clinical Laboratory Fee Schedule rate for two drug tests, presumptive, capable of being read by direct optical observation only and for a drug test, definitive, 1–7 drug classes.

(iii) *No medication provided episodes of care.* The bundled payment amount for CY 2020 for an episode of care in which no medication is provided is based on the non-drug component rate for an episode of care in which a drug is dispensed or administered, not including any amounts reflecting the cost of dispensing or administration of a drug.

(iv) *Increased level of psychotherapy.* For CY 2023 and subsequent years, the payment for the non-drug component of the bundled payment for an episode of care under paragraph (d)(2) of this section is adjusted to reflect the CY 2019 Medicare physician fee schedule non-facility rate for psychotherapy, 45 minutes with patient.

(3) At least one OUD treatment service described in paragraphs (i) through (v) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) Adjustments will be made to the bundled payment for the following:

(i) If the opioid treatment program furnishes:

(A) Counseling or therapy services in excess of the amount specified in the beneficiary's treatment plan and for which medical necessity is documented in the medical record, an adjustment will be made for each additional 30 minutes of counseling or individual therapy furnished during the episode of care.

(B) Intake activities described in paragraph (b)(6) of this section, an adjustment will be made when intake activities are furnished.

(C) Periodic assessments described in paragraph (b)(7) of this section, an adjustment will be made when this service is furnished.

(D) Additional take home supply of oral drugs of up to 21 days, in increments of 7 days, an adjustment will be made when oral medications are dispensed.

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days, except

when a further take home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception. The amount of the drug component of the adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section. The amount of the non-drug component of the adjustment will be determined based on the CY 2020 Medicare payment rate for CPT code 96161.

(F) For OTP intensive outpatient services, an adjustment will be made when at least nine OTP intensive outpatient services described in paragraph (ix) of the definition of *opioid use disorder treatment service* in paragraph (b) of this section are furnished in a week. This adjustment will be based on the per diem payment rate for intensive outpatient services at hospital-based programs defined at § 410.44(c) and multiplied by a factor of three for a weekly payment adjustment.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the geographic adjustment factor described in § 414.26 of this chapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this chapter.

(5) Payment for medications delivered, administered or dispensed to a beneficiary as part of the bundled payment or an adjustment to the bundled payment under paragraph (d)(4)(i) of this section is considered a duplicative payment if a claim for delivery, administration or dispensing of the same medications for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. CMS will recoup the duplicative payment made to the opioid treatment program.

(6) For purposes of the adjustment to the bundled payment under paragraph (d)(4)(i)(A) of this section, after the end of the Public Health Emergency as defined in § 400.200 of this chapter, when services are furnished using audio-only technology the practitioner must certify, in a form and manner specified by CMS, that they had the capacity to furnish the services using two-way, audio/video communication technology, but used audio-only technology because audio/video communication technology was not available to the beneficiary.

(e) *Beneficiary cost-sharing.* A beneficiary copayment amount of zero will apply.

[84 FR 63189, Nov. 15, 2019, as amended at 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 85026, Dec. 28, 2020; 86 FR 65664, 66036, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022; 88 FR 79528, Nov. 16, 2023; 88 FR 82178, Nov. 22, 2023]

§ 410.68 Antigens: Scope and conditions.

Medicare Part B pays for—

(a) Antigens that are furnished as services incident to a physician's professional services; or

(b) A supply of antigen sufficient for not more than 12 months that is—

(1) Prepared for a patient by a doctor of medicine or osteopathy who has examined the patient and developed a plan of treatment including dosage levels; and

(2) Administered—

(i) In accord with the plan of treatment developed by the doctor of medicine or osteopathy who prepared the antigen; and

(ii) By a doctor of medicine or osteopathy or by a properly instructed person under the supervision of a doctor of medicine or osteopathy.

[54 FR 4026, Jan. 27, 1989, as amended at 65 FR 65440, Nov. 1, 2000]

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

(a) *Basic rule.* Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) *Definitions.* For purposes of this part—

Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

Anesthesiologist's assistant means a person who—

(1) Works under the direction of an anesthesiologist;

(2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and

(3) Is a graduate of a medical school-based anesthesiologist's assistant educational program that—

(A) Is accredited by the Committee on Allied Health Education and Accreditation; and

(B) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

Anesthetist includes both an anesthesiologist's assistant and a certified registered nurse anesthetist.

Certified registered nurse anesthetist means a registered nurse who:

(1) Is licensed as a registered professional nurse by the State in which the nurse practices;

(2) Meets any licensure requirements the State imposes with respect to nonphysician anesthetists;

(3) Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

(5) For certified registered nurse anesthetist services, the certified registered nurse anesthetist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified registered nurse anesthetist's presence and participation in the service.

[57 FR 33896, July 31, 1992, as amended at 77 FR 69363, Nov. 16, 2012; 84 FR 63190, Nov. 15, 2019]

§ 410.71 Clinical psychologist services and services and supplies incident to clinical psychologist services.

(a) *Included services.* (1) Medicare Part B covers services furnished by a clinical psychologist, who meets the requirements specified in paragraph (d) of this section, that are within the scope of his or her State license, if the services would be covered if furnished by a physician or as an incident to a physician's services.

(2) Medicare Part B covers services and supplies incident to the services of a clinical psychologist if the requirements of § 410.26 are met.

(b) *Application of mental health treatment limitation.* The treatment services of a clinical psychologist and services and supplies furnished as an incident to

those services are subject to the limitation on payment for outpatient mental health treatment services set forth in § 410.155.

(c) *Payment for consultations.* A clinical psychologist or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (e) of this section.

(d) *Qualifications.* For purposes of this subpart, a clinical psychologist is an individual who—

(1) Holds a doctoral degree in psychology; and

(2) Is licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(e) *Agreement to consult.* A clinical psychologist who bills Medicare Part B must agree to meet the requirements of paragraphs (e)(1) through (e)(3) of this section. The clinical psychologist's signature on a Medicare provider/supplier enrollment form indicates his or her agreement.

(1) Unless the beneficiary's primary care or attending physician has referred the beneficiary to the clinical psychologist, to inform the beneficiary that it is desirable for the clinical psychologist to consult with the beneficiary's attending or primary care physician (if the beneficiary has such a physician) to consider any conditions contributing to the beneficiary's symptoms.

(2) If the beneficiary assents to the consultation, in accordance with accepted professional ethical norms and taking into consideration patient confidentiality—

(i) To attempt, within a reasonable time after receiving the consent, to consult with the physician; and

(ii) If attempts to consult directly with the physician are not successful, to notify the physician, within a reasonable time, that he or she is furnishing services to the beneficiary.

(3) Unless the primary care or attending physician referred the beneficiary to the clinical psychologist, to document, in the beneficiary's medical record, the date the patient consented or declined consent to consultation, the date of consultation, or, if attempts to consult did not succeed, the date and manner of notification to the physician.

[63 FR 20128, Apr. 23, 1998, as amended at 78 FR 74811, Dec. 10, 2013]

§ 410.72 Registered dietitians' and nutrition professionals' services.

(a) *Definition: Registered dietitians and nutrition professionals.* Meet the qualifications at § 410.134.

(b) *Covered registered dietitian and nutrition professional services.* Medicare Part B covers:

(1) *Coverage condition.* Medical nutrition therapy (MNT) services as defined at § 410.130 under the conditions of coverage at § 410.132.

(2) *Other services.* Registered dietitians and nutrition professionals may also provide diabetes self-management (DSMT) services if they are or represent an accredited DSMT entity and have an order from a physician or qualified nonphysician practitioner who is treating the patient's diabetic condition.

(3) *Limits on MNT and DSMT.* (i) DSMT and MNT cannot be furnished to a patient on the same date of service, and

(ii) MNT and DSMT services cannot be furnished incident to the professional services of a physician or nonphysician practitioner service.

(c) *Limitations.* The following services are not registered dietitian or nutrition professional services for purposes of billing Medicare Part B:

(1) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating hospital.

(2) Services furnished by a registered dietitian or nutrition professional to an inpatient of a Medicare-participating SNF.

(3) Services furnished by a registered dietitian or nutrition professional to a patient in a Medicare-participating ESRD facility in accordance with the limitation on coverage of MNT service listed at § 410.132(b)(1).

(d) *Professional services.* Except for DSMT services furnished as, or on behalf of, an accredited DSMT entity,

registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

(e) *Telehealth services.* MNT and DSMT services may be provided as telehealth services (meeting the requirements in § 410.78) when registered dietitians or nutrition professionals act as distant site practitioners.

(f) *Restrictions.* The services of a registered dietitian or nutrition professional are provided on an assignment-related basis, and a registered dietitian or nutrition professional may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the registered dietitian or nutrition professional must refund the full amount of the impermissible charge to the beneficiary.

[86 FR 65665, Nov. 19, 2021, as amended at 88 FR 79528, Nov. 16, 2023]

§ 410.73 Clinical social worker services.

(a) *Definition: clinical social worker.* For purposes of this part, a clinical social worker is defined as an individual who—

(1) Possesses a master's or doctor's degree in social work;

(2) After obtaining the degree, has performed at least 2 years of supervised clinical social work; and

(3) Either is licensed or certified as a clinical social worker by the State in which the services are performed or, in the case of an individual in a State that does not provide for licensure or certification as a clinical social worker—

(i) Is licensed or certified at the highest level of practice provided by the laws of the State in which the services are performed; and

(ii) Has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's degree level social worker in an appropriate setting such as a hospital, SNF, or clinic.

(b) *Covered clinical social worker services.* Medicare Part B covers clinical social worker services.

(1) *Definition.* ''Clinical social worker services'' means, except as specified in paragraph (b)(2) of this section, the services of a clinical social worker furnished for the diagnosis and treatment of mental illness that the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which the services are performed. The services must be of a type that would be covered if they were furnished by a physician or as an incident to a physician's professional service and must meet the requirements of this section.

(2) *Exception.* The following services are not clinical social worker services for purposes of billing Medicare Part B:

(i) Services furnished by a clinical social worker to an inpatient of a Medicare-participating hospital.

(ii) Services furnished by a clinical social worker to an inpatient of a Medicare-participating SNF.

(iii) Services furnished by a clinical social worker to a patient in a Medicare-participating dialysis facility if the services are those required by the conditions for coverage for ESRD facilities under § 405.2163 of this chapter.

(c) *Agreement to consult.* A clinical social worker must comply with the consultation requirements set forth at § 410.71(f) (reading ''clinical psychologist'' as ''clinical social worker'').

(d) *Prohibited billing.* (1) A clinical social worker may not bill Medicare for the services specified in paragraph (b)(2) of this section.

(2) A clinical social worker or an attending or primary care physician may not bill Medicare or the beneficiary for the consultation that is required under paragraph (c) of this section.

[63 FR 20128, Apr. 23, 1998]

§ 410.74 Physician assistants' services.

(a) *Basic rule.* Medicare Part B covers physician assistants' services only if the following conditions are met:

(1) The services would be covered as physicians' services if furnished by a physician (a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act).

(2) The physician assistant—

(i) Meets the qualifications set forth in paragraph (c) of this section;

(ii) Is legally authorized to perform the services in the State in which they are performed;

(iii) Performs services that are not otherwise precluded from coverage because of a statutory exclusion;

(iv) Performs the services in accordance with state law and state scope of practice rules for physician assistants in the state in which the physician assistant's professional services are furnished. Any state laws and scope of practice rules that describe the required practice relationship between physicians and physician assistants, including explicit supervisory or collaborative practice requirements, describe a form of supervision for purposes of section 1861(s)(2)(K)(i) of the Act. For states with no explicit state law and scope of practice rules regarding physician supervision of physician assistant's services, physician supervision is a process in which a physician assistant has a working relationship with one or more physicians to supervise the delivery of their health care services. Such physician supervision is evidenced by documenting at the practice level the physician assistant's scope of practice and the working relationships the physician assistant has with the supervising physician/s when furnishing professional services.

(v) Prior to January 1, 2022, furnishes services that are billed by the employer of a physician assistant; and

(vi) Performs the services—

(A) In all settings in either rural and urban areas; or

(B) As an assistant at surgery.

(b) *Services and supplies furnished incident to a physician assistant's services.* Medicare Part B covers services and supplies incident to the services of a physician assistant if the requirements of § 410.26 are met.

(c) *Qualifications.* For Medicare Part B coverage of his or her services, a physician assistant must meet all of the following conditions:

(1) Have graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(2) Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(3) Be licensed by the State to practice as a physician assistant.

(d) *Professional services.* Physician assistants can be paid for professional services only if the services have been professionally performed by them and no facility or other provider charges for the service or is paid any amount for the furnishing of those professional services.

(1) Supervision of other nonphysician staff by a physician assistant does not constitute personal performance of a professional service by the physician assistant.

(2) The services of a physician assistant are provided on an assignment-related basis, and the physician assistant may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the physician assistant must refund the full amount of the impermissible charge to the beneficiary.

(e) *Medical record documentation.* For physician assistants' services, the physician assistant may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the physician assistant's presence and participation in the service.

[63 FR 58907, Nov. 2, 1998; 64 FR 25457, May 12, 1999, as amended at 78 FR 74811, Dec. 10, 2013; 84 FR 63190, Nov. 15, 2019; 86 FR 65665, Nov. 19, 2021]

§ 410.75 Nurse practitioners' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a nurse practitioner must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

(i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

(ii) Possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in paragraph (b)(1)(i) of this section.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

(c) *Services.* Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner.

(d) *Services and supplies incident to a nurse practitioners' services.* Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

(e) *Professional services.* Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by a nurse practitioner does not constitute personal performance of a professional service by a nurse practitioner.

(2) The services of a nurse practitioner are provided on an assignment-related basis, and the nurse practitioner may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the nurse practitioner must refund the full amount of the impermissible charge to the beneficiary.

(f) *Medical record documentation.* For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

[63 FR 58908, Nov. 2, 1998; 64 FR 25457, May 12, 1999, as amended at 64 FR 59440, Nov. 2, 1999; 73 FR 69933, Nov. 19, 2008; 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019; 86 FR 65665, Nov. 19, 2021]

§ 410.76 Clinical nurse specialists' services.

(a) *Definition.* As used in this section, the term ''physician'' means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) *Qualifications.* For Medicare Part B coverage of his or her services, a clinical nurse specialist must—

(1) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(2) Have a master's degree in a defined clinical area of nursing from an accredited educational institution or a Doctor of Nursing Practice (DNP) doctoral degree; and

(3) Be certified as a clinical nurse specialist by a national certifying body that has established standards for clinical nurse specialists and that is approved by the Secretary.

(c) *Services.* Medicare Part B covers clinical nurse specialists' services in all settings in both rural and urban areas only if the services would be covered if furnished by a physician and the clinical nurse specialist—

(1) Is legally authorized to perform them in the State in which they are performed;

(2) Is not performing services that are otherwise excluded from coverage by one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a clinical nurse specialist works with one or more physicians to deliver health care services within the scope of the practitioner's expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a clinical nurse specialist has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by clinical nurse specialists documenting the clinical nurse specialists' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Clinical nurse specialists must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the clinical nurse specialist when the services are furnished, or to make an independent evaluation of each patient who is seen by the clinical nurse specialist.

(d) *Services and supplies furnished incident to clinical nurse specialists' services.* Medicare Part B covers services and supplies incident to the services of a clinical nurse specialist if the requirements of § 410.26 are met.

(e) *Professional services.* Clinical nurse specialists can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by clinical nurse specialists does not constitute personal performance of a professional service by clinical nurse specialists.

(2) The services of a clinical nurse specialist are provided on an assignment-related basis, and the clinical nurse specialist may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the clinical nurse specialist must refund the full amount of the impermissible charge to the beneficiary.

(f) *Medical record documentation.* For clinical nurse specialists' services, the clinical nurse specialist may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the clinical nurse specialist's presence and participation in the service.

[63 FR 58908, Nov. 2, 1998, as amended at 67 FR 80040, Dec. 31, 2002; 73 FR 69934, Nov. 19, 2008; 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019; 86 FR 65665, Nov. 19, 2021]

§ 410.77 Certified nurse-midwives' services: Qualifications and conditions.

(a) *Qualifications.* For Medicare coverage of his or her services, a certified nurse-midwife must:

(1) Be a registered nurse who is legally authorized to practice as a nurse-

midwife in the State where services are performed;

(2) Have successfully completed a program of study and clinical experience for nurse-midwives that is accredited by an accrediting body approved by the U.S. Department of Education; and

(3) Be certified as a nurse-midwife by the American College of Nurse-Midwives or the American College of Nurse-Midwives Certification Council.

(b) *Services.* A certified nurse-midwife's services are services furnished by a certified nurse-midwife and services and supplies furnished as an incident to the certified nurse-midwife's services that—

(1) Are within the scope of practice authorized by the law of the State in which they are furnished and would otherwise be covered if furnished by a physician or as an incident to a physician's service; and

(2) Unless required by State law, are provided without regard to whether the certified nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

(c) *Incident to services: Basic rule.* Medicare Part B covers services and supplies incident to the services of a certified nurse-midwife if the requirements of § 410.26 are met.

(d) *Professional services.* A nurse-midwife can be paid for professional services only when the services have been performed personally by the nurse-midwife.

(1) Supervision of other nonphysician staff by a nurse-midwife does not constitute personal performance of a professional service by the nurse-midwife.

(2) The services of a certified nurse-midwife are provided on an assignment-related basis, and the certified nurse-midwife may not charge a beneficiary in excess of the amounts permitted under 42 CFR 424.55. If a beneficiary has made payment for a service in excess of these limits, the certified nurse-midwife must refund the full amount of the impermissible charge to the beneficiary.

(3) A nurse-midwife may provide services that he or she is legally authorized to perform under State law as a nurse-midwife, if the services would otherwise be covered by the Medicare program when furnished by a physician or incident to a physicians' professional services.

(e) *Medical record documentation.* For certified nurse-midwives' services, the certified nurse-midwife may review and verify (sign and date), rather than redocument, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team, including, as applicable, notes documenting the certified nurse-midwife's presence and participation in the service.

[63 FR 58909, Nov. 2, 1998, as amended at 78 FR 74811, Dec. 10, 2013; 84 FR 63191, Nov. 15, 2019; 86 FR 65665, Nov. 19, 2021]

§ 410.78 Telehealth services.

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

(1) *Asynchronous store and forward technologies* means the transmission of a patient's medical information from an originating site to the physician or practitioner at the distant site. The physician or practitioner at the distant site can review the medical case without the patient being present. An asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs visualized by a telecommunications system must be specific to the patient's medical condition and adequate for furnishing or confirming a diagnosis and or treatment plan. Dermatological photographs, for example, a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this provision.

(2) *Distant site* means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-

time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology. A modifier designated by CMS must be appended to the claim for services described in this paragraph to verify that these conditions have been met.

(4) *Originating site* means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous store and forward telecommunications technologies, the only originating sites are Federal telemedicine demonstration programs conducted in Alaska or Hawaii.

(b) *General rule.* Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following conditions are met, except that for the duration of the Public Health Emergency as defined in § 400.200 of this chapter, Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment furnished by an interactive telecommunications system if the following conditions are met:

(1) The physician or practitioner at the distant site must be licensed to furnish the service under State law. The physician or practitioner at the distant site who is licensed under State law to furnish a covered telehealth service described in this section may bill, and receive payment for, the service when it is delivered via a telecommunications system.

(2) The practitioner at the distant site is one of the following:

(i) A physician as described in § 410.20.

(ii) A physician assistant as described § 410.74.

(iii) A nurse practitioner as described in § 410.75.

(iv) A clinical nurse specialist as described in § 410.76.

(v) A nurse-midwife as described in § 410.77.

(vi) A clinical psychologist as described in § 410.71.

(vii) A clinical social worker as described in § 410.73.

(viii) A registered dietitian or nutrition professional as described in § 410.134.

(ix) A certified registered nurse anesthetist as described in § 410.69.

(x) Any distant site practitioner who can appropriately bill for diabetes self-management training services may do so on behalf of others who personally furnish the services as part of the DSMT entity.

(xi) A marriage and family therapist as described in 410.53.

(xii) A mental health counselor as described in 410.54.

(3) The services are furnished to a beneficiary at an originating site, which is one of the following:

(i) The office of a physician or practitioner.

(ii) A critical access hospital (as described in section 1861(mm)(1) of the Act).

(iii) A rural health clinic (as described in section 1861(aa)(2) of the Act).

(iv) A Federally qualified health center (as defined in section 1861(aa)(4) of the Act).

(v) A hospital (as defined in section 1861(e) of the Act).

(vi) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(vii) A skilled nursing facility (as defined in section 1819(a) of the Act).

(viii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Act).

(ix) A renal dialysis facility (only for purposes of the home dialysis monthly ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act);

(x) The home of an individual (only for purposes of the home dialysis ESRD-related clinical assessment in section 1881(b)(3)(B) of the Act).

(xi) A mobile stroke unit (only for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke provided in accordance with section 1834(m)(6) of the Act).

(xii) The home of an individual (only for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis.

(xiii) A rural emergency hospital (as defined in section 1861(kkk)(2) of the Act), for services furnished on or after January 1, 2023.

(xiv) The home of a beneficiary for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder for services that are furnished during the period beginning on the first day after the end of the emergency period as defined in our regulation at § 400.200 and ending on December 31, 2024 except as otherwise provided in this paragraph. Payment will not be made for a telehealth service furnished under this paragraph unless the following conditions are met:

(A) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service;

(B) The physician or practitioner has furnished an item or service in-person, without the use of telehealth, at least once within 12 months of each subsequent telehealth service described in this paragraph, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens associated with an in-person service outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reason(s) for this decision in the patient's medical record.

(C) The requirements of paragraphs (b)(3)(xiv)(A) and (B) may be met by another physician or practitioner of the same specialty and subspecialty in the same group as the physician or practitioner who furnishes the telehealth service, if the physician or practitioner who furnishes the telehealth service described under this paragraph is not available.

(4) Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be:

(i) Located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA as determined by the Office of Rural Health Policy of the Health Resources and Services Administration as of December 31st of the preceding calendar year, or

(ii) Located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or

(iii) An entity participating in a Federal telemedicine demonstration project that has been approved by, or receive funding from, the Secretary as of December 31, 2000, regardless of its geographic location.

(iv) The geographic requirements specified in paragraph (b)(4) of this section do not apply to the following telehealth services:

(A) Home dialysis monthly ESRD-related clinical assessment services furnished on or after January 1, 2019, at an originating site described in paragraphs (b)(3)(vi), (ix) or (x) of this section, in accordance with section 1881(b)(3)(B) of the Act; and

(B) Services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

(C) Services furnished on or after July 1, 2019 to an individual with a substance use disorder diagnosis, for purposes of treatment of a substance use disorder or a co-occurring mental health disorder.

(D) Services furnished on or after January 1, 2025 for the purposes of diagnosis, evaluation, and/or treatment of a mental health disorder. Payment will

not be made for a telehealth service furnished under this paragraph unless the physician or practitioner has furnished an item or service in person, without the use of telehealth, for which Medicare payment was made (or would have been made if the patient were entitled to, or enrolled for, Medicare benefits at the time the item or service is furnished) within 6 months prior to the initial telehealth service and within 6 months of any subsequent telehealth service.

(5) The medical examination of the patient is under the control of the physician or practitioner at the distant site.

(c) *Telepresenter not required.* A telepresenter is not required as a condition of payment unless a telepresenter is medically necessary as determined by the physician or practitioner at the distant site.

(d) *Exception to the interactive telecommunications system requirement.* For Federal telemedicine demonstration programs conducted in Alaska or Hawaii only, Medicare payment is permitted for telehealth when asynchronous store and forward technologies, in single or multimedia formats, are used as a substitute for an interactive telecommunications system.

(e) *Limitations.* (1) A clinical psychologist and a clinical social worker, a marriage and family therapist (MFT), and a mental health counselor (MHC) may bill and receive payment for individual psychotherapy via a telecommunications system, but may not seek payment for medical evaluation and management services.

(2) The physician visits required under § 483.40(c) of this title may not be furnished as telehealth services.

(3) The distant site practitioner who reports the DSMT services may bill and receive payment when a professional furnishes injection training for an insulin-dependent patient using interactive telecommunications technology when such training is included as part of the DSMT plan of care referenced at § 410.141(b)(2).

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency, taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

[66 FR 55330, Nov. 1, 2001, as amended at 67 FR 80041, Dec. 31, 2002; 69 FR 66423, Nov. 15, 2004; 70 FR 70330, Nov. 21, 2005; 72 FR 66399, Nov. 27, 2007; 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009; 75 FR 73615, Nov. 29, 2010; 76 FR 73470, Nov. 28, 2011; 77 FR 69363, Nov. 16, 2012; 78 FR 74811, Dec. 10, 2013; 79 FR 68002, Nov. 13, 2014; 80 FR 71373, Nov. 16, 2015; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27621, May 8, 2020; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 87 FR 70224, Nov. 18, 2022; 88 FR 79528, Nov. 16, 2023]

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

(a) Medicare Diabetes Prevention Program (MDPP) services will be available beginning on April 1, 2018.

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

Baseline weight means the MDPP beneficiary's body weight recorded during that beneficiary's first core session.

CDC-approved DPP curriculum refers to the content of the core sessions, core maintenance sessions, and ongoing maintenance sessions. The curriculum may be either the CDC-preferred curriculum as designated by the CDC DPRP Standards or an alternative curriculum approved for use in DPP by the CDC.

Combination delivery. MDPP sessions that are delivered by trained Coaches and are furnished in a manner consistent with the DPRP Standards for distance learning and in-person sessions for each individual participant.

Core maintenance session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during a core maintenance session interval;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for maintenance sessions.

Core session means an MDPP service that—

(i) Is furnished by an MDPP supplier to an MDPP beneficiary during months 1 through 6 of the MDPP services period;

(ii) Is approximately 1 hour in length; and

(iii) Adheres to a CDC-approved DPP curriculum for core sessions.

Diabetes Prevention Recognition Program (DPRP) refers to a program administered by the Centers for Disease Control and Prevention (CDC) that recognizes organizations that are able to furnish diabetes prevention program (DPP) services, follow a CDC-approved DPP curriculum, and meet CDC's performance standards and reporting requirements.

Distance learning refers to an MDPP session that is delivered by trained Coaches via remote classroom and is furnished in a manner consistent with the DPRP Standards for distance learning sessions. The Coach provides live (synchronous) delivery of session content in one location and participants call-in or video-conference from another location.

Extended flexibilities refer to the flexibilities as described in paragraphs (e)(3)(iii) and (iv) of this section.

Extended flexibilities period refers to the 4-year period (January 1, 2024 to December 31, 2027) for the Extended flexibilities to apply.

Full CDC DPRP recognition refers to the designation from the CDC that an organization has consistently furnished CDC-approved DPP sessions, met CDC-performance standards and met CDC reporting requirements for at least 24–36 months following the organization's application to participate in the DPRP.

Full-Plus CDC DPRP recognition refers to organizations that have met the Full CDC DPRP recognition, and at the time full recognition is achieved, has met the following retention criterion: Eligible participants in the evaluation cohort must have been retained at the following percentages: A minimum of 50 percent at the beginning of the fourth month since the cohorts held their first sessions; A minimum of 40 percent at the beginning of the seventh month since the cohorts held their first sessions; and A minimum of 30 percent at the beginning of the tenth month since the cohorts held their first sessions.

Make-up session means a core session or a core maintenance session furnished to an MDPP beneficiary when the MDPP beneficiary misses a regularly scheduled core session or core maintenance session.

MDPP beneficiary means a Medicare beneficiary who meets the criteria specified in paragraph (c)(1)(i) of this section, who has initiated the MDPP services period by attending the first core session, and for whom the MDPP services period has not ended as specified in paragraph (c)(3) of this section.

MDPP services means structured health behavior change sessions that are furnished under the MDPP expanded model with the goal of preventing diabetes among Medicare beneficiaries with prediabetes, and that follow a CDC-approved curriculum. The sessions provide practical training in long-term dietary change, increased physical activity, and problem-solving strategies for overcoming challenges to maintaining weight loss and a healthy lifestyle.

MDPP services period means the time period, beginning on the date an MDPP beneficiary attends his or her first core session, over which the Set of MDPP services is furnished to the MDPP beneficiary, to include the core services period described in paragraph (c)(2)(i) and, subject to paragraph (c)(3) of this section.

MDPP session means a core session or a core maintenance session.

MDPP supplier means an entity that is enrolled in Medicare to furnish MDPP services as provided in § 424.205 of this chapter.

Medicare Diabetes Prevention Program (MDPP) refers to a model test expanded under section 1115A(c) of the Act that makes MDPP services available to MDPP beneficiaries.

National Diabetes Prevention Program (National DPP) refers to an evidence-

based intervention targeted to individuals with pre-diabetes that is furnished in community and health care settings and administered by the Centers for Disease Control and Prevention (CDC).

Ongoing maintenance session interval means one of the up to four consecutive 3-month time periods during the ongoing services period described in paragraph (c)(2)(ii) of this section, during which an MDPP supplier offers at least one ongoing maintenance session to an MDPP beneficiary per month.

Online delivery refers to an MDPP session that is delivered online for all participants and is furnished in a manner consistent with the DPRP Standards for online sessions. The program is experienced through the internet via phone, tablet, laptop, in an asynchronous classroom where participants are experiencing the content on their own time without a live Coach teaching the content. However, live Coach interaction should be provided to each participant no less than once per week during the first 6 months and once per month during the second 6 months. Emails and text messages can count toward the requirement for live coach interaction as long as there is bi-directional communication between coach and participant.

Required minimum weight loss refers to the percentage by which the beneficiary's updated weight is less than the baseline weight. The required minimum weight loss percentage is 5 percent.

Set of MDPP services means the series of MDPP sessions, composed of core sessions, core maintenance sessions, and subject to paragraph (c)(3) of this section, ongoing maintenance sessions, offered over the course of the MDPP services period.

Virtual make-up session means a make-up session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for virtual sessions.

Virtual session refers to an MDPP session that is not furnished in person and that is furnished in a manner consistent with the DPRP standards for distance learning sessions.

(c) Coverage for *MDPP services*—(1) *Beneficiary eligibility*. (i) A Medicare beneficiary is eligible for MDPP services offered during the core services period described in paragraph (c)(2)(i) of this section if the beneficiary meets all of the following criteria:

(A) Is enrolled under Medicare Part B;

(B) Attended the first core session within the most recent 12-month time period and, prior to attending this first core session, had not previously received the set of MDPP services in his or her lifetime;

(C) Has, on the date of attendance at the first core session, a body mass index (BMI) of at least 25 if not self-identified as Asian or a BMI of at least 23 if self-identified as Asian;

(D) Has received, within the 12-month time period prior to the date of attendance at the first core session, a hemoglobin A1c test with a value of between 5.7 and 6.4 percent, a fasting plasma glucose test with a value of between 110 and 125 mg/dL, or a 2-hour plasma glucose test (oral glucose tolerance test) with a value of between 140 and 199 mg/dL;

(E) Has, as of the date of attendance at the first core session, no previous diagnosis of diabetes, other than gestational diabetes; and

(F) Does not have end-stage renal disease (ESRD).

(ii) Weight measurements used to determine the achievement or maintenance of the required minimum weight loss must be taken in person by an MDPP supplier during an MDPP session.

(2) *MDPP services period*. An MDPP beneficiary's MDPP services period is composed of the following periods and intervals:

(i) The core services period, which is the first 12 months of the MDPP services period, and consists of:

(A) Up to 16 core sessions offered at least 1 week apart during months 1 through 6 of the MDPP services period; and

(B) Up to 6 core maintenance sessions offered at least 1 month apart during months 7 through 12 of the MDPP services period.

(ii) [Reserved]

(3) *Limitations on the MDPP services period*.

(i) The MDPP services period ends upon completion of the core services

period described in paragraph (c)(2)(i) of this section.

(ii) [Reserved]

(d) *Make-up sessions.* (1) An MDPP supplier may offer a make-up session to an MDPP beneficiary who missed a regularly scheduled session. If an MDPP supplier offers one or more make-up sessions to an MDPP beneficiary, each such session must be furnished in accordance with the following requirements:

(i) The curriculum furnished during the make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session that the beneficiary missed;

(ii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session on the same day as a regularly scheduled session; and

(iii) The MDPP supplier may furnish to the beneficiary a maximum of one make-up session per week.

(2) An MDPP supplier may offer virtual make-up sessions only if consistent with the requirements in paragraph (d)(1) of this section. Virtual make-up sessions are also subject to the following requirements:

(i) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(ii) An MDPP supplier may only offer virtual make-up sessions based on an individual MDPP beneficiary's request; and

(iii) An MDPP supplier may offer to an MDPP beneficiary:

(A) No more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions are core maintenance sessions; and

(B) [Reserved]

(3) Make-up sessions furnished in accordance with paragraph (d)(1) of this section that an MDPP beneficiary attends in person are counted toward meeting the attendance requirements described in paragraph (c)(1) of this section and toward achieving the performance goals described in §414.84(b) of this chapter as if the MDPP beneficiary attended a regularly scheduled session. Virtual make-up sessions furnished in accordance with paragraph (d)(2) of this section are also counted toward such attendance requirements and performance goals, subject to the following limitations:

(i) The MDPP beneficiary receives no more than 4 virtual make-up sessions within the core services period described in paragraph (c)(2)(i) of this section, of which no more than 2 virtual make-up sessions may be core maintenance sessions; and

(ii) [Reserved]

(e) *MDPP expanded model emergency policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE) as defined in §400.200 of this chapter and during any future 1135 waiver event that CMS determines may disrupts in-person MDPP services (an ''applicable 1135 waiver event''). For purposes of this paragraph (e), ''1135 waiver event'' means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one or more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in §424.205(a) of this chapter, during an 1135 waiver event.

(ii) If CMS determines that an 1135 waiver event may disrupt in-person MDPP services, CMS will communicate such determination for purposes of the policies described in this paragraph (e), to all affected MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and

(c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(3)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, a date-stamped photo or video recording of the beneficiary's weight with the beneficiary visible on the scale, or a recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually, through distance learning or a combination of in-person or distance learning, during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the Extended flexibilities period, a PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the Set of MDPP services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session addresses the same CDC-approved DPP curriculum topic as the regularly scheduled session.

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session.

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week.

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for distance learning sessions.

(E) The MDPP supplier offers virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually.

(F) The MDPP supplier offers to an MDPP beneficiary:

(*1*) Up to 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) Up to 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period.

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by CMS. Upon resumption of the set of MDPP services on an in-person basis, the following paragraphs apply:

(A) Beneficiaries who were receiving MDPP services as of March 31, 2020 whose in-person sessions are suspended due to the PHE as defined in § 400.200 of this chapter may elect to restart the set of MDPP services at the beginning

or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the set of MDPP services at the beginning or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services between January 1, 2021 and December 31, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually can elect to attend ongoing maintenance sessions; and may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

(D) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually, as described in paragraph (e)(2)(i) of this section, are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record.

(E) Beneficiaries may make an election as described in paragraph (e)(3)(v)(A), (B), (C), or (D) of this section, as applicable, only one time per applicable1135 waiver event.

(F) Beneficiary eligibility, as described in paragraph (c)(1)(i) of this section, will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or any intervening time in which a beneficiary has suspended the set of MDPP services. MDPP suppliers will utilize the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements:

(*1*) For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts the set of MDPP services.

(*2*) For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either at the most recent attendance session of record or restarts the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

(vi) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived only for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021.

[81 FR 80552, Nov. 15, 2016; 81 FR 81698, Nov. 18, 2016, as amended at 82 FR 53358, Nov. 15, 2017; 85 FR 19287, Apr. 6, 2020; 85 FR 85027, Dec. 28, 2020; 86 FR 65666, Nov. 19, 2021; 88 FR 79528, Nov. 16, 2023]

Subpart C—Home Health Services Under SMI

§ 410.80 Applicable rules.

Home health services furnished under Medicare Part B are subject to the rules set forth in subpart E of part 409 of this chapter.

Subpart D—Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 410.100 Included services.

Subject to the conditions and limitations set forth in §§ 410.102 and 410.105,

CORF services means the following services furnished to an outpatient of the CORF by personnel that meet the qualifications set forth in § 485.70 of this chapter. Payment for CORF services are made in accordance with § 414.1105.

(a) *Physician's services.* CORF facility physician services are administrative in nature and include consultation with and medical supervision of nonphysician staff, participation in plan of treatment reviews and patient care review conferences, and other medical and facility administration activities. Diagnostic and therapeutic services furnished to an individual CORF patient by a physician in a CORF facility are not CORF physician services. These services, if covered, are physician services under § 410.20 with payment for these services made to the physician in accordance with part 414 subpart B.

(b) *Physical therapy services.* (1) These services include—

(i) Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular and respiratory systems; and.

(ii) Assessment and treatment related to dysfunction caused by illness or injury, and aimed at preventing or reducing disability or pain and restoring lost function.

(2) The establishment of a maintenance therapy program for an individual whose restoration potential has been reached is a physical therapy service; however, maintenance therapy itself is not covered as part of these services.

(c) *Occupational therapy services.* These services include—

(1) Teaching of compensatory techniques to permit an individual with a physical impairment or limitation to engage in daily activities.

(2) Evaluation of an individual's level of independent functioning.

(3) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; and

(4) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(d) *Speech-language pathology services.* These are services for the diagnosis and treatment of speech and language disorders that create difficulties in communication.

(e) *Respiratory therapy services.* (1) Respiratory therapy services are for the assessment, treatment, and monitoring of patients with deficiencies or abnormalities of cardiopulmonary function.

(2) Respiratory therapy services include the following:

(i) Application of techniques for support of oxygenation and ventilation of the patient.

(ii) Therapeutic use and monitoring of gases, mists, and aerosols and related equipment.

(iii) Bronchial hygiene therapy.

(iv) Pulmonary rehabilitation techniques to develop strength and endurance of respiratory muscles and other techniques to increase respiratory function, such as graded activity services; these services include physiologic monitoring and patient education.

(f) *Prosthetic device services.* These services include—

(1) Prosthetic devices (excluding dental devices and renal dialysis machines), that replace all or part of an internal body organ or external body member (including contiguous tissue) or replace all or part of the function of a permanently inoperative or malfunctioning external body member or internal body organ; and

(2) Services necessary to design the device, select materials and components, measure, fit, and align the device, and instruct the patient in its use.

(g) *Orthotic device services.* These services include—

(1) Orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning; and

(2) Services necessary to design the device, select the materials and components, measure, fit, and align the device, and instruct the patient in its use.

(h) *Social and psychological services.* Social and psychological services include the assessment and treatment of an individual's mental and emotional functioning and the response to and

rate of progress as it relates to the individual's rehabilitation plan of treatment, including physical therapy services, occupational therapy services, speech-language pathology services and respiratory therapy services.

(i) *Nursing care services.* Nursing care services include nursing services provided by a registered nurse that are prescribed by a physician and are specified in or directly related to the rehabilitation treatment plan and necessary for the attainment of the rehabilitation goals of the physical therapy, occupational therapy, speech-language pathology, or respiratory therapy plan of treatment.

(j) *Drugs and biologicals.* These are drugs and biologicals that are the following:

(1) Prescribed by a physician and administered by or under the supervision of a physician or by a registered professional nurse; and

(2) Not excluded from Medicare Part B payment for reasons specified in §410.29.

(k) *Supplies and durable medical equipment.* Supplies and durable medical equipment include the following:

(1) Disposable supplies.

(2) Durable medical equipment of the type specified in §410.38 (except for renal dialysis systems) for a patient's use outside the CORF, whether purchased or rented.

(l) *Home environment evaluation.* A home environment evaluation—

(1) Is a single home visit to evaluate the potential impact of the home situation on the patient's rehabilitation goals.

(2) Requires the presence of the patient and the physical therapist, occupational therapist, or speech-language pathologist, as appropriate.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987, as amended at 72 FR 66399, Nov. 27, 2007]

§410.102 Excluded services.

None of the services specified in §410.100 is covered as a CORF service if the service—

(a) Would not be covered as an inpatient hospital service if furnished to a hospital inpatient;

(b) Is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. An example would be services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists.

§410.105 Requirements for coverage of CORF services.

Services specified in §410.100 and not excluded under §410.102 are covered as CORF services if they are furnished by a participating CORF (that is, a CORF that meets the conditions of subpart B of part 485 of this chapter, and has in effect a provider agreement under part 489 of this chapter) and if the following requirements are met:

(a) *Referral and medical history.* The services must be furnished to an individual who is referred by a physician who certifies that the individual needs skilled rehabilitation services, and makes the following information available to the CORF before or at the time treatment is begun:

(1) The individual's significant medical history.

(2) Current medical findings.

(3) Diagnosis(es) and contraindications to any treatment modality.

(4) Rehabilitation goals, if determined.

(b) *When and where services are furnished.* (1) All services must be furnished while the individual is under the care of a physician.

(2) Except as provided in paragraph (b)(3) of this section, the services must be furnished on the premises of the CORF.

(3) *Exceptions.* (i) Physical therapy, occupational therapy, and speech-language pathology services may be furnished away from the premises of the CORF including the individual's home when payment is not otherwise made under Title XVIII of the Act.

(ii) The single home environment evaluation visit specified in §410.100(m) is also covered.

(c) *Plan of treatment.* (1) The service must be furnished under a written plan of treatment that—

(i) Is established and signed by a physician before treatment is begun; and

(ii) Prescribes the type, amount, frequency, and duration of the services to

be furnished, and indicates the diagnosis and anticipated rehabilitation goals.

(2) The plan must be reviewed at least every 60 days for respiratory therapy services and every 90 days for physical therapy, occupational therapy and speech-language pathology services by a facility physician or the referring physician who, when appropriate, consults with the professional personnel providing the services.

(3) The reviewing physician must certify or recertify that the plan is being followed, the patient is making progress in attaining the rehabilitation goals, and the treatment is having no harmful effects on the patient.

(d) *Claims.* Effective for dates of service on and after January 1, 2020 physical therapy or occupational therapy services covered as part of a rehabilitation plan of treatment described in paragraph (c) of this section, as applicable—

(1) Claims for such services furnished in whole or in part by a physical therapist assistant or an occupational therapy assistant must be identified with the inclusion of the respective prescribed modifier; and

(2) Effective for dates of service on and after January 1, 2022, such claims are paid an amount equal to 85 percent of the amount of payment otherwise applicable for the service as defined at section 1834(k) of the Act.

(3) For purposes of this paragraph, ''furnished in whole or in part'' means when the physical therapist assistant or occupational therapy assistant either—

(i) Furnishes all the minutes of a service exclusive of the respective physical therapist or occupational therapist; or

(ii) Except as provided in paragraph (d)(3)(iii) of this section, furnishes a portion of a service, or in the case of a 15-minute (or other time interval) timed code, a portion of a unit of service, separately from the part furnished by the physical or occupational therapist such that the minutes for that portion of a service (or unit of a service) exceed 10 percent of the total time for that service (or unit of a service).

(iii) Paragraph (d)(3)(ii) of this section does not apply when determining whether the prescribed modifier applies to the last 15-minute unit of a service billed for a patient on a treatment day when the physical or occupational therapist provides more than the midpoint of a 15-minute timed code, that is, 8 or more minutes, regardless of any minutes for the same service furnished by the physical therapist assistant or occupational therapy assistant.

(iv) Where there are two remaining 15-minute units to bill of the same service and the physical therapist and the physical therapist assistant or the occupational therapist and the occupational therapy assistant, as applicable, each provided between 9 and 14 minutes, with a total time of at least 23 minutes, one unit of the service is billed with the prescribed modifier for the minutes furnished by the physical therapist assistant or occupational therapy assistant and one unit is billed without the prescribed modifier for the service provided by the physical therapist or occupational therapist.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8841, Mar. 1, 1991; 72 FR 66400, Nov. 27, 2007; 77 FR 69363, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 84 FR 63191, Nov. 15, 2019; 86 FR 65666, Nov. 19, 2021]

Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services and Intensive Outpatient Services

§ 410.110 Requirements for coverage of partial hospitalization services by CMHCs.

Medicare part B covers partial hospitalization services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(e)(1) of this subchapter; and

(c) Furnished under a plan of treatment that meets the requirements of § 424.24(e)(2) of this subchapter.

[59 FR 6577, Feb. 11, 1994]

§ 410.111 Requirements for coverage of intensive outpatient services in CMHCs.

Medicare part B covers intensive outpatient services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(d)(1) of this chapter; and

(c) Furnished under a plan of treatment that meets the requirements of § 424.24(d)(2) of this chapter.

[88 FR 82179, Nov. 22, 2023]

Subpart F [Reserved]

Subpart G—Medical Nutrition Therapy

SOURCE: 66 FR 55331, Nov. 1, 2001, unless otherwise noted.

§ 410.130 Definitions.

For the purposes of this subpart, the following definitions apply:

Chronic renal insufficiency means the stage of renal disease associated with a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate [GFR] 15–59 ml/min/1.73m^2).

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism .

Episode of care means services covered in a 12-month time period when coordinated with initial diabetes self-management training (DSMT) and one calendar year for each year thereafter, starting with the assessment and including all covered interventions based on referral(s) from a physician as specified in § 410.132(c). The time period covered for gestational diabetes extends only until the pregnancy ends.

Medical nutrition therapy services means nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action (including a physician within the meaning of section of 1101(a)(7) of the Act).

Renal disease means chronic renal insufficiency, end-stage renal disease when dialysis is not received, or the medical condition of a beneficiary for 36 months after kidney transplant.

[66 FR 55331, Nov. 1, 2001, as amended at 68 FR 63261, Nov. 7, 2003; 86 FR 65667, Nov. 19, 2021; 88 FR 79529, Nov. 16, 2023]

§ 410.132 Medical nutrition therapy.

(a) *Conditions for coverage of MNT* services. Medicare Part B pays for MNT services provided by a registered dietitian or nutrition professional as defined in § 410.134 when the beneficiary is referred for the service by a physician.

(b) *Limitations on coverage of MNT services.* (1) MNT services based on a diagnosis of renal disease as described in this subpart are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act.

(2) A beneficiary may only receive the maximum number of hours covered under the DSMT benefit for both DSMT and MNT during the initial DSMT training period unless additional hours are determined to be medically necessary under the national coverage determination process.

(3) In years when the beneficiary is eligible for MNT and follow-up DSMT, the beneficiary may only receive the maximum number of hours covered under MNT unless additional hours are determined to be medically necessary under the national coverage determination process.

(4) If a beneficiary has both diabetes and renal disease, the beneficiary may only receive the maximum number of hours covered under the renal MNT benefit in one episode of care unless he or she is receiving initial DSMT services, in which case the beneficiary would receive whichever is greater.

(5) An exception to the maximum number of hours in paragraphs (b)(2), (3), and (4) of this section may be made when a physician determines that

there is a change of diagnosis, medical condition, or treatment regimen related to diabetes or renal disease that requires a change in MNT during an episode of care.

(c) *Referrals.* Referral may only be made by a physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this subpart with documentation noted by a referring physician in the beneficiary's medical record.

[66 FR 55331, Nov. 1, 2001, as amended at 72 FR 66400, Nov. 27, 2007; 86 FR 65667, Nov. 19, 2021]

§ 410.134 Provider qualifications.

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. ''Registered dietitian or nutrition professional'' means an individual who, on or after December 22, 2000:

(a) Holds a bachelor's or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics accredited by an appropriate national accreditation organization recognized for this purpose.

(b) Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional.

(c) Is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed. In a State that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a ''registered dietitian'' by the Commission on Dietetic Registration or its successor organization, or meets the requirements of paragraphs (a) and (b) of this section.

(d) *Exceptions.* (i) A dietitian or nutritionist licensed or certified in a State as of December 21, 2000 is not required to meet the requirements of (a) and (b) of this section.

(ii) A ''registered dietitian'' in good standing, as recognized by the Commission of Dietetic Registration or its successor organization, is deemed to have met the requirements of (a) and (b) of this section.

[66 FR 55331, Nov. 1, 2001; 67 FR 20684, Apr. 26, 2002]

Subpart H—Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

SOURCE: 65 FR 83148, Dec. 29, 2000, unless otherwise noted.

§ 410.140 Definitions.

For purposes of this subpart, the following definitions apply:

ADA stands for the American Diabetes Association.

Approved entity means an individual, physician, or entity accredited by an approved organization as meeting one of the sets of quality standards described in § 410.144 and approved by CMS under § 410.141(e) to furnish training.

Deemed entity means an individual, physician, or entity accredited by an approved organization, but that has not yet been approved by CMS under § 410.145(b) to furnish training.

Diabetes means diabetes mellitus, a condition of abnormal glucose metabolism.

NSDSMEP stands for the National Standards for Diabetes Self Management Education Programs.

Organization means a national accreditation organization.

Rural means an area that meets one of the following conditions:

(1) Is not urbanized (as defined by the Bureau of the Census) and that is designated by the chief executive officer of the State, and certified by the Secretary, as an area with a shortage of personal health services.

(2) Is designated by the Secretary either as an area with a shortage of personal health services or as a health professional shortage area.

(3) Is designated by the Indian Health Service as a health service delivery area as defined in § 36.15 of this title.

Training means outpatient diabetes self-management training.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011, 88 FR 79529, Nov. 16, 2023]

§410.141 Outpatient diabetes self-management training.

(a) *General rule.* Medicare Part B covers training defined in §410.140 if all of the conditions and requirements of this subpart are met.

(b) *Conditions for coverage.* The training must meet the following conditions:

(1) *Training orders.* Following an evaluation of the beneficiary's need for the training, the training is ordered by the physician (or qualified nonphysician practitioner) (as defined in §410.32(a)(2)) treating the beneficiary's diabetes.

(2) *Plan of care.* It is included in a comprehensive plan of care established by the physician (or qualified nonphysician practitioner) treating the beneficiary for diabetes that meets the following requirements:

(i) Describes the content, number of sessions, frequency, and duration of the training as written by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(ii) Contains a statement specified by CMS and signed by the physician (or qualified nonphysician practitioner) managing the beneficiary's diabetic condition. By signing this statement, the physician (or qualified nonphysician practitioner) certifies that he or she is managing the beneficiary's diabetic condition and the training described in the plan of care is needed to ensure therapy compliance or to provide the beneficiary with the skills and knowledge to help manage the beneficiary's diabetes. The physician's (or qualified nonphysician practitioner's) statement must identify the beneficiary's specific medical conditions (described in paragraph (d) of this section) that the training will address.

(iii) Provides that any changes to the plan of care are signed by the physician (or qualified nonphysician practitioner) treating the beneficiary.

(iv) Is incorporated into the approved entity's medical record for the beneficiary and is made available, upon request, to CMS.

(3) *Reasonable and necessary.* It is reasonable and necessary for treating or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) Types and frequency of training—(1) Initial training—

General rule. (i) Medicare Part B covers initial training that meets the following conditions:

(A) Is furnished to a beneficiary who has not previously received initial training under this benefit.

(B) Is furnished within a continuous 12-month period.

(C) Does not exceed a total of 10 hours.

(D) Except as permitted under paragraph (c)(1)(ii) of this section, 9 hours of the training are furnished in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

(E) Is furnished in increments of no less than one-half hour.

(F) May include 1 hour of individual training for an assessment of the beneficiary's training needs.

(ii) *Exception.* Medicare covers training on an individual basis for a Medicare beneficiary who meets any of the following conditions:

(A) No group session is available within 2 months of the date the training is ordered.

(B) The beneficiary's physician (or qualified nonphysician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing, or language limitations that will hinder effective participation in a group training session.

(2) *Follow-up training.* After receiving the initial training described in paragraph (c)(1) of this section, Medicare covers follow-up training that meets the following conditions:

(i) Consists of no more than 2 hours individual or group training for a beneficiary each year.

(ii) Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries.

(iii) Is furnished any time in a calendar year following the year in which the beneficiary completes the initial training.

(iv) Is furnished in increments of no less than one-half hour.

(v) The physician (or qualified nonphysician practitioner) treating the

beneficiary must document, in the referral for training and the beneficiary's medical record, the specific medical condition (described in paragraph (d) of this section) that the follow-up training must address.

(d) *Beneficiaries who may be covered.* Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes.

(e) *Who may furnish services.* Training may be furnished by a physician, individual, or entity that meets the following conditions:

(1) Furnishes other services for which direct Medicare payment may be made.

(2) May properly receive Medicare payment under § 424.73 or § 424.80 of this chapter, which set forth prohibitions on assignment and reassignment of benefits.

(3) Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under § 410.142 to meet one of the sets of quality standards described in § 410.144.

(4) Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at § 410.146.

[65 FR 83148, Dec. 29, 2000, as amended at 68 FR 63261, Nov. 7, 2003; 76 FR 73471, Nov. 28, 2011]

§ 410.142 CMS process for approving national accreditation organizations.

(a) *General rule.* CMS may approve and recognize a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals with diabetes to accredit entities to furnish training.

(b) *Required information and materials.* An organization requesting CMS's approval and recognition of its accreditation program must furnish to CMS the following information and materials:

(1) The requirements and quality standards that the organization uses to accredit entities to furnish training.

(2) If an organization does not use the CMS quality standards or the NSDSMEP quality standards described in § 410.144(a) or (b), a detailed comparison including a crosswalk between the organization's standards and the CMS quality standards described in § 410.144(a).

(3) Detailed information about the organization's accreditation process, including all of the following information:

(i) Frequency of accreditation.

(ii) Copies of accreditation forms, guidelines, and instructions to evaluators.

(iii) Descriptions of the following:

(A) The accreditation review process and the accreditation status decision making process.

(B) The procedures used to notify a deemed entity of deficiencies in its outpatient diabetes self-management training program and procedures to monitor the correction of those deficiencies.

(C) The procedures used to enforce compliance with the accreditation requirements and standards.

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

(i) The education and experience requirements for the individuals who perform evaluations.

(ii) The content and frequency of continuing education furnished to the individuals who perform evaluations.

(iii) The process used to monitor the performance of individuals who perform evaluations.

(iv) The organization's policies and practices for participation in the accreditation process by an individual who is professionally or financially affiliated with the entity being evaluated.

(5) A description of the organization's data management and analysis system for its accreditation activities and 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 an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

(7) A description of the organization's policies and procedures for withholding

or removing a certificate of accreditation for failure to meet the 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 will serve as a basis for accreditation if CMS approves the organization.

(9) A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

(10) The name and address of each person with an ownership or control interest in the organization.

(11) Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

(12) A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

(13) A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§410.142 through 410.146.

(14) Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

(c) *Onsite visit.* CMS may visit the prospective organization's offices to verify information in the organization's application, including, but not limited to, review of documents, and interviews with the organization's staff.

(d) *Notice and comment*—(1) *Proposed notice.* CMS publishes a proposed notice in the FEDERAL REGISTER announcing its intention to approve an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training. The notice includes the following information:

(i) The basis for approving the organization.

(ii) A description of how the organization's accreditation program applies and enforces quality standards that have been determined by CMS to meet or exceed the CMS quality standards described in §410.144(a) or how the organization would use the NSDSMEP quality standards described in §410.144(b).

(iii) An opportunity for public comment.

(2) *Final notice.* (i) After considering public comments CMS receives on the proposed notice, it publishes a final notice in the FEDERAL REGISTER indicating whether it has approved an organization's request for CMS approval and recognition of its accreditation program and the standards it uses to accredit entities to furnish training.

(ii) If CMS approves the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(e) *Criteria CMS uses to approve national accreditation organizations.* In deciding to approve and recognize an organization's accreditation program to accredit entities to furnish training, CMS considers the following criteria:

(1) The organization uses and enforces quality standards that CMS has determined meet or exceed the CMS quality standards described in §410.144(a), or uses the NSDSMEP quality standards described in §410.144(b).

(2) The organization meets the requirements for approved organizations in §410.143.

(3) The organization is not owned or controlled by the entities it accredits, as defined in §413.17(b)(2) or (b)(3), respectively, of this chapter.

(4) The organization does not accredit any entity it owns or controls.

(f) *Notice of CMS's decision.* CMS notifies the prospective organization in writing of its decision. The notice includes the following information:

(1) Statement of approval or denial.

(2) If approved, the expiration date of CMS's approval and recognition of the accreditation program.

(3) If denied, the rationale for the denial and the reconsideration and reapplication procedures.

(g) *Reconsideration of adverse decision.* An organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may request reconsideration of CMS's decision in accordance with part 488 subpart D of this chapter.

(h) *Request for approval following denial.* (1) Except as provided in paragraph (h)(2) of this section, an organization that has received CMS's notice of denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training may submit a new request to CMS if it meets the following conditions:

(i) Has revised its accreditation program to correct the deficiencies CMS noted in its denial notice.

(ii) Demonstrates, through documentation, the use of one of the sets of quality standards described in § 410.144.

(iii) Resubmits the application in its entirety.

(2) For an organization that has requested reconsideration of CMS's denial of its request for CMS approval and recognition of its accreditation program to accredit entities to furnish training, CMS will not consider the organization's new request until all administrative proceedings on the previous request have been completed.

(i) *Withdrawal.* An organization requesting CMS approval and recognition of its accreditation program to accredit entities may withdraw its application at any time.

(j) *Applying for continued CMS approval.* At least 6 months before the expiration of CMS's approval and recognition of the organization's program, an organization must request from CMS continued approval and recognition.

(k) *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 is subject to the requirements set out at § 488.5(f) of this chapter.

[65 FR 83148, Dec. 29, 2000, as amended at 87 FR 25427, Apr. 29, 2022]

§ 410.143 Requirements for approved accreditation organizations.

(a) *Ongoing responsibilities of an approved accreditation organization.* An organization approved and recognized by CMS must undertake the following activities on an ongoing basis:

(1) Provide to CMS in writing, on a monthly basis, all of the following:

(i) Copies of all accreditation decisions and any accreditation-related information that CMS may require (including corrective action plans and summaries of unmet quality standards described in § 410.144).

(ii) Notice of all complaints related to approved entities.

(iii) Within 30 days of taking remedial or adverse action (including revocation, withdrawal, or revision of an approved entity's deemed status) against an approved entity, information describing the remedial or adverse action and the circumstances that led to taking the action.

(iv) Notice of any proposed changes in its accreditation standards and requirements or evaluation process. If an organization implements changes without CMS approval (other than changes to the NSDSMEP quality standards described in § 410.144(b)), CMS may withdraw its approval and recognition of the organization's accreditation program.

(2) If an organization does not use the NSDSMEP quality standards described in § 410.144(b), and wishes to change its quality standards that CMS previously approved, the organization must submit its plan to alter its quality standards and include a crosswalk between the set of quality standards described in § 410.144 and the organization's revised standards. If an organization implements changes in its quality standards without CMS approval, CMS may withdraw its approval and recognition of the organization's accreditation program.

(3) If CMS notifies an organization that uses the CMS quality standards described in § 410.144(a) that it has changed the CMS quality standards,

the organization must meet the following requirements:

(i) Submit to CMS, within 30 days of CMS's notification of a change in the quality standards, its organization's plan to alter its quality standards to conform to the revised quality standards described in §410.144(a).

(ii) Implement the changes to its accreditation program by the implementation date specified in CMS's notification of the changes in the quality standards.

(b) *CMS oversight of approved national accreditation organizations.* CMS, or its agent, performs oversight activities to ensure that an approved organization and the entities the organization accredits continue to meet a set of quality standards described in §410.144. CMS (or its agent) uses the following procedures:

(1) *Equivalency review.* CMS compares the organization's standards and its application and enforcement of its standards to a set of quality standards (described in §410.144) and processes when any of the following conditions exist:

(i) CMS imposes new requirements or changes its process for approving and recognizing an organization.

(ii) Except for an organization that uses the NSDSMEP quality standards, the organization proposes to adopt new standards or changes its accreditation process.

(iii) The organization reapplies to CMS for continuation of its approval and recognition by CMS of its program to accredit entities to furnish training.

(2) *Validation reviews.* CMS validates an organization's accreditation process by conducting evaluations of approved entities accredited by the organization and comparing its results to the results of the organization's evaluation of the approved entities.

(3) *Onsite inspections.* CMS may conduct an onsite inspection of the organization's operations and offices to verify information 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 documentation of meetings concerning the accreditation process, evaluating accreditation results or the accreditation status decision making process, and interviewing the organization's staff.

(4) *Withdrawal of CMS approval and recognition.* (i) CMS gives an organization written notice of CMS's intent to withdraw its approval and recognition of the organization's program to accredit entities if CMS determines through an equivalency review, validation review, onsite inspection, or CMS's daily experience with the organization that any of the following conditions exist:

(A) Except for those accrediting organizations using quality standards in §410.144(b), the quality standards that the organization applies and enforces do not meet or exceed the CMS quality standards described in §410.144(a).

(B) The organization has failed to meet the requirements for accreditation in §§410.142 through 410.144.

(ii) *Request for reconsideration.* An organization may request a reconsideration of CMS's decision to withdraw its approval and recognition of the organization in accordance with part 488, subpart D of this chapter.

§410.144 Quality standards for deemed entities.

An organization approved and recognized by CMS may accredit an entity to meet one of the following sets of quality standards:

(a) *CMS quality standards.* Standards prescribed by CMS, which include the following:

(1) *Organizational structure.* (i) Provides the educational resources to support the programs offered and the beneficiaries served, including adequate space, personnel, budget, instructional materials, confidentiality, privacy, and operational support.

(ii) Defines clearly and documents the organizational relationships, lines of authority, staffing, job descriptions, and operational policies.

(iii) Maintains a written policy that affirms education as an integral component of diabetes care.

(iv) Includes in its operational policies, specific standards and procedures identifying the amount of collaborative, interactive, skill-based training methods and didactic training methods furnished to the beneficiary.

(v) Assesses the service area to define the target population in order to appropriately allocate personnel and resources.

(vi) Identifies in its operational policies, the minimal amount that each team member must be involved in the following:

(A) Development of training materials.

(B) Instruction of beneficiaries.

(2) *Environment.* Maintains a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of all patients and that meets all applicable fire protection and life safety codes.

(3) *Program staff.* (i) Requires a program coordinator who is responsible for program planning, implementation, and evaluation.

(ii) Requires nonphysician professional staff to obtain 12 hours of continuing diabetes education concerning educational principles and behavior change strategies every 2 years.

(4) *Team approach.* (i) Except as provided in paragraph (a)(4)(ii) of this section for a rural area, furnishes services using a multidisciplinary instructional team that meets the following requirements:

(A) The team includes at least a registered dietitian, as recognized under State law, and a certified diabetes educator (CDE), certified by a qualified organization that has registered with CMS, who have didactic experience and knowledge of diabetes clinical and educational issues. (If the team includes a registered nurse, an approved entity may delay implementation of the requirement for a CDE until February 27, 2004.)

(B) The team is qualified to teach the training content areas required in paragraph (a)(5) of this section.

(C) All appropriate team members must be present during the portion of the training for which they are responsible and must directly furnish the training within the scope of their practices.

(ii) In a rural area, an individual who is qualified as a registered dietitian and as a CDE that is currently certified by an organization approved by CMS (or until February 27, 2004 an individual who is qualified as a registered dietitian and as a registered nurse) may furnish training and is deemed to meet the multidisciplinary team requirement in paragraph (a)(4)(i) of this section.

(5) Training content. Offers training and is capable of meeting the needs of its patients on the following subjects:

(i) Diabetes overview/pathophysiology of diabetes.

(ii) Nutrition.

(iii) Exercise and activity.

(iv) Diabetes medications (including skills related to the self-administration of injectable drugs).

(v) Self-monitoring and use of the results.

(vi) Prevention, detection, and treatment of acute complications.

(vii) Prevention, detection, and treatment of chronic complications.

(viii) Foot, skin, and dental care.

(ix) Behavior change strategies, goal setting, risk factor reduction, and problem solving.

(x) Preconception care, pregnancy, and gestational diabetes.

(xi) Relationships among nutrition, exercise, medication, and blood glucose levels.

(xii) Stress and psychosocial adjustment.

(xiii) Family involvement and social support.

(xiv) Benefits, risks, and management options for improving glucose control.

(xv) Use of health care systems and community resources.

(6) *Training methods.* (i) Offers individual and group instruction for effective training.

(ii) Uses instructional methods and materials that are appropriate for the target population, and participants being served.

(iii) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.

(7) *Review of plan of care and goals.* (i) Reviews each beneficiary's plan of care.

(ii) Develops and updates an individual assessment, in collaboration with each beneficiary, that includes relevant medical history, present

health status, health service or resource utilization, risk factors, diabetes knowledge and skills, cultural influences, health beliefs and attitudes, health behaviors and goals, support systems, barriers to learning, and socioeconomic factors.

(iii) Based on the assessment, develops, in collaboration with each beneficiary, an individual education plan. Includes in the education plan, the goals for education, the periodic updates, the specific amount of interactive, collaborative, skill-based training methods and didactic training methods that have been and will be furnished.

(iv) Documents the results, including assessment, intervention, evaluation and follow-up in the beneficiary's medical record.

(v) Forwards a copy of the documentation in paragraph (a)(7)(ii) through (iv) of this section to the referring physician (or qualified nonphysician practitioner).

(vi) Periodically updates the beneficiary's referring physician (or qualified nonphysician practitioner) about the beneficiary's educational status.

(8) Educational intervention. Offers appropriate and timely educational intervention based on referral from the beneficiary's physician (or qualified nonphysician practitioner) and based on periodic reassessments of health status, knowledge, skills, attitudes, goals, and self-care behaviors.

(9) *Performance measurement and quality improvement.* Establishes and maintains an effective internal performance measurement and quality improvement program that focuses on maximizing outcomes by improving patient safety and quality of care. The program must meet the following requirements:

(i) Stresses health outcomes (for example, improved beneficiary diabetes control, beneficiary understanding, or beneficiary compliance) and provides for the collection, analysis, and reporting of data that permits measurement of performance outcomes, or other quality indicators.

(ii) Requires an entity to take the following actions:

(A) Evaluate itself on an annual basis as to its effectiveness in using performance measures.

(B) Improve its performance on at least one outcome or quality indicator each year.

(10) *Quality improvement.* Has an agreement with a QIO to participate in quality improvement projects defined by the QIO, or if a program elects not to participate in a QIO project, it must be able to demonstrate a level of achievement through a project of its own design that is comparable to or better than the achievement to be expected from participation in the QIO quality improvement project.

(b) *The National Standards for Diabetes Self-Management Education Programs.* The set of quality standards contained in the NSDSMEP or any NSDSMEP standards subsequently revised.

(c) *Standards of a national accreditation organization that represents individuals with diabetes.* Standards that meet or exceed the CMS quality standards described in paragraph (a) of this section that have been developed by a national organization (and approved by CMS) that is either a nonprofit or not-for-profit organization with demonstrated experience in representing the interest of individuals, including health care professionals and Medicare beneficiaries, with diabetes.

§410.145 Requirements for entities.

(a) *Deemed entities.* (1) Except as permitted in paragraph (a)(2) of this section, an entity may be deemed to meet a set of quality standards described in §410.144 if the following conditions are met:

(i) The entity has submitted necessary documentation and is fully accredited (and periodically reaccredited) by an organization approved by CMS under §410.142.

(ii) The entity is not accredited by an organization that owns or controls the entity.

(2) Before August 27, 2002 CMS may deem an entity to meet the NSDSMEP quality standards described in §410.144(b), if the entity provides the Medicare contractor that will process its claims with a copy of a current certificate the entity received from the ADA that verifies the training program it furnishes meets the NSDSMEP quality standards described in §410.144(b).

(b) *Approved entities.* An entity may be approved to furnish training if the entity meets the following conditions:

(1) Before submitting a claim for Medicare payment, forwards a copy of its certificate or proof of accreditation from an organization approved by CMS under § 410.142 indicating that the entity meets a set of quality standards described in § 410.144, or before August 27, 2002, submits documentation of its current ADA recognition status.

(2) Agrees to submit to evaluation (including onsite inspections) by CMS (or its agent) to validate its approved organization's accreditation process.

(3) Authorizes its approved organization to release to CMS a copy of its most recent accreditation evaluation, and any accreditation-related information that CMS may require.

(4) At a minimum, allows the QIO (under a contract with CMS) access to beneficiary or group training records.

(c) *Effective dates*—(1) *Deemed to meet quality standards.* Except as permitted in paragraph (c)(2) of this section, the date on which an entity is deemed to meet a set of quality standards described in § 410.144 is the later of one of the following dates:

(i) The date CMS approves and recognizes the accreditation organization to accredit entities to furnish training.

(ii) The date an organization accredits the entity to meet a set of quality standards described in § 410.144.

(2) *Approved to furnish training.* CMS covers the training furnished by an entity beginning on the later of one of the following dates:

(i) The date CMS approves the deemed entity as meeting the conditions for coverage in § 410.141(e).

(ii) The date the entity is deemed to meet a set of quality standards described in § 410.144.

(d) *Removal of approved status*—(1) *General rule.* CMS removes an entity's approved status for any of the following reasons:

(i) CMS determines, on the basis of its own evaluation or the results of the accreditation evaluation, that the entity does not meet a set of quality standards described in § 410.144.

(ii) CMS withdraws its approval of the organization that deemed the entity to meet a set of quality standards described in § 410.144.

(iii) The entity fails to meet the requirements of paragraphs (a) and (b) of this section.

(2) *Effective date.* The effective date of CMS's removal of an entity's approved status is 60 days after the date of CMS's notice to the entity.

§ 410.146 Diabetes outcome measurements.

(a) *Information collection.* An approved entity must collect and record in an organized systematic manner the following patient assessment information at least on a quarterly basis for a beneficiary who receives training under § 410.141:

(1) Medical information that includes the following:

(i) Duration of the diabetic condition.

(ii) Use of insulin or oral agents.

(iii) Height and weight by date.

(iv) Results and date of last lipid test.

(v) Results and date of last HbA1C.

(vi) Information on self-monitoring (frequency and results).

(vii) Blood pressure with the corresponding dates.

(viii) Date of the last eye exam.

(2) Other information that includes the following:

(i) Educational goals.

(ii) Assessment of educational needs.

(iii) Training goals.

(iv) Plan for a follow-up assessment of achievement of training goals between 6 months and 1 year after the beneficiary completes the training.

(v) Documentation of the training goals assessment.

(b) *Follow-up assessment information.* An approved entity may obtain information from the beneficiary's survey, primary care physician contact, and follow-up visits.

Subpart I—Payment of SMI Benefits

SOURCE: 51 FR 41339, Nov. 14, 1986, unless otherwise noted. Redesignated at 59 FR 6577, Feb. 11, 1994.

§ 410.150 To whom payment is made.

(a) *General rules.* (1) Any SMI enrollee is, subject to the conditions, limitations, and exclusions set forth in this part and in parts 405, 416 and 424 of this chapter, entitled to have payment made as specified in paragraph (b) of this section.

(2) The services specified in paragraphs (b)(5) through (b)(14) of this section must be furnished by a facility that has in effect a provider agreement or other appropriate agreement to participate in Medicare.

(b) *Specific rules.* Subject to the conditions set forth in paragraph (a) of this section, Medicare Part B pays as follows:

(1) To the individual, or to a physician or other supplier on the individual's behalf, for medical and other health services furnished by the physician or other supplier.

(2) To a nonparticipating hospital on the individual's behalf for emergency outpatient services furnished by the hospital, in accordance with subpart G of part 424 of this chapter.

(3) To the individual, for emergency outpatient services furnished by a nonparticipating hospital, in accordance with § 424.53 of this chapter.

(4) To the individual, for physicians' services and ambulance services furnished outside the United States in accordance with § 424.53 of this chapter.

(5) To a provider on the individual's behalf for medical and other health services furnished by the provider (or by others under arrangements made with them by the provider).

(6) To a home health agency on the individual's behalf for home health services furnished by the home health agency.

(7) To a clinic, rehabilitation agency, or public health agency on the individual's behalf for outpatient physical therapy or speech pathology services furnished by the clinic or agency (or by others under arrangements made with them by the clinic or agency).

(8) To a rural health clinic or Federally qualified health center on the individual's behalf for rural health clinic or Federally qualified health center services furnished by the rural health clinic or Federally qualified health center, respectively.

(9) To an ambulatory surgical center (ASC) on the individual's behalf for covered ambulatory surgical center facility services that are furnished in connection with surgical procedures performed in an ASC, as provided in part 416 of this chapter.

(10) To a comprehensive outpatient rehabilitation facility (CORF) on the individual's behalf for comprehensive outpatient rehabilitation facility services furnished by the CORF.

(11) To a renal dialysis facility, on the individual's behalf, for institutional or home dialysis services, supplies, and equipment furnished by the facility.

(12) To a critical access hospital (CAH) on the individual's behalf for outpatient CAH services furnished by the CAH.

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services or intensive outpatient services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

(14) To an SNF for services (other than those described in § 411.15(p)(2) of this chapter) that it furnishes to a resident (as defined in § 411.15(p)(3) of this chapter) of the SNF who is not in a covered Part A stay.

(15)(i) Prior to January 1, 2022, to the qualified employer of a physician assistant for professional services furnished by the physician assistant and for services and supplies provided incident to his or her services. Payment is made to the employer of a physician assistant regardless of whether the physician assistant furnishes services under a W–2, employer-employee employment relationship, or whether the physician assistant is an independent contractor who receives a 1099 reflecting the relationship. Both types of relationships must conform to the appropriate guidelines provided by the Internal Revenue Service. A qualified employer is not a group of physician assistants that incorporate to bill for their services. Payment is made only if no facility or other provider charges or is paid any amount for services furnished by a physician assistant.

(ii) Effective on or after January 1, 2022, payment is made to a physician

assistant for professional services furnished by a physician assistant in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of professional services of the physician assistant.

(16) To a nurse practitioner or clinical nurse specialist for professional services furnished by a nurse practitioner or clinical nurse specialist in all settings in both rural and nonrural areas and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges, or is paid, any amount for the furnishing of the professional services of the nurse practitioner or clinical nurse specialist.

(17) To a clinical psychologist on the individual's behalf for clinical psychologist services and for services and supplies furnished as an incident to his or her services.

(18) To a clinical social worker on the individual's behalf for clinical social worker services.

(19) To a participating HHA, for home health services (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who at the time the item or service is furnished is under a plan of care of an HHA (without regard to whether the item or service is furnished by the HHA directly, under arrangement with the HHA, or under any other contracting or consulting arrangement).

(20) To a certified nurse-midwife for professional services furnished by the certified nurse-midwife in all settings and for services and supplies furnished incident to those services. Payment is made only if no facility or other provider charges or is paid any amount for the furnishing of the professional services of the certified nurse-midwife.

(21) To a marriage and family therapist on the individual's behalf for marriage and family therapist services.

(22) To a mental health counselor on the individual's behalf for mental health counseling services.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 24981, June 12, 1992; 58 FR 30668, May 26, 1993; 59 FR 6577, Feb. 11, 1994; 63 FR 20129, Apr. 23, 1998; 63 FR 26308, May 12, 1998; 63 FR 58909, Nov. 2, 1998; 65 FR 41211, July 3, 2000; 66 FR 39599, July 31, 2001; 75 FR 73615, Nov. 29, 2010; 86 FR 65667, Nov. 19, 2021; 88 FR 79529, Nov. 16, 2023; 88 FR 82179, Nov. 22, 2023]

§ 410.152 Amounts of payment.

(a) *General provisions*—(1) *Exclusion from incurred expenses.* As used in this section, ''incurred expenses'' are expenses incurred by an individual, during his or her coverage period, for covered Part B services, excluding the following:

(i) Expenses incurred for services for which the beneficiary is entitled to have payment made under Medicare Part A or would be so entitled except for the application of the Part A deductible and coinsurance requirements.

(ii) Expenses incurred in meeting the Part B blood deductible (§ 410.161).

(iii) In the case of services payable under a formula that takes into account reasonable charges, reasonable costs, customary charges, customary (insofar as reasonable) charges, charges related to reasonable costs, fair compensation, a pre-treatment prospective payment rate, or a standard overhead amount, or any combination of two or more of these factors, expenses in excess of any factor taken into account under that formula.

(iv) Expenses in excess of the outpatient mental health treatment limitation described in § 410.155.

(v) In the case of expenses incurred for outpatient physical therapy services including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.60(e). In the case of expenses incurred for outpatient occupational therapy including speech-language pathology services, the expenses excluded are from the incurred expenses under § 410.59(e).

(2) *Other applicable provisions.* Medicare Part B pays for incurred expenses the amounts specified in paragraphs (b) through (k) of this section, subject to the following:

(i) The principles and procedures for determining reasonable costs and reasonable charges and the conditions for Medicare payment, as set forth in parts 405 (subparts E and X), 413, and 424 of this chapter.

(ii) The Part B annual deductible (§410.160).

(iii) The special rules for payment to health maintenance organizations (HMOs), health care prepayment plans (HCPPs), and competitive medical plans (CMPs) that are set forth in part 417 of this chapter. (A prepayment organization that does not qualify as an HMO, CMP, or HCPP is paid in accordance with paragraph (b)(4) of this section.)

(b) *Basic rules for payment.* Except as specified in paragraphs (c) through (h) and (m) and (n) of this section, Medicare Part B pays the following amounts:

(1) For services furnished by, or under arrangements made by, a provider other than a nominal charge provider, whichever of the following is less:

(i) 80 percent of the reasonable cost of the services.

(ii) The reasonable cost of, or the customary charges for, the services, whichever is less, minus 20 percent of the customary (insofar as reasonable) charges for the services.

(2) For services furnished by, or under arrangements made by, a nominal charge provider, 80 percent of fair compensation.

(3) For emergency outpatient hospital services furnished by a nonparticipating hospital that is eligible to receive payment for those services under subpart G of part 424 of this chapter, the amount specified in paragraph (b)(1) of this section.

(4) For services furnished by a person or an entity other than those specified in paragraphs (b)(1) through (b)(3) of this section, 80 percent of the reasonable charges or 80 percent of the payment amount computed on any other payment basis for the services.

(c) *Amount of payment: Home health services other than durable medical equipment (DME).* For home health services other than DME furnished by, or under arrangements made by, a participating HHA, Medicare Part B pays the following amounts:

(1) For services furnished by an HHA that is a nominal charge provider, 100 percent of fair compensation.

(2) For services furnished by an HHA that is not a nominal charge provider, the lesser of the reasonable cost of the services and the customary charges for the services.

(d) *Amount of payment: DME furnished as a home health service*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section—

(i) For DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 80 percent of fair compensation.

(ii) For DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays the lesser of the following:

(A) 80 percent of the reasonable cost of the service.

(B) The reasonable cost of, or the customary charge for, the service, whichever is less, minus 20 percent of the customary (insofar as reasonable) charge for the service.

(2) *Exception.* If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for new equipment—

(i) For used DME furnished by an HHA that is a nominal charge provider, Medicare Part B pays 100 percent of fair compensation.

(ii) For used DME furnished by an HHA that is not a nominal charge provider, Medicare Part B pays 100 percent of the reasonable cost of, or the customary charge for, the services, whichever is less.

(e) *Amount of payment: Renal dialysis services, supplies, and equipment.* Effective for services furnished on or after August 1, 1983, Medicare Part B pays for the institutional dialysis services specified in §409.250 and the home dialysis services, supplies, and equipment specified in §409.252, as follows:

(1) Except as provided in paragraph (d)(2) of this section, 80 percent of the per treatment prospective reimbursement rate established under §413.170 of

this chapter, for outpatient maintenance dialysis furnished by ESRD facilities approved in accordance with part 494 of this chapter.

(2) *Exception.* If a home dialysis patient elects to obtain home dialysis supplies or equipment (or both) from a party other than an approved ESRD facility, payment is in accordance with paragraph (b)(4) of this section.

(f) *Amount of payment: Rural health clinic (RHC) and Federally qualified health center (FQHC) services.* Medicare Part B pays, for services by a participating RHC or FQHC that is authorized to bill under the reasonable cost system, 80 percent of the costs determined under subpart X of part 405 of this chapter, to the extent those costs are reasonable and related to the cost of furnishing RHC or FQHC services or reasonable on the basis of other tests specified by CMS.

(g) *Amount of payment: Used durable medical equipment furnished by otherthan an HHA.* Medicare Part B pays the following amounts for used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment:

(1) For used DME furnished by, or under arrangements made by, a nominal charge provider, 100 percent of fair compensation.

(2) For used DME furnished by or under arrangements made by a provider that is not a nominal charge provider, 100 percent of the reasonable cost of the service or the customary charge for the service, whichever is less.

(3) For used DME furnished by other than a provider, 100 percent of the reasonable charge.

(h) *Amount of payment: Preventive vaccine administration.* For the administration of the preventive vaccines described in paragraph (l)(1) of this section, as furnished by providers described in §§ 409.100 and 410.150 of this subchapter, Medicare Part B pays the following amounts, except as otherwise provided under this subchapter:

(1) Effective January 1, 2022, for administration of an influenza, hepatitis B or pneumococcal vaccine, $30 per dose.

(2) For the administration of a COVID–19 vaccine:

(i) Effective January 1, 2022, for administration of a COVID–19 vaccine, $40 per dose.

(ii) For services furnished on or after January 1 of the year following the year in which the Secretary ends the March 27, 2020 Emergency Use Authorization declaration for drugs and biologicals (issued at 85 FR 18250) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), for administration of a COVID–19 vaccine, an amount equal to the amount that would be paid for the administration of a preventive vaccine described in paragraph (h)(1) of this section.

(3) Subject to conditions specified in this paragraph, in addition to the payment described in paragraph (h)(1) or (2) of this section, an additional payment for preventive vaccine administration in the patient's home:

(i) Effective January 1, 2022 for administration of a COVID–19 vaccine in the home, an additional payment of $35.50.

(ii) Effective January 1, 2024, for the administration of one or more of the preventive vaccines described in paragraphs (h)(1) and (2) of this section in the home, a payment equal to that of the payment in paragraph (h)(3)(i) of this section.

(iii) An additional payment for preventive vaccine administration in the home can be made if:

(A) The patient has difficulty leaving the home, or faces barriers to getting a vaccine in settings other than their home.

(B) The sole purpose of the visit is to administer one or more preventive vaccines.

(C) The home is not an institution that meets the requirements of sections 1861(e)(1), 1819(a)(1), or 1919(a)(1) of the Act, or §§ 409.42(a) of this subchapter.

(4) The payment amount for the administration of a preventive vaccine described in paragraphs (h)(1) and (2) of

this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is adjusted to reflect geographic cost variations:

(i) For services furnished before January 1, 2023, using the Geographic Practice Cost Indices (GPCIs) established for the year, as described in section 1848(e)(1) of the Act and §§414.2 and 414.26 of this subchapter.

(ii) For services furnished on or after January 1, 2023, using the Geographic Adjustment Factor (GAF) established for the year as described in section 1848(e)(2) of the Act and §§414.2 and 414.26 of this subchapter.

(5) For services furnished on or after January 1, 2023, the payment amount for administration of a preventive vaccine described in paragraphs (h)(1) and (2) of this section, and the additional payment for the administration of a preventive vaccine in the home as described in paragraph (h)(3) of this section, is updated annually using the percentage change in the Medicare Economic Index (MEI), as described in section 1842(i)(3) of the Act and §405.504(d) of this subchapter.

(i) *Amount of payment: ASC facility services.* (1) For ASC facility services furnished on or after July 1, 1987 and before January 1, 2008, in connection with the surgical procedures specified in part 416 of this chapter, Medicare Part B pays 80 percent of a standard overhead amount as specified in §416.120(c) of this chapter, except that, for screening flexible sigmoidoscopies and screening colonoscopies, Part B coinsurance is 25 percent of the standard overhead amount and Medicare Part B pays 75 percent of the standard overhead amount.

(2) For ASC services furnished on or after January 1, 2008, in connection with the covered surgical procedures specified in §416.166 of this subchapter, except as provided in paragraphs (i)(2)(i), (i)(2)(ii), and (l) of this section, Medicare Part B pays the lesser of 80 percent of the actual charge or 80 percent of the prospective payment amount, geographically adjusted, if applicable, as determined under Subpart F of Part 416 of this subchapter. Part B coinsurance is 20 percent of the actual charge or 20 percent of the prospective payment amount, geographically adjusted, if applicable

(i) If the limitation described in §416.167(b)(3) of this subchapter applies, Medicare pays 80 percent of the amount determined under Subpart B of Part 414 of this subchapter and Part B coinsurance is 20 percent of the applicable payment amount, except as provided in paragraph (l) of this section.

(ii) Between January 1, 2008 and December 31, 2010, Medicare Part B pays 75 percent of the applicable payment amount for screening flexible sigmoidoscopies and screening colonoscopies, and Part B coinsurance is 25 percent of the applicable payment amount.

(j) *Amount of payment: services of Federally funded health facilities prior to October 1, 1991.* Medicare Part B pays 80 percent of charges related to the reasonable costs that a Federally funded health facility incurs in furnishing the services. See §411.8(b)(6) of this chapter.

(k) *Amount of payment: Outpatient CAH services.* (1) Payment for CAH outpatient services is the reasonable cost of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act, with §413.70(b) and (c) of this chapter, and with the applicable principles of cost reimbursement in part 413 and in part 415 of this chapter.

(2) Payment for CAH outpatient services is subject to the applicable Medicare Part B deductible and coinsurance amounts, except as described in §413.70(b)(2)(iii) of this chapter, with Part B coinsurance being calculated as 20 percent of the customary (insofar as reasonable) charges of the CAH for the services.

(l) *Amount of payment*: Preventive services. Except as provided otherwise in this paragraph, Medicare Part B pays 100 percent of the Medicare payment amount established under the applicable payment methodology for the service furnished by a provider or supplier for the following preventive services:

(1) Pneumococcal, influenza, hepatitis B, and COVID–19 vaccine and administration.

(2) Screening mammography.

(3) Screening pap tests and screening pelvic exam.

(4) Prostate cancer screening tests (excluding digital rectal examinations).

(5) Colorectal cancer screening tests (excluding barium enemas).

(i) For the colorectal cancer screening tests described in § 410.37(j), Medicare Part B pays at the specified percentage as follows:

(A) 80 percent for CY 2022.

(B) 85 percent for CY 2023 through 2026.

(C) 90 percent for 2027 through 2029.

(D) 100 percent beginning January 1, 2030.

(ii) [Reserved]

(6) Bone mass measurement.

(7) Medical nutrition therapy (MNT) services.

(8) Cardiovascular screening blood tests.

(9) Diabetes screening tests.

(10) Ultrasound screening for abdominal aortic aneurysm (AAA).

(11) Additional preventive services identified for coverage through the national coverage determination (NCD) process.

(12) Initial Preventive Physical Examination (IPPE).

(13) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS).

(m) *Amount of payment: Rebatable drugs.* In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the Act), including a selected drug (as defined in section 1192(c) of the Act), furnished by providers on or after April 1, 2023, in a calendar quarter during which the payment amount for such drug as specified in section 1847A(i)(3)(A)(ii)(I)(aa) or (bb), as applicable, exceeds the inflation-adjusted amount (as defined in section 1847A(i)(3)(C) of the Act) for such drug, Medicare Part B pays, subject to the deductible, the difference between the allowed payment amount determined under section 1847A of the Act and 20 percent of the inflation-adjusted amount, which is applied as a percent to the payment amount for such calendar quarter.

(n) *Amount of payment: Insulin furnished through an item of durable medical equipment.* For insulin furnished on or after July 1, 2023 through an item of durable medical equipment (as defined in § 414.202), Medicare Part B pays the difference between the applicable payment amount for such insulin and the coinsurance amount, with the coinsurance amount not to exceed $35 for a month's supply.

[51 FR 41339, Nov. 14, 1986; 52 FR 4499, Feb. 12, 1987]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 410.152, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 410.155 Outpatient mental health treatment limitation.

(a) *Limitation.* For services subject to the limitation as specified in paragraph (b) of this section, the percentage of the expenses incurred for such services during a calendar year that is considered incurred expenses under Medicare Part B when determining the amount of payment and deductible under § 410.152 and § 410.160 of this part, respectively, is as follows:

(1) For expenses incurred in years before 2010, 62½ percent.

(2) For expenses incurred in 2010 and 2011, 68¾ percent.

(3) For expenses incurred in 2012, 75 percent.

(4) For expenses incurred in 2013, 81¼ percent.

(5) For expenses incurred in CY 2014 and subsequent years, 100 percent.

(b) *Application of the limitation*—(1) *Services subject to the limitation.* Except as specified in paragraph (b)(2) of this section, services furnished by physicians and other practitioners, whether furnished directly or incident to those practitioners' services, are subject to the limitation if they are furnished in connection with the treatment of a mental, psychoneurotic, or personality disorder (that is, any condition identified by a diagnosis code within the range of 290 through 319) and are furnished to an individual who is not an inpatient of a hospital:

(i) Services furnished by physicians and other practitioners, whether furnished directly or as an incident to those practitioners' services.

(ii) Services provided by a CORF.

(2) *Services not subject to the limitation.* Services not subject to the limitation include the following:

(i) Services furnished to a hospital inpatient.

(ii) Brief office visits for the sole purpose of monitoring or changing drug prescriptions used in the treatment of mental, psychoneurotic, or personality disorders *billed under HCPCS code M0064 (or its successor).*

(iii) Partial hospitalization services or intensive outpatient services not directly provided by a physician.

(iv) Psychiatric diagnostic services billed under CPT codes 90801 and 90802 (or successor codes) and diagnostic psychological and neuropsychological tests billed under CPT code range 96101 through 96125 (or successor codes) that are performed to establish a diagnosis.

(v) Medical management such as that furnished under CPT code 90862 (or its successor code), as opposed to psychotherapy, furnished to a patient diagnosed with Alzheimer's disease or a related disorder.

(3) *Payment amounts.* The Medicare payment amount and the patient liability amounts for outpatient mental health services subject to the limitation for each year during which the limitation is phased out are as follows:

Calendar year	Recognized incurred expenses	Patient pays	Medicare pays
CY 2009 and prior calendar years	62.50%	50%	50%
CYs 2010 and 2011	68.75%	45%	55%
CY 2012	75.00%	40%	60%
CY 2013	81.25%	35%	65%
CY 2014	100.00%	20%	80%

(c) *General formula.* A general formula for calculating the amount of Medicare payment and the patient liability for outpatient mental health services subject to the limitation is as follows:

(1) Multiply the Medicare approved amount by the percentage of incurred expenses that is recognized as incurred expenses for Medicare payment purposes for the year involved;

(2) Subtract from this amount the amount of any remaining Part B deductible for the patient and year involved; and,

(3) Multiply this amount by 0.80 (80 percent) to obtain the Medicare payment amount.

(4) Subtract the Medicare payment amount from the Medicare-approved amount to obtain the patient liability amount.

[63 FR 20129, Apr. 23, 1998, as amended at 73 FR 69934, Nov. 19, 2008; 74 FR 62005, Nov. 25, 2009; 88 FR 82179, Nov. 22, 2023]

§410.160 Part B annual deductible.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, incurred expenses (as defined in §410.152) are subject to, and count toward meeting the annual deductible.

(b) *Exceptions.* Expenses incurred for the following services are not subject to the Part B annual deductible and do not count toward meeting that deductible:

(1) Home health services.

(2) Pneumococcal, influenza, and hepatitis b, and COVID–19 vaccines and their administration.

(3) Federally qualified health center services.

(4) ASC facility services furnished before July 1987 and physician services furnished before April 1988 that met the requirements for payment of 100 percent of the reasonable charges.

(5) Screening mammography services as described in §410.34 (c) and (d).

(6) Screening pelvic examinations as described in §410.56.

(7) Beginning January 1, 2007, colorectal cancer screening tests as described in §410.37.

(8) Beginning January 1, 2011, for a surgical service, and beginning January 1, 2015, for an anesthesia service, furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical or anesthesia service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical or anesthesia service furnished on the same date as a planned colorectal cancer screening test as described in §410.37.

(9) Beginning January 1, 2009, initial preventive physical examinations as described in §410.16.

(10) Bone mass measurement.

(11) Medical nutrition therapy (MNT) services.

(12) Annual Wellness Visit (AWV), providing Personalized Prevention Plan Services (PPPS).

(13) Additional preventive services identified for coverage through the national coverage determination (NCD) process.

(c) *Application of the Part B annual deductible.* (1) Before payment is made under § 410.152, an individual's incurred expenses for the calendar year are reduced by the Part B annual deductible.

(2) The Part B annual deductible is applied to incurred expenses in the order in which claims for those expenses are processed by the Medicare program.

(3) Only one Part B annual deductible may be imposed for any calendar year and it may be met by any combination of expenses incurred in that year.

(d) *Special rule for services reimbursable on a formula basis.* (1) In applying the formula that takes into account reasonable costs, customary charges, and customary (insofar as reasonable) charges, and is used to determine payment for services furnished by a provider that is not a nominal charge provider, the Medicare intermediary takes the following steps:

(i) Reduces the customary charges for the services by an amount equal to any unmet portion of the deductible for the calendar year, in accordance with paragraph (b) of this section. (The amount of this reduction is considered to be the amount of the deductible that is met on the basis of the services to which it is applied.)

(ii) Determines 20 percent of any remaining portion of the customary (insofar as reasonable) charge.

(iii) Determines the lesser of the reasonable cost of the services and the customary charges for the services.

(iv) Reduces the amount determined under paragraph (c)(1)(iii) of this section by the sum of the reduction made under paragraph (c)(1)(i) of this section and the amount determined under parargaph (c)(1)(ii) of this section.

(v) Reduces the reasonable cost of the services by the amount of the reduction made under paragraph (c)(1)(i) of this section and multiplies the result by 80 percent.

(2) In accordance with § 410.152(b)(1), the amount payable is the amount determined under paragraph (c)(1)(iv) of this section, or the amount determined under paragraph (c)(1)(v) of this section, whichever is less.

(e) *Special rule for services of an independent rural health clinic.* Application of the Part B annual deductible to rural health clinic services is in accordance with § 405.2425(b)(2) of this chapter.

(f) *Amount of the Part B annual deductible.* (1) Beginning with expenses for services furnished during calendar year 2006, and for all succeeding years, the annual deductible is the previous year's deductible plus the annual percentage increase in the monthly actuarial rate for Medicare enrollees age 65 and over, rounded to the nearest dollar.

(2) For 2005, the deductible is $110.

(3) From 1991 through 2004, the deductible was $100.

(4) From 1982 through 1990, the deductible was $75.

(5) From 1973 through 1981, the deductible was $60.

(6) From 1966 through 1972, the deductible was $50.

(g) *Carryover of Part B annual deductible.* For calendar years before 1982, the Part B annual deductible was reduced by the amount of expenses incurred during the last quarter of the preceding year that was applied to meet the deductible for that preceding year. *Example:* If $20 of expenses incurred in November 1980 was used to meet the 1980 deductible, the 1981 deductible was reduced to $40 ($60–$20).

(h) *Examples of application of the annual deductible.* (1) Mr. A submitted claims for the following expenses incurred during 1982: $20 for services furnished in March by physician X; $30 for services furnished in April by physician Y; $50 for services furnished in June by physician Z, for a total of $100. The carrier determined that the charges as submitted were the reasonable charges. The first $75 of expenses for which claims were processed is applied to meet the $75 deductible for that year. Medicare Part B pays 80 percent of the remaining $25, or $20.

(2) Mr. B submitted a claim that included a $25 charge by a doctor for an examination to prescribe a hearing aid and an $80 charge for office surgery. This was the first claim relating to Mr.

B's medical expenses processed in the calendar year. The carrier disallowed the $25 charge because the type of examination is not covered by Medicare. The carrier reduced the $80 surgery charge to a reasonable charge of $40. Only the $40 reasonable charge for covered services will count toward meeting Mr. B's deductible. Since the remainder of the surgery charge constitutes and excess over the reasonable charge, it cannot be applied to satisfy Mr. B's deductible.

(3) Mr. C became entitled to Medicare Part B benefits on July 1, 1982. He incurred expenses of $200 in July, August, and September. The carrier determined that the changes as submitted were reasonable. Even though Mr. C was entitled to benefits for only half the year, he must meet the full $75 deductible. Thus, $75 of this expense constitutes Mr. C's deductible. Medicare would pay $100, which is 80 percent of the remaining $125.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 8842, 8852, Mar. 1, 1991; 57 FR 24981, June 12, 1992; 62 FR 59101, Oct. 31, 1997; 69 FR 66423, Nov. 15, 2004; 71 FR 69785, Dec. 1, 2006; 73 FR 69934, Nov. 19, 2008; 75 FR 73615, Nov. 29, 2010; 77 FR 69363, Nov. 16, 2012; 80 FR 71373, Nov. 16, 2015; 85 FR 71197, Nov. 6, 2020]

§ 410.161 Part B blood deductible.

(a) *General rules.* (1) As used in this section, *packed red cells* means the red blood cells that remain after plasma is separated from whole blood.

(2) A unit of packed red cells is treated as the equivalent of a pint of whole blood, which in this section is referred to as a unit of whole blood.

(3) Medicare does not pay for the first 3 units of whole blood or units of packed red cells that are furnished under Part A or Part B in a calendar year. The Part B blood deductible is reduced to the extent that a blood deductible has been applied under Part A.

(4) The blood deductible does not apply to other blood components such as platelets, fibrinogen, plasma, gamma globulin and serum albumin, or to the costs of processing, storing, and administering blood.

(5) The blood deductible is in addition to the Part B annual deductible specified in § 410.160.

(b) *Beneficiary's responsibility for the first 3 units of blood.* (1) The beneficiary is responsible for the first three units of whole blood or packed red cells received during a calendar year.

(2) If the blood is furnished by a hospital or CAH, the rules set forth in § 409.87 (b), (c), and (d) of this chapter apply.

(3) If the blood is furnished by a physician, clinic, or other supplier that has accepted assignment of Medicare benefits, or claims payment under § 424.64 of this chapter because the beneficiary died without assigning benefits, the supplier may charge the beneficiary the reasonable charge for the first 3 units, to the extent that those units are not replaced.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 56 FR 8852, Mar. 1, 1991; 58 FR 30668, May 26, 1993]

§ 410.163 Payment for services furnished to kidney donors.

Notwithstanding any other provisions of this chapter, there are no deductible or coinsurance requirements with respect to services furnished to an individual who donates a kidney for transplant surgery.

§ 410.165 Payment for rural health clinic services and ambulatory surgical center services: Conditions.

(a) Medicare Part B pays for covered rural health clinic and Federally qualified health center services if—

(1) The services are furnished in accordance with the requirements of subpart X of part 405 of this chapter and subpart A of part 491 of this chapter; and

(2) The clinic or center files a written request for payment on the form and in the manner prescribed by CMS.

(b) Medicare Part B pays for covered ambulatory surgical center (ASC) services if—

(1) The services are furnished in accordance with the requirements of part 416 of this chapter; and

(2) The ASC files a written request for payment on the form and in the manner prescribed by CMS.

[51 FR 41339, Nov. 14, 1986, as amended at 57 FR 24981, June 12, 1992]

§ 410.170 Payment for home health services, for medical and other health services furnished by a provider or an approved ESRD facility, and for comprehensive outpatient rehabilitation facility (CORF) services: Conditions.

Payment under Medicare Part B, for home health services, for medical and other health services, or for CORF services, may be made to the provider or facility only if the following conditions are met:

(a) *Request for payment.* A written request for payment is filed by or on behalf of the individual to whom the services were furnished.

(b) *Physician or allowed practitioner certification.* For home health services, a physician or allowed practitioner provides certification and recertification in accordance with § 424.22 of this chapter.

(c) In the case of home dialysis support services described in § 410.52, the services are furnished in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition as required by § 494.90 of this chapter.

[51 FR 41339, Nov. 14, 1986, as amended at 53 FR 6648, Mar. 2, 1988; 73 FR 20474, Apr. 15, 2008; 85 FR 70354, Nov. 4, 2020]

§ 410.172 Payment for partial hospitalization services in CMHCs: Conditions.

Medicare Part B pays for partial hospitalization services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.110.

[59 FR 6578, Feb. 11, 1994]

§ 410.173 Payment for intensive outpatient services in CMHCs: Conditions.

Medicare Part B pays for intensive outpatient services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.111.

[88 FR 82179, Nov. 22, 2023]

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an individual who is not a citizen or a national of the United States if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the alien is back in the United States.

[53 FR 6634, Mar. 2, 1988]

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

Subpart A—General Exclusions and Exclusion of Particular Services

Sec.

AUTHORITY: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

SOURCE: 54 FR 41734, Oct. 11, 1989, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 411 appear at 71 FR 9471, Feb. 24, 2006

Subpart A—General Exclusions and Exclusion of Particular Services

§ 411.1 Basis and scope.

(a) *Statutory basis.* Sections 1814(a) and 1835(a) of the Act require that a physician certify or recertify a patient's need for home health services but, in general, prohibit a physician from certifying or recertifying the need for services if the services will be furnished by an HHA in which the physician has a significant ownership interest, or with which the physician has a significant financial or contractual relationship. Sections 1814(c), 1835(d), and 1862 of the Act exclude from Medicare payment certain specified services. The Act provides special rules for payment of services furnished by the following: Federal providers or agencies (sections 1814(c) and 1835(d)); hospitals and physicians outside of the U.S. (sections 1814(f) and 1862(a)(4)); and hospitals and SNFs of the Indian Health Service (section 1880 of the Act). Section 1877 of the Act sets forth limitations on referrals and payment for designated health services furnished by entities with which the referring physician (or an immediate family member of the referring physician) has a financial relationship.

(b) *Scope.* This subpart identifies:

(1) The particular types of services that are excluded;

(2) The circumstances under which Medicare denies payment for certain services that are usually covered; and

(3) The circumstances under which Medicare pays for services usually excluded from payment.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 41978, Aug. 14, 1995; 60 FR 45361, Aug. 31, 1995; 66 FR 952, Jan. 4, 2001]

§411.2 Conclusive effect of QIO determinations on payment of claims.

If a utilization and quality control quality improvement organization (QIO) has assumed review responsibility, in accordance with part 466 of this chapter, for services furnished to Medicare beneficiaries, Medicare payment is not made for those services unless the conditions of subpart C of part 466 of this chapter are met.

§411.4 Services for which neither the beneficiary nor any other person is legally obligated to pay.

(a) *General rule.* Except as provided in §411.8(b) (for services paid by a governmental entity), Medicare does not pay for a service if—

(1) The beneficiary has no legal obligation to pay for the service; and

(2) No other person or organization (such as a prepayment plan of which the beneficiary is a member) has a legal obligation to provide or pay for that service.

(b) *Special conditions for services furnished to individuals in custody of penal authorities.* Individuals who are in custody include, but are not limited to, individuals who are under arrest, incarcerated, imprisoned, escaped from confinement, under supervised release, on medical furlough, required to reside in mental health facilities, required to reside in halfway houses, required to live under home detention, or confined completely or partially in any way under a penal statute or rule. Payment may be made for services furnished to individuals or groups of individuals who are in the custody of police or other penal authorities or in the custody of a government agency under a penal statute only if the following conditions are met:

(1) State or local law requires those individuals or groups of individuals to repay the cost of medical services they receive while in custody.

(2) The State or local government entity enforces the requirement to pay by billing all such individuals, whether or not covered by Medicare or any other health insurance, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts.

[54 FR 41734, Oct. 11, 1989, as amended at 72 FR 47410, Aug. 22, 2007]

§411.6 Services furnished by a Federal provider of services or other Federal agency.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services furnished by a Federal provider of services or other Federal agency.

(b) *Exceptions.* Payment may be made—

(1) For emergency hospital services, if the conditions of §424.103 of this chapter are met;

(2) For services furnished by a participating Federal provider which CMS has determined is providing services to the public generally as a community institution or agency;

(3) For services furnished by participating hospitals and SNFs of the Indian Health Service; and

(4) For services furnished under arrangements (as defined in §409.3 of this chapter) made by a participating hospital.

§411.7 Services that must be furnished at public expense under a Federal law or Federal Government contract.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, payment may not be made for services that any provider or supplier is obligated to furnish at public expense, in accordance with a law of, or a contract with, the United States.

(b) *Exception.* Payment may be made for services that a hospital or SNF of the Indian Health Service is obligated to furnish at public expense.

§411.8 Services paid for by a Government entity.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, Medicare does not pay for services that are paid for directly or indirectly by a government entity.

(b) *Exceptions.* Payment may be made for the following:

(1) Services furnished under a health insurance plan established for employees of the government entity.

(2) Services furnished under a title of the Social Security Act other than title XVIII.

(3) Services furnished in or by a participating general or special hospital that—

(i) Is operated by a State or local government agency; and

(ii) Serves the general community.

(4) Services furnished in a hospital or elsewhere, as a means of controlling infectious diseases or because the individual is medically indigent.

(5) Services furnished by a participating hospital or SNF of the Indian Health Service.

(6) Services furnished by a public or private health facility that—

(i) Is not a Federal provider or other facility operated by a Federal agency;

(ii) Receives U.S. government funds under a Federal program that provides support to facilities that furnish health care services;

(iii) Customarily seeks payment for services not covered under Medicare from all available sources, including private insurance and patients' cash resources; and

(iv) Limits the amounts it collects or seeks to collect from a Medicare Part B beneficiary and others on the beneficiary's behalf to:

(A) Any unmet deductible applied to the charges related to the reasonable costs that the facility incurs in providing the covered services;

(B) Twenty percent of the remainder of those charges;

(C) The charges for noncovered services.

(7) Rural health clinic services that meet the requirements set forth in part 491 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 56 FR 2139, Jan. 22, 1991]

§ 411.9 Services furnished outside the United States.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, Medicare does not pay for services furnished outside the United States. For purposes of this paragraph (a), the following rules apply:

(1) The United States includes the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, The Northern Mariana Islands, and for purposes of services rendered on board ship, the territorial waters adjoining the land areas of the United States.

(2) Services furnished on board ship are considered to have been furnished in United States territorial waters if they were furnished while the ship was in a port of one of the jurisdictions listed in paragraph (a)(1) of this section, or within 6 hours before arrival at, or 6 hours after departure from, such a port.

(3) A hospital that is not physically situated in one of the jurisdictions listed in paragraph (a)(1) of this section is considered to be outside the United States, even if it is owned or operated by the United States Government.

(b) *Exception.* Under the circumstances specified in subpart H of part 424 of this chapter, payment may be made for covered inpatient services furnished in a foreign hospital and, on the basis of an itemized bill, for covered physicians' services and ambulance service furnished in connection with those inpatient services, but only for the period during which the inpatient hospital services are furnished.

§ 411.10 Services required as a result of war.

Medicare does not pay for services that are required as a result of war, or an act of war, that occurs after the effective date of a beneficiary's current coverage for hospital insurance benefits or supplementary medical insurance benefits.

§ 411.12 Charges imposed by an immediate relative or member of the beneficiary's household.

(a) *Basic rule.* Medicare does not pay for services usually covered under Medicare if the charges for those services are imposed by—

(1) An immediate relative of the beneficiary; or

(2) A member of the beneficiary's household.

(b) *Definitions.* As used in this section—

Immediate relative means any of the following:

(1) Husband or wife.

(2) Natural or adoptive parent, child, or sibling.

(3) Stepparent, stepchild, stepbrother, or stepsister.

(4) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

(5) Grandparent or grandchild.

(6) Spouse of grandparent or grandchild.

Member of the household means any person sharing a common abode as part of a single family unit, including domestic employees and others who live together as part of a family unit, but not including a mere roomer or boarder.

Professional corporation means a corporation that is completely owned by one or more physicians and is operated for the purpose of conducting the practice of medicine, osteopathy dentistry, podiatry, optometry, or chiropractic, or is owned by other health care professionals as authorized by State law.

(c) *Applicability of the exclusion.* The exclusion applies to the following charges in the specified circumstances:

(1) *Physicians' services.* (i) Charges for physicians' services furnished by an immediate relative of the beneficiary or member of the beneficiary's household, even if the bill or claim is submitted by another individual or by an entity such as a partnership or a professional corporation.

(ii) Charges for services furnished incident to a physician's professional services (for example by the physician's nurse or technician), only if the physician who ordered or supervised the services has an excluded relationship to the beneficiary.

(2) *Services other than physicians' services.* (i) Charges imposed by an individually owned provider or supplier if the owner has an excluded relationship to the beneficiary; and

(ii) Charges imposed by a partnership if any of the partners has an excluded relationship to the beneficiary.

(d) *Exception to the exclusion.* The exclusion does not apply to charges imposed by a corporation other than a professional corporation.

§411.15 Particular services excluded from coverage.

The following services are excluded from coverage:

(a) Routine physical checkups such as:

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury, except for screening mammography, colorectal cancer screening tests, screening pelvic exams, prostate cancer screening tests, glaucoma screening exams, ultrasound screening for abdominal aortic aneurysms (AAA), cardiovascular disease screening tests, diabetes screening tests, a screening electrocardiogram, initial preventive physical examinations that meet the criteria specified in paragraphs (k)(6) through (k)(15) of this section, additional preventive services that meet the criteria in §410.64 of this chapter, or annual wellness visits providing personalized prevention plan services.

(2) Examinations required by insurance companies, business establishments, government agencies, or other third parties.

(b) *Low vision aid exclusion*—(1) *Scope.* The scope of the eyeglass exclusion encompasses all devices irrespective of their size, form, or technological features that use one or more lens to aid vision or provide magnification of images for impaired vision.

(2) *Exceptions.* (i) Post-surgical prosthetic lenses customarily used during convalescence for eye surgery in which the lens of the eye was removed (for example, cataract surgery).

(ii) Prosthetic intraocular lenses and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(iii) Prosthetic lenses used by Medicare beneficiaries who are lacking the natural lens of the eye and who were not furnished with an intraocular lens.

(c) *Eye examinations* for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses for refractive error only and procedures performed in the course of any eye examination to

determine the refractive state of the eyes, without regard to the reason for the performance of the refractive procedures. Refractive procedures are excluded even when performed in connection with otherwise covered diagnosis or treatment of illness or injury.

(d) *Hearing aids* or examinations for the purpose of prescribing, fitting, or changing hearing aids.

(1) *Scope.* The scope of the hearing aid exclusion encompasses all types of air conduction hearing aids that provide acoustic energy to the cochlea via stimulation of the tympanic membrane with amplified sound and bone conduction hearing aids that provide mechanical stimulation of the cochlea via stimulation of the scalp with amplified mechanical vibration or by direct contact with the tympanic membrane or middle ear ossicles.

(2) *Devices not subject to the hearing aid exclusion.* Paragraph (d)(1) of this section shall not apply to the following devices that produce the perception of sound by replacing the function of the middle ear, cochlea, or auditory nerve:

(i) Osseointegrated implants in the skull bone that provide mechanical energy to the cochlea via a mechanical transducer, or

(ii) Cochlear implants and auditory brainstem implants that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays.

(e) *Immunizations, except for—*

(1) Vaccinations or inoculations directly related to the treatment of an injury or direct exposure such as antirabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenom sera, or immune globulin;

(2) Pneumococcal vaccinations that are reasonable and necessary for the prevention of illness;

(3) Hepatitis B vaccinations that are reasonable and necessary for the prevention of illness for those individuals, as defined in § 410.63(a) of this chapter, who are at high or intermediate risk of contracting hepatitis B;

(4) Influenza vaccinations that are reasonable and necessary for the prevention of illness; and

(5) COVID–19 vaccinations that are reasonable and necessary for the prevention of illness.

(f) *Orthopedic shoes* or other supportive devices for the feet, *except when* shoes are integral parts of leg braces.

(g) *Custodial care, except as necessary* for the palliation or management of terminal illness, as provided in part 418 of this chapter. (Custodial care is any care that does not meet the requirements for coverage as SNF care as set forth in §§ 409.31 through 409.35 of this chapter.)

(h) *Cosmetic surgery and related services,* except as required for the prompt repair of accidental injury or to improve the functioning of a malformed body member.

(i) *Dental services*—(1) *Basic rule. Dental services* in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth.

(2) *Exception. Except f*or inpatient hospital services in connection with such dental procedures when hospitalization is required because of—

(i) The individual's underlying medical condition and clinical status; or

(ii) The severity of the dental procedures.[577]

(3) *Inapplicability.* (i) Dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not excluded; payment may be made under Medicare Parts A and B for services furnished in the inpatient or outpatient setting. Such services include, but are not limited to:

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures,

[577] Before July 1981, inpatient hospital care in connection with dental procedures was covered only when required by the patient's underlying medical condition and clinical status.

chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

(B) The reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor.

(C) The stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints.

(D) The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.

(E) Dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation, chemotherapy, surgery, or any combination of these.

(ii) Ancillary services and supplies furnished incident to covered dental services are not excluded, and Medicare payment may be made under Part A or Part B, as applicable, whether the service is performed in the inpatient or outpatient setting, including, but not limited to the administration of anesthesia, diagnostic x-rays, use of operating room, and other related procedures.

(j) *Personal comfort services, except* as necessary for the palliation or management of terminal illness as provided in part 418 of this chapter. The use of a television set or a telephone are examples of personal *comfort* services.

(k) *Any services that are not reasonable and necessary* for one of the following purposes:

(1) For the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(2) In the case of hospice services, for the palliation or management of terminal illness, as provided in part 418 of this chapter.

(3) In the case of pneumococcal vaccine for the prevention of illness.

(4) In the case of the patient outcome assessment program established under section 1875(c) of the Act, for carrying out the purpose of that section.

(5) In the case of hepatitis B vaccine, for the prevention of illness for those individuals at high or intermediate risk of contracting hepatitis B. (Section 410.63(a) of this chapter sets forth criteria for identifying those individuals.)

(6) In the case of screening mammography, for the purpose of early detection of breast cancer subject to the conditions and limitations specified in §410.34 of this chapter.

(7) In the case of colorectal cancer screening tests, for the purpose of early detection of colorectal cancer subject to the conditions and limitations specified in §410.37 of this chapter.

(8) In the case of screening pelvic examinations, for the purpose of early detection of cervical or vaginal cancer subject to the conditions and limitations specified in §410.56 of this chapter.

(9) In the case of prostate cancer screening tests, for the purpose of early detection of prostate cancer, subject to the conditions and limitations specified in §410.39 of this chapter.

(10) In the case of screening exams for glaucoma, for the purpose of early detection of glaucoma, subject to the conditions and limitations specified in §410.23 of this chapter.

(11) In the case of initial preventive physical examinations, with the goal of health promotion and disease prevention, subject to the conditions and limitations specified in §410.16 of this chapter.

(12) In the case of ultrasound screening for abdominal aortic aneurysms, with the goal of early detection of abdominal aortic aneurysms, subject to the conditions and limitation specified in §410.19 of this chapter.

(13) In the case of cardiovascular disease screening tests for the early detection of cardiovascular disease or abnormalities associated with an elevated risk for that disease, subject to the

conditions specified in § 410.17 of this chapter.

(14) In the case of diabetes screening tests furnished to an individual at risk for diabetes for the purpose of the early detection of that disease, subject to the conditions specified in § 410.18 of this chapter.

(15) In the case of additional preventive services not otherwise described in this title, subject to the conditions and limitation specified in § 410.64 of this chapter.

(16) In the case of an annual wellness visit providing a personalized prevention plan, subject to the conditions and limitations specified in § 410.15 of this subpart.

(l) *Foot care*—(1) *Basic rule.* Except as provided in paragraph (l)(2) of this section, any services furnished in connection with the following:

(i) *Routine foot care*, such as the cutting or removal of corns, or calluses, the trimming of nails, routine hygienic care (preventive maintenance care ordinarily within the realm of self care), and any service performed in the absence of localized illness, injury, or symptoms involving the feet.

(ii) *The evaluation or treatment of subluxations of the feet* regardless of underlying pathology. (Subluxations are structural misalignments of the joints, other than fractures or complete dislocations, that require treatment only by nonsurgical methods.

(iii) *The evaluation or treatment of flattened arches* (including the prescription of supportive devices) regardless of the underlying pathology.

(2) *Exceptions.* (i) Treatment of warts is not excluded.

(ii) Treatment of mycotic toenails may be covered if it is furnished no more often than every 60 days or the billing physician documents the need for more frequent treatment.

(iii) The services listed in paragraph (l)(1) of this section are not excluded if they are furnished—

(A) As an incident to, at the same time as, or as a necessary integral part of a primary covered procedure performed on the foot; or

(B) As initial diagnostic services (regardless of the resulting diagnosis) in connection with a specific symptom or complaint that might arise from a condition whose treatment would be covered.

(m) *Services to hospital patients*—(1) *Basic rule.* Except as provided in paragraph (m)(3) of this section, any service furnished to an inpatient of a hospital or to a hospital outpatient (as defined in § 410.2 of this chapter) during an encounter (as defined in § 410.2 of this chapter) by an entity other than the hospital unless the hospital has an arrangement (as defined in § 409.3 of this chapter) with that entity to furnish that particular service to the hospital's patients. As used in this paragraph (m)(1), the term ''hospital'' includes a CAH.

(2) *Scope of exclusion.* Services subject to exclusion from coverage under the provisions of this paragraph (m) include, but are not limited to, clinical laboratory services; pacemakers and other prostheses and prosthetic devices (other than dental) that replace all or part of an internal body organ (for example, intraocular lenses); artificial limbs, knees, and hips; equipment and supplies covered under the prosthetic device benefits; and services incident to a physician service.

(3) *Exceptions.* The following services are not excluded from coverage:

(i) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a reasonable charge or fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(vi) Services of an anesthetist, as defined in § 410.69 of this chapter.

(n) *Certain services of an assistant-at-surgery.* (1) Services of an assistant-at-surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate QIO or a

carrier has approved the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition.

(2) Services on an assistant-at-surgery in a surgical procedure (or class of surgical procedures) for which assistants-at-surgery on average are used in fewer than 5 percent of such procedures nationally.

(o) Experimental or investigational devices, except for certain devices.

(1) Categorized by the FDA as a Category B (Nonexperimental/investigational) device as defined in §405.201(b) of the chapter; and

(2) Furnished in accordance with the coverage requirements in §405.211(b).

(p) *Services furnished to SNF residents*—(1) *Basic rule.* Except as provided in paragraph (p)(2) of this section, any service furnished to a resident of an SNF during a covered Part A stay by an entity other than the SNF, unless the SNF has an arrangement (as defined in §409.3 of this chapter) with that entity to furnish that particular service to the SNF's residents. Services subject to exclusion under this paragraph include, but are not limited to—

(i) Any physical, occupational, or speech-language therapy services, regardless of whether the services are furnished by (or under the supervision of) a physician or other health care professional, and regardless of whether the resident who receives the services is in a covered Part A stay; and

(ii) Services furnished as an incident to the professional services of a physician or other health care professional specified in paragraph (p)(2) of this section.

(2) *Exceptions.* The following services are not excluded from coverage, provided that the claim for payment includes the SNF's Medicare provider number in accordance with §424.32(a)(5) of this chapter:

(i) Physicians' services that meet the criteria of §415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(iii) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(iv) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(v) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(vi) Services performed by a marriage and family therapist, as defined in section 1861(lll)(2) of the Act.

(vii) Services performed by a mental health counselor, as defined in section 1861(lll)(4) of the Act.

(viii) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(ix) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(x) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(xi) Hospice care, as defined in section 1861(dd) of the Act.

(xii) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in paragraphs (p)(3)(i) through (p)(3)(iv) of this section as ending the individual's status as an SNF resident.

(xiii) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(xiv) Services described in paragraphs (p)(2)(i) through (viii) of this section when furnished via telehealth under section 1834(m)(4)(C)(ii)(VII) of the Act.

(xv) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(xvi) Those chemotherapy administration services identified, as of July 1,

1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(xvii) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(xviii) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(xix) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

(xx) Those RHC and FQHC services that are described in § 405.2411(b)(2) of this chapter.

(3) *SNF resident defined.* For purposes of this paragraph, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF for the duration of the beneficiary's covered Part A stay. In addition, for purposes of the services described in paragraph (p)(1)(i) of this section, a beneficiary who is admitted to a Medicare-participating SNF is considered to be a resident of the SNF regardless of whether the beneficiary is in a covered Part A stay. Whenever the beneficiary leaves the facility, the beneficiary's status as an SNF resident for purposes of this paragraph (along with the SNF's responsibility to furnish or make arrangements for the services described in paragraph (p)(1) of this section) ends when one of the following events occurs—

(i) The beneficiary is admitted as an inpatient to a Medicare-participating hospital or CAH, or as a resident to another SNF;

(ii) The beneficiary receives services from a Medicare-participating home health agency under a plan of care;

(iii) The beneficiary receives outpatient services from a Medicare-participating hospital or CAH (but only for those services that CMS designates as being beyond the general scope of SNF comprehensive care plans, as required under § 483.21(b) of this chapter); or

(iv) The beneficiary is formally discharged (or otherwise departs) from the SNF, unless the beneficiary is readmitted (or returns) to that or another SNF before the following midnight.

(q) *Assisted suicide.* Any health care service used for the purpose of causing, or assisting to cause, the death of any individual. This does not pertain to the withholding or withdrawing of medical treatment or care, nutrition or hydration or to the provision of a service for the purpose of alleviating pain or discomfort, even if the use may increase the risk of death, so long as the service is not furnished for the specific purpose of causing death.

(r) A home health service (including medical supplies described in section 1861(m)(5) of the Act, but excluding durable medical equipment to the extent provided for in such section) as defined in section 1861(m) of the Act furnished to an individual who is under a plan of care of an HHA, unless that HHA has submitted a claim for payment for such services.

(s) Unless § 414.404(d) or § 414.408(e)(2) of this subchapter applies, Medicare does not make payment if an item or service that is included in a competitive bidding program (as described in part 414, subpart F of this subchapter) is furnished by a supplier other than a contract supplier (as defined in § 414.402 of this subchapter).

[54 FR 41734, Oct. 11, 1989; 55 FR 1820, Jan. 19, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 411.15, see the List of CFR

Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

Subpart B—Insurance Coverage That Limits Medicare Payment: General Provisions

§ 411.20 Basis and scope.

(a) *Statutory basis.* (1) Section 1862(b)(2)(A)(i) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under a group health plan with respect to—

(i) A beneficiary entitled to Medicare on the basis of ESRD during the first 18 months of that entitlement;

(ii) A beneficiary who is age 65 or over, entitled to Medicare on the basis of age, and covered under the plan by virtue of his or her current employment status or the current employment status of a spouse of any age; or

(iii) A beneficiary who is under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of his or her current employment status or the current employment status of a family member.

(2) Section 1862(b)(2)(A)(ii) of the Act precludes Medicare payment for services to the extent that payment has been made or can reasonably be expected to be made under any of the following:

(i) Workers' compensation.

(ii) Liability insurance.

(iii) No-fault insurance.

(b) *Scope.* This subpart sets forth general rules that apply to the types of insurance specified in paragraph (a) of this section. Other general rules that apply to group health plans are set forth in subpart E of this part.

[60 FR 45361, Aug. 31, 1995, as amended at 71 FR 9470, Feb. 24, 2006]

§ 411.21 Definitions.

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise—

Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.

Coverage or *covered services,* when used in connection with primary payments, means services for which a primary payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyses at home or as an outpatient in an approved ESRD facility.

Plan means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Primary payer means, when used in the context in which Medicare is the secondary payer, any entity that is or was required or responsible to make payment with respect to an item or service (or any portion thereof) under a primary plan. These entities include, but are not limited to, insurers or self-insurers, third party administrators, and all employers that sponsor or contribute to group health plans or large group health plans.

Primary payment means, when used in the context in which Medicare is the secondary payer, payment by a primary payer for services that are also covered under Medicare.

Primary plan means, when used in the context in which Medicare is the secondary payer, a group health plan or large group health plan, a workers' compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan), or no-fault insurance.

Prompt or *promptly,* when used in connection with primary payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

Proper claim means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

Secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be

made under other coverage that is primary to Medicare.

Secondary payments means payments made for Medicare covered services or portions of services that are not payable under other coverage that is primary to Medicare.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 45361, Aug. 31, 1995; 71 FR 9470, Feb. 24, 2006]

§ 411.22 Reimbursement obligations of primary payers and entities that received payment from primary payers.

(a) A primary payer, and an entity that receives payment from a primary payer, must reimburse CMS for any payment if it is demonstrated that the primary payer has or had a responsibility to make payment.

(b) A primary payer's responsibility for payment may be demonstrated by—

(1) A judgment;

(2) A payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary payer or the primary payer's insured; or

(3) By other means, including but not limited to a settlement, award, or contractual obligation.

(c) The primary payer must make payment to either of the following:

(1) To the entity designated to receive repayments if the demonstration of primary payer responsibilities is other than receipt of a recovery demand letter from CMS or designated contractor.

(2) As directed in a recovery demand letter.

[71 FR 9470, Feb. 24, 2006, as amended at 73 FR 9684, Feb. 22, 2008]

§ 411.23 Beneficiary's cooperation.

(a) If CMS takes action to recover conditional payments, the beneficiary must cooperate in the action.

(b) If CMS's recovery action is unsuccessful because the beneficiary does not cooperate, CMS may recover from the beneficiary.

§ 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) *Release of information.* The filing of a Medicare claim by on or behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possesses information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery.* CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) *Amount of recovery.* (1) If it is not necessary for CMS to take legal action to recover, CMS recovers the lesser of the following:

(i) The amount of the Medicare primary payment.

(ii) The full primary payment amount that the primary payer is obligated to pay under this part without regard to any payment, other than a full primary payment that the primary payer has paid or will make, or, in the case of a primary payment beneficiary, the amount of the primary payment.

(2) If it is necessary for CMS to take legal action to recover from the primary payer, CMS may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery.* CMS may recover by direct collection or by offset against any monies CMS owes the entity responsible for refunding the conditional payment.

(e) *Recovery from primary payers.* CMS has a direct right of action to recover from any primary payer.

(f) *Claims filing requirements.* (1) CMS may recover without regard to any claims filing requirements that the insurance program or plan imposes on the beneficiary or other claimant such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for or receipt of services.

(2) However, CMS will not recover its payment for particular services in the face of a claims filing requirement unless it has filed a claim for recovery by the end of the year following the year in which the Medicare intermediary or carrier that paid the claim has notice that the third party is a primary plan to Medicare for those particular services. (A notice received during the last three months of a year is considered received during the following year.)

(g) *Recovery from parties that receive primary payments.* CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a primary payment.

(h) *Reimbursement to Medicare.* If the beneficiary or other party receives a primary payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans, workers' compensation insurance or plan, and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the primary payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a primary payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

(3) In situations that involve procurement costs, the rule of §411.37(b) applies.

(j) *Recovery against Medicaid agency.* If a primary payment is made to a State Medicaid agency and that agency does not reimburse Medicare, CMS may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the primary payment, whichever is less.

(k) *Recovery against Medicare contractor.* If a Medicare contractor, including an intermediary or carrier, also insures, underwrites, or administers as a third party administrator, a program or plan that is primary to Medicare, and does not reimburse Medicare, CMS may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act or due the contractor under the contract.

(l) *Recovery when there is failure to file a proper claim*—(1) *Basic rule.* If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim with a primary payer, and Medicare is unable to recover from the primary payer, Medicare may recover from the beneficiary or provider or supplier that was responsible for the failure to file a proper claim.

(2) *Exceptions.* (i) This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.

(ii) CMS will not recover from providers or suppliers that are in compliance with the requirements of §489.20 of this chapter and can show that the reason they failed to file a proper claim is that the beneficiary, or someone acting on his or her behalf, failed to give, or gave erroneous, information regarding coverage that is primary to Medicare.

(m) *Interest charges.* (1) With respect to recovery of payments for items and services furnished before October 31, 1994, CMS charges interest, exercising common law authority in accordance with 45 CFR 30.13, consistent with the Federal Claims Collection Act (31 U.S.C. 3711).

(2) In addition to its common law authority with respect to recovery of payments for items and services furnished on or after October 31, 1994, CMS charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision—

(i) CMS may charge interest if reimbursement is not made to the appropriate trust fund before the expiration of the 60-day period that begins on the date on which notice or other information is received by CMS that payment has been or could be made under a primary plan;

(ii) Interest may accrue from the date when that notice or other information is received by CMS, is charged

until reimbursement is made, and is applied for full 30-day periods; and

(iii) The rate of interest is that provided at § 405.378(d) of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45361, 45362, Aug. 31, 1995; 69 FR 45607, July 30, 2004; 71 FR 9470, Feb. 24, 2006]

§ 411.25 Primary payer's notice of primary payment responsibility.

(a) If it is demonstrated to a primary payer that CMS has made a Medicare primary payment for services for which the primary payer has made or should have made primary payment, it must provide notice about primary payment responsibility and information about the underlying MSP situation to the entity or entities designated by CMS to receive and process that information.

(b) The notice must describe the specific situation and the circumstances (including the particular type of insurance coverage as specified in § 411.20(a)) and, if appropriate, the time period during which the insurer is primary to Medicare.

(c) The primary payer must provide additional information to the designated entity or entities as the designated entity or entities may require this information to update CMS' system of records.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 73 FR 9684, Feb. 22, 2008]

§ 411.26 Subrogation and right to intervene.

(a) *Subrogation.* With respect to services for which Medicare paid, CMS is subrogated to any individual, provider, supplier, physician, private insurer, State agency, attorney, or any other entity entitled to payment by a primary payer.

(b) *Right to intervene.* CMS may join or intervene in any action related to the events that gave rise to the need for services for which Medicare paid.

§ 411.28 Waiver of recovery and compromise of claims.

(a) CMS may waive recovery, in whole or in part, if the probability of recovery, or the amount involved, does not warrant pursuit of the claim.

(b) General rules applicable to compromise of claims are set forth in subpart F of part 401 and § 405.376 of this chapter.

(c) Other rules pertinent to recovery are contained in subpart C of part 405 of this chapter.

[54 FR 41734, Oct. 11, 1989, as amended at 61 FR 63749, Dec. 2, 1996]

§ 411.30 Effect of primary payment on benefit utilization and deductibles.

(a) *Benefit utilization.* Inpatient psychiatric hospital and SNF care that is paid for by a primary payer is not counted against the number of inpatient care days available to the beneficiary under Medicare Part A.

(b) *Deductibles.* Expenses for Medicare covered services that are paid for by primary payers are credited toward the Medicare Part A and Part B deductibles.

§ 411.31 Authority to bill primary payers for full charges.

(a) The fact that Medicare payments are limited to the DRG amount, or the reasonable charge, reasonable cost, capitation or fee schedule rate, does not affect the amount that a primary payer may pay.

(b) With respect to workers' compensation plans, no-fault insurers, and employer group health plans, a provider or supplier may bill its full charges and expect those charges to be paid unless there are limits imposed by laws other than title XVIII of the Act or by agreements with the primary payer.

§ 411.32 Basis for Medicare secondary payments.

(a) *Basic rules.* (1) Medicare benefits are secondary to benefits payable by a primary payer even if State law or the primary payer states that its benefits are secondary to Medicare benefits or otherwise limits its payments to Medicare beneficiaries.

(2) Except as provided in paragraph (b) of this section, Medicare makes secondary payments, within the limits specified in paragraph (c) of this section and in § 411.33, to supplement the primary payment if that payment is less than the charges for the services and, in the case of services paid on

other than a reasonable charge basis, less than the gross amount payable by Medicare under § 411.33(e).

(b) *Exception.* Medicare does not make a secondary payment if the provider or supplier is either obligated to accept, or voluntarily accepts, as full payment, a primary payment that is less than its charges.

(c) *General limitation: Failure to file a proper claim.* When a provider or supplier, or a beneficiary who is not physically or mentally incapacitated, receives a reduced primary payment because of failure to file a proper claim, the Medicare secondary payment may not exceed the amount that would have been payable under § 411.33 if the primary payer had paid on the basis of a proper claim.

The provider, supplier, or beneficiary must inform CMS that a reduced payment was made, and the amount that would have been paid if a proper claim had been filed.

§ 411.33 Amount of Medicare secondary payment.

(a) *Services for which CMS pays on a Medicare fee schedule or reasonable charge basis.* The Medicare secondary payment is the lowest of the following:

(1) The actual charge by the supplier (or the amount the supplier is obligated to accept as payment in full if that is less than the charges) minus the amount paid by the primary payer.

(2) The amount that Medicare would pay if the services were not covered by a primary payer.

(3) The higher of the Medicare fee schedule, Medicare reasonable charge, or other amount which would be payable under Medicare (without regard to any applicable Medicare deductible or coinsurance amounts) or the primary payer's allowable charge (without regard to any deductible or co-insurance imposed by the policy or plan) minus the amount actually paid by the primary payer.

(b) *Example:* An individual received treatment from a physician for which the physician charged $175. The primary payer allowed $150 of the charge and paid 80 percent of this amount or $120. The Medicare fee schedule for this treatment is $125. The individual's Part B deductible had been met. As secondary payer, Medicare pays the lowest of the following amounts:

(1) Excess of actual charge minus the primary payment: $175 − 120 = $55.

(2) Amount Medicare would pay if the services were not covered by a primary payer: .80 × $125 = $100.

(3) Primary payer's allowable charge without regard to its coinsurance (since that amount is higher than the Medicare fee schedule in this case) minus amount paid by the primary payer: $150 − 120 = $30.

The Medicare payment is $30.

(c)–(d) [Reserved]

(e) *Services reimbursed on a basis other than fee schedule, reasonable charge, or monthly capitation rate.* The Medicare secondary payment is the lowest of the following:

(1) The gross amount payable by Medicare (that is, the amount payable without considering the effect of the Medicare deductible and coinsurance or the payment by the primary payer), minus the applicable Medicare deductible and coinsurance amounts.

(2) The gross amount payable by Medicare, minus the amount paid by the primary payer.

(3) The provider's charges (or the amount the provider is obligated to accept as payment in full, if that is less than the charges), minus the amount payable by the primary payer.

(4) The provider's charges (or the amount the provider is obligated to accept as payment in full if that is less than the charges), minus the applicable Medicare deductible and coinsurance amounts.

(f) *Examples:* (1) A hospital furnished 7 days of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totaled $2,800. The primary payer paid $2,360. No part of the Medicare inpatient hospital deductible of $520 had been met. If the gross amount payable by Medicare in this case is $2,700, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare inpatient hospital deductible: $2,700 − $520 = $2,180.

(ii) The gross amount payable by Medicare minus the primary payment: $2,700 − $2,360 = $340.

(iii) The provider's charges minus the primary payment: $2,800 − $2,360 = $440.

(iv) The provider's charges minus the Medicare deductible: $2,800 − $520 = $2,280. Medicare's secondary payment is $340 and the combined payment made by the primary payer and Medicare on behalf of the beneficiary is $2,700. The $520 deductible was satisfied by the primary payment so that the beneficiary incurred no out-of-pocket expenses.

(2) A hospital furnished 1 day of inpatient hospital care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services totalled $750. The primary payer paid $450. No part of the Medicare inpatient hospital deductible had been met previously. The primary payment is credited toward that deductible. If the gross amount payable by Medicare in this case is $850, then as secondary payer, Medicare pays the lowest of the following amounts:

(i) The gross amount payable by Medicare minus the Medicare deductible: $850 − $520 = $330.

(ii) The gross amount payable by Medicare minus the primary payment: $850 − $450 = $400.

(iii) The provider's charges minus the primary payment: $750 − $450 = $300.

(iv) The provider's charges minus the Medicare deductible: $750 − $520 = $230. Medicare's secondary payment is $230, and the combined payment made by the primary payer and Medicare on behalf of the beneficiary is $680. The hospital may bill the beneficiary $70 (the $520 deductible minus the $450 primary payment). This fully discharges the beneficiary's deductible obligation.

(3) An ESRD beneficiary received 8 dialysis treatments for which a facility charged $160 per treatment for a total of $1,280. No part of the beneficiary's $75 Part B deductible had been met. The primary payer paid $1,024 for Medicare-covered services. The composite rate per dialysis treatment at this facility is $131 or $1,048 for 8 treatments. As secondary payer, Medicare pays the lowest of the following:

(i) The gross amount payable by Medicare minus the applicable Medicare deductible and coinsurance: $1,048 − $75 − $194.60 = $778.40. (The coinsurance is calculated as follows: $1,048 composite rate − $75 deductible = $973 × .20 = $194.60).

(ii) The gross amount payable by Medicare minus the primary payment: $1,048 − $1,024 = $24.

(iii) The provider's charges minus the primary payment: $1,280 − $1,024 = $256.

(iv) The provider's charge minus the Medicare deductible and coinsurance: $1,280 − $75 − $194.60 = 1010.40. Medicare pays $24. The beneficiary's Medicare deductible and coinsurance were met by the primary payment.

(4) A hospital furnished 5 days of inpatient care in 1987 to a Medicare beneficiary. The provider's charges for Medicare-covered services were $4,000 and the gross amount payable was $3,500. The provider agreed to accept $3,000 from the primary payer as payment in full. The primary payer paid $2,900 due to a deductible requirement under the primary plan. Medicare considers the amount the provider is obligated to accept as full payment ($3,000) to be the provider charges. The Medicare secondary payment is the lowest of the following:

(i) The gross amount payable by Medicare minus the Medicare inpatient deductible: $3,500 − $520 = $2,980.

(ii) The gross amount payable by Medicare minus the primary payment: $3,500 − $2,900 = $600.

(iii) The provider's charge minus the primary payment: $3,000 − $2,900 = $100.

(iv) The provider's charges minus the Medicare inpatient deductible: $3,000 − $520 = $2,480. The Medicare secondary payment is $100. When Medicare is the secondary payer, the combined payment made by the primary payer and Medicare on behalf of the beneficiary is $3,000. The beneficiary has no liability for Medicare-covered services since the primary payment satisfied the $520 deductible.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 60 FR 45362, Aug. 31, 1995; 71 FR 9470, Feb. 24, 2006]

§ 411.35 Limitations on charges to a beneficiary or other party when a workers' compensation plan, a no-fault insurer, or an employer group health plan is primary payer.

(a) *Definition.* As used in this section *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for the Medicare deductible and coinsurance provisions and the amounts payable by the primary payer.

(b) *Applicability.* This section applies when a workers' compensation plan, a no-fault insurer or an employer group health plan is primary to Medicare.

(c) *Basic rule.* Except as provided in paragraph (d) of this section, the amounts the provider or supplier may collect or seek to collect, for the Medicare-covered services from the beneficiary or any entity other than the workers' compensation plan, the no-fault insurer, or the employer plan and Medicare, are limited to the following:

(1) The amount paid or payable by the primary payer to the beneficiary. If this amount exceeds the amount payable by Medicare (without regard to deductible or coinsurance), the provider or supplier may retain the primary payment in full without violating the terms of the provider agreement or the conditions of assignment.

(2) The amount, if any, by which the applicable Medicare deductible and coinsurance amounts exceed any primary payment made or due to the beneficiary or to the provider or supplier for the medical services.

(3) The amount of any charges that may be made to a beneficiary under § 413.35 of this chapter when cost limits are applied to the services, or under § 489.32 of this chapter when the services are partially covered, but only to the extent that the primary payer is not responsible for those charges.

(d) *Exception.* The limitations of paragraph (c) of this section do not apply if the services were furnished by a supplier that is not a participating supplier and has not accepted assignment for the services or claimed payment under § 424.64 of this chapter.

§ 411.37 Amount of Medicare recovery when a primary payment is made as a result of a judgment or settlement.

(a) *Recovery against the party that received payment*—(1) *General rule.* Medicare reduces its recovery to take account of the cost of procuring the judgment or settlement, as provided in this section, if—

(i) Procurement costs are incurred because the claim is disputed; and

(ii) Those costs are borne by the party against which CMS seeks to recover.

(2) *Special rule.* If CMS must file suit because the party that received payment opposes CMS's recovery, the recovery amount is as set forth in paragraph (e) of this section.

(b) *Recovery against the primary payer.* If CMS seeks recovery from the primary payer, in accordance with § 411.24(i), the recovery amount will be no greater than the amount determined under paragraph (c) or (d) or (e) of this section.

(c) *Medicare payments are less than the judgment or settlement amount.* If Medicare payments are less than the judgment or settlement amount, the recovery is computed as follows:

(1) Determine the ratio of the procurement costs to the total judgment or settlement payment.

(2) Apply the ratio to the Medicare payment. The product is the Medicare share of procurement costs.

(3) Subtract the Medicare share of procurement costs from the Medicare payments. The remainder is the Medicare recovery amount.

(d) *Medicare payments equal or exceed the judgment or settlement amount.* If Medicare payments equal or exceed the judgment or settlement amount, the recovery amount is the total judgment or settlement payment minus the total procurement costs.

(e) *CMS incurs procurement costs because of opposition to its recovery.* If CMS must bring suit against the party that received payment because that party opposes CMS's recovery, the recovery amount is the lower of the following:

(1) Medicare payment.

(2) The total judgment or settlement amount, minus the party's total procurement cost.

§ 411.39 Automobile and liability insurance (including self-insurance), no-fault insurance, and workers' compensation: Final conditional payment amounts via Web portal.

(a) *Definitions.* For the purpose of this section the following definitions are applicable:

Applicable plan means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan or arrangement:

(1) Liability insurance (including self-insurance).

(2) No fault insurance.

(3) Workers' compensation laws or plans.

(b) *Accessing conditional payment information through the Medicare Secondary Payer Web portal*—(1) *Beneficiary access.* A beneficiary may access his or her Medicare Secondary Payer conditional payment information via the Medicare Secondary Payer Recovery Portal (Web portal), provided the following conditions are met:

(i) The beneficiary creates an account to access his or her Medicare information through the CMS Web site.

(ii) The appropriate Medicare contractor has received initial notice of a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment and has posted the recovery case on the Web portal.

(2) *Beneficiary's attorney or other representative or applicable plan's access using the multifactor authentication process.* A beneficiary's attorney or other representative or an applicable plan may do the following:

(i) Access conditional payment information via the MSP Recovery Portal (Web portal).

(ii) Dispute claims.

(iii) Upload settlement information via the Web portal using multifactor authentication.

(c) *Obtaining a final conditional payment amount.* (1) A beneficiary, or his or her attorney or other representative, or an authorized applicable plan, may obtain a final conditional payment amount related to a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment using the following process:

(i) The beneficiary, his or her attorney or other representative, or an applicable plan, provides initial notice of a pending liability insurance (including self-insurance), no-fault insurance, and workers' compensation settlement, judgment, award, or other payment to the appropriate Medicare contractor before accessing information via the Web portal.

(ii) The Medicare contractor compiles claims for which Medicare has paid conditionally that are related to the pending settlement, judgment, award, or other payment within 65 days or less of receiving the initial notice of the pending settlement, judgment, award, or other payment and posts a recovery case on the Web portal.

(iii) If the underlying liability insurance (including self-insurance), no-fault insurance, or workers' compensation claim derives from one of the following, the beneficiary, or his or her attorney or other representative, must provide notice to CMS' contractor via the Web portal in order to obtain a final conditional payment summary statement and amount through the Web portal:

(A) Alleged exposure to a toxic substance.

(B) Environmental hazard.

(C) Ingestion of pharmaceutical drug or other product or substance.

(D) Implantation of a medical device, joint replacement, or something similar.

(iv) Up to 120 days before the anticipated date of a settlement, judgment, award, or other payment, the beneficiary, or his or her attorney, other representative, or authorized applicable plan may notify CMS, once and only once, via the Web portal, that a settlement, judgment, award or other payment is expected to occur within 120 days or less from the date of notification.

(A) CMS may extend its response timeframe by an additional 30 days when it determines that additional time is required to address claims that Medicare has paid conditionally that

are related to the settlement, judgment, award, or other payment in situations including, but not limited to, the following:

(*1*) A recovery case that requires manual filtering to ensure that associated claims are related to the pending settlement, judgment, award, or other payment.

(*2*) Internal CMS systems failures not otherwise considered caused by exceptional circumstances.

(B) In exceptional circumstances, CMS may further extend its response timeframe by the number of days required to address the issue that resulted from such exceptional circumstances. Exceptional circumstances include, but are not limited to the following:

(*1*) Systems failure(s) due to consequences of extreme adverse weather (loss of power, flooding, etc.).

(*2*) Security breaches of facilities or network(s).

(*3*) Terror threats; strikes and similar labor actions.

(*4*) Civil unrest, uprising, or riot.

(*5*) Destruction of business property (as by fire, etc.).

(*6*) Sabotage.

(*7*) Workplace attack on personnel.

(*8*) Similar circumstances beyond the ordinary control of government, private sector officers or management.

(v) The beneficiary, or his or her attorney, or other representative may then address discrepancies by disputing individual conditional payments, once and only once, if he or she believes that the conditional payment included in the most up-to-date conditional payment summary statement is unrelated to the pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment.

(A) The dispute process is not an appeals process, nor does it establish a right of appeal regarding that dispute. There will be no administrative or judicial review related to this dispute process.

(B) The beneficiary, or his or her attorney or other representative may be required to submit supporting documentation in the form and manner specified by the Secretary to support his or her dispute.

(vi) Disputes submitted through the Web portal and after the beneficiary, or his or her attorney, other representative, or authorized applicable plan has notified CMS that he or she is 120 days or less from the anticipated date of a settlement, judgment, award, or other payment, are resolved within 11 business days of receipt of the dispute and any required supporting documentation.

(vii) When any disputes have been fully resolved, the beneficiary, or his or her attorney or other representative, may download or otherwise request a time and date stamped conditional payment summary statement through the Web portal.

(A) If the download or request is within 3 days of the date of settlement, judgment, award, or other payment, that conditional payment summary statement will constitute Medicare's final conditional payment amount.

(B) If the beneficiary, or his or her attorney or other representative, is within 3 days of the date of settlement, judgment, award, or other payment and any claim disputes have not been fully resolved, he or she may not download or otherwise request a final conditional payment summary statement.

(viii) Within 30 days or less of securing a settlement, judgment, award, or other payment, the beneficiary, or his or her attorney or other representative, must submit through the Web portal documentation specified by the Secretary, including, but not limited to the following:

(A) The date of settlement, judgment, award, or other payment, including the total settlement amount, the attorney fee amount or percentage.

(B) Additional costs borne by the beneficiary to obtain his or her settlement, judgment, award, or other payment.

(*1*) If settlement information is not provided within 30 days or less of securing the settlement, the final conditional payment amount obtained through the Web portal is void.

(*2*) [Reserved]

(ix) Once settlement, judgment, award, or other payment information

is received, CMS applies a pro rata reduction to the final conditional payment amount in accordance with § 411.37 and issues a final MSP recovery demand letter.

(2) An applicable plan may only obtain a final conditional payment amount related to a pending liability insurance (including self-insurance), no-fault insurance, or workers' compensation settlement, judgment, award, or other payment in the form and manner described in § 411.38(b) if the applicable plan has properly registered to use the Web portal and has obtained from the beneficiary, and submitted to the appropriate CMS contractor, proper proof of representation. The applicable plan may obtain read only access if the applicable plan obtains from the beneficiary, and submits to the appropriate CMS contractor, proper consent to release.

(d) *Obligations with respect to future medical items and services.* Final conditional payment amounts obtained via the Web portal represent Medicare covered and otherwise reimbursable items and services that are related to the beneficiary's settlement, judgment, award, or other payment furnished before the time and date stamped on the final conditional payment summary form.

[78 FR 57804, Sept. 20, 2013, as amended at 81 FR 30492, May 17, 2016]

Subpart C—Limitations on Medicare Payment for Services Covered Under Workers' Compensation

§ 411.40 General provisions.

(a) *Definition.* *''Workers' compensation plan of the United States''* includes the workers' compensation plans of the 50 States, the District of Columbia, American Samoa, Guam, Puerto Rico, and the Virgin Islands, as well as the systems provided under the Federal Employees' Compensation Act and the Longshoremen's and Harbor Workers' Compensation Act.

(b) *Limitations on Medicare payment.* (1) Medicare does not pay for any services for which—

(i) Payment has been made, or can reasonably be expected to be made under a workers' compensation law or plan of the United States or a state; or

(ii) Payment could be made under the Federal Black Lung Program, but is precluded solely because the provider of the services has failed to secure, from the Department of Labor, a provider number to include in the claim.

(2) If the payment for a service may not be made under workers' compensation because the service is furnished by a source not authorized to provide that service under the particular workers' compensation program, Medicare pays for the service if it is a covered service.

(3) Medicare makes secondary payments in accordance with §§ 411.32 and 411.33.

[54 FR 41734, Oct. 11, 1989, as amended at 71 FR 9470, Feb. 24, 2006]

§ 411.43 Beneficiary's responsibility with respect to workers' compensation.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under workers' compensation.

(b) Except as specified in § 411.45(a), Medicare does not pay until the beneficiary has exhausted his or her remedies under workers' compensation.

(c) Except as specified in § 411.45(b), Medicare does not pay for services that would have been covered under workers' compensation if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.45 Basis for conditional Medicare payment in workers' compensation cases.

(a) A conditional Medicare payment may be made under either of the following circumstances:

(1) The beneficiary has filed a proper claim for workers' compensation benefits, but the intermediary or carrier determines that the workers' compensation carrier will not pay promptly. This includes cases in which a workers' compensation carrier has denied a claim.

(2) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006, as amended at 73 FR 9685, Feb. 22, 2008]

§ 411.46 Lump-sum payments.

(a) *Lump-sum commutation of future benefits.* If a lump-sum compensation award stipulates that the amount paid is intended to compensate the individual for all future medical expenses required because of the work-related injury or disease, Medicare payments for such services are excluded until medical expenses related to the injury or disease equal the amount of the lump-sum payment.

(b) *Lump-sum compromise settlement.* (1) A lump-sum compromise settlement is deemed to be a workers' compensation payment for Medicare purposes, even if the settlement agreement stipulates that there is no liability under the workers' compensation law or plan.

(2) If a settlement appears to represent an attempt to shift to Medicare the responsibility for payment of medical expenses for the treatment of a work-related condition, the settlement will not be recognized. For example, if the parties to a settlement attempt to maximize the amount of disability benefits paid under workers' compensation by releasing the workers' compensation carrier from liability for medical expenses for a particular condition even though the facts show that the condition is work-related, Medicare will not pay for treatment of that condition.

(c) *Lump-sum compromise settlement: Effect on services furnished before the date of settlement.* Medicare pays for medical expenses incurred before the lump-sum compromise settlement only to the extent specified in § 411.47.

(d) *Lump-sum compromise settlement: Effect on payment for services furnished after the date of settlement*—(1) *Basic rule.* Except as specified in paragraph (d)(2) of this section, if a lump-sum compromise settlement forecloses the possibility of future payment of workers' compensation benefits, medical expenses incurred after the date of the settlement are payable under Medicare.

(2) *Exception.* If the settlement agreement allocates certain amounts for specific future medical services, Medicare does not pay for those services until medical expenses related to the injury or disease equal the amount of the lump-sum settlement allocated to future medical expenses.

§ 411.47 Apportionment of a lump-sum compromise settlement of a workers' compensation claim.

(a) *Determining amount of compromise settlement considered as a payment for medical expenses.* (1) If a compromise settlement allocates a portion of the payment for medical expenses and also gives reasonable recognition to the income replacement element, that apportionment may be accepted as a basis for determining Medicare payments.

(2) If the settlement does not give reasonable recognition to both elements of a workers' compensation award or does not apportion the sum granted, the portion to be considered as payment for medical expenses is computed as follows:

(i) Determine the ratio of the amount awarded (less the reasonable and necessary costs incurred in procuring the settlement) to the total amount that would have been payable under workers' compensation if the claim had not been compromised.

(ii) Multiply that ratio by the total medical expenses incurred as a result of the injury or disease up to the date of the settlement. The product is the amount of the workers' compensation settlement to be considered as payment for medical expenses.

Example: As the result of a work injury, an individual suffered loss of income and incurred medical expenses for which the total workers' compensation payment would have been $24,000 if the case had not been compromised. The medical expenses amounted to $18,000. The workers' compensation carrier made a settlement with the beneficiary under which it paid $8,000 in total. A separate award was made for legal fees. Since the workers' compensation compromise settlement was for one-third of the amount which would have been payable under workers' compensation had the case not been compromised ($8,000/$24,000=⅓), the workers'

compensation compromise settlement is considered to have paid for one-third of the total medical expenses (⅓ × $18,000 = $6,000).

(b) *Determining the amount of the Medicare overpayment.* When conditional Medicare payments have been made, and the beneficiary receives a compromise settlement payment, the Medicare overpayment is determined as set forth in this paragraph (b). The amount of the workers' compensation payment that is considered to be for medical expenses (as determined under paragraph (a) of this section) is applied, at the workers' compensation rate of payment prevailing in the particular jurisdiction, in the following order:

(1) First to any beneficiary payments for services payable under workers' compensation but not covered under Medicare.

(2) Then to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part B. (These include deductible and coinsurance amounts and, in unassigned cases, the charge in excess of the reasonable charge.)

(3) Last to any beneficiary payments for services payable under workers' compensation and also covered under Medicare Part A. (These include Part A deductible and coinsurance amounts and charges for services furnished after benefits are exhausted.)

The difference between the amount of the workers' compensation payment for medical expenses and any beneficiary payments constitutes the Medicare overpayment. The beneficiary is liable for that amount.

Example: In the example in paragraph (a) of this section, it was determined that the workers' compensation settlement paid for $6,000 of the total medical expenses. The $18,000 in medical expenses included $1,500 in charges for services not covered under Medicare, $7,500 in charges for services covered under Medicare Part B, and $9,000 in hospital charges for services covered under Medicare Part A. All charges were at the workers' compensation payment rate, that is, in amounts the provider or supplier must accept as payment in full.

The Medicare reasonable charge for physicians' services was $7,000 and Medicare paid $5,600 (80 percent of the reasonable charge). The Part B deductible had been met. The Medicare payment rate for the hospital services was $8,000. Medicare paid the hospital $7,480 ($8,000—the Part A deductible of $520).

In this situation, the beneficiary's payments totalled $3,920:

Services not covered under Medicare	$1,500
Excess of physicians' charges over reasonable charges	500
Medicare Part B coinsurance	1,400
Part A deductible	520
Total	3,920

The Medicare overpayment, for which the beneficiary is liable, would be $2,080 ($6,000–$3,920).

Subpart D—Limitations on Medicare Payment for Services Covered Under Liability or No-Fault Insurance

§ 411.50 General provisions.

(a) *Limits on applicability.* The provisions of this subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) *Definitions.*

Automobile means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

Liability insurance payment means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

No-fault insurance means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called

''medical payments coverage'', ''personal injury protection'', or ''medical expense coverage''.

Prompt or *promptly*, when used in connection with payment by a liability insurer means payment within 120 days after the earlier of the following:

(1) The date a claim is filed with an insurer or a lien is filed against a potential liability settlement.

(2) The date the service was furnished or, in the case of inpatient hospital services, the date of discharge.

Self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. This term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of a non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort Claims Act. An entity that engages in a business, trade, or profession is deemed to have a self-insured plan for purposes of liability insurance if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

Underinsured motorist insurance means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

Uninsured motorist insurance means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) *Limitation on payment for services covered under no-fault insurance.* Except as provided under §§ 411.52 and 411.53 with respect to conditional payments. Medicare does not pay for the following:

(1) Services for which payment has been made or can reasonably be expected to be made under automobile no-fault insurance.

(2) Services furnished on or after November 13, 1989 for which payment has been made or can reasonably be expected to be made under any no-fault insurance other than automobile no-fault.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990; 71 FR 9470, Feb. 24, 2006]

§ 411.51 Beneficiary's responsibility with respect to no-fault insurance.

(a) The beneficiary is responsible for taking whatever action is necessary to obtain any payment that can reasonably be expected under no-fault insurance.

(b) Except as specified in § 411.53, Medicare does not pay until the beneficiary has exhausted his or her remedies under no-fault insurance.

(c) Except as specified in § 411.53, Medicare does not pay for services that would have been covered by the no-fault insurance if the beneficiary had filed a proper claim.

(d) However, if a claim is denied for reasons other than not being a proper claim, Medicare pays for the services if they are covered under Medicare.

§ 411.52 Basis for conditional Medicare payment in liability cases.

(a) A conditional Medicare payment may be made in liability cases under either of the following circumstances:

(1) The beneficiary has filed a proper claim for liability insurance benefits but the intermediary or carrier determines that the liability insurer will not pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the liability insurance carrier has denied the claim.

(2) The beneficiary has not filed a claim for liability insurance benefits.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006]

§ 411.53 Basis for conditional Medicare payment in no-fault cases.

(a) A conditional Medicare payment may be made in no-fault cases under either of the following circumstances:

(1) The beneficiary has filed a proper claim for no-fault insurance benefits but the intermediary or carrier determines that the no-fault insurer will not

pay promptly for any reason other than the circumstances described in § 411.32(a)(1). This includes cases in which the no-fault insurance carrier has denied the claim.

(2) The beneficiary, because of physical or mental incapacity, failed to meet a claim-filing requirement stipulated in the policy.

(b) Any conditional payment that CMS makes is conditioned on reimbursement to CMS in accordance with subpart B of this part.

[71 FR 9470, Feb. 24, 2006]

§ 411.54 Limitation on charges when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer.

(a) *Definition.* As used in this section, *Medicare-covered services* means services for which Medicare benefits are payable or would be payable except for applicable Medicare deductible and coinsurance provisions. Medicare benefits are payable notwithstanding potential liability insurance payments, but are recoverable in accordance with § 411.24.

(b) *Applicability.* This section applies when a beneficiary has received a liability insurance payment or has a claim pending against a liability insurer for injuries or illness allegedly caused by another party.

(c) *Itemized bill.* A hospital must, upon request, furnish to the beneficiary or his or her representative an itemized bill of the hospital's charges.

(d) *Exception—(1) Prepaid health plans.* If the services were furnished through an organization that has a contact under section 1876 of the Act (that is, an HMO or CMP), or through an organization that is paid under section 1833(a)(1)(A) of the Act (that is, through an HCPP) the rules of § 417.528 of this chapter apply.

(2) *Special rules for Oregon.* For the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision, there are the following special rules:

(i) The provider or supplier may elect to bill a liability insurer or place a lien against the beneficiary's liability settlement for Medicare covered services, rather than bill only Medicare for Medicare covered services, if the liability insurer pays within 120 days after the earlier of the following dates:

(A) The date the provider or supplier files a claim with the insurer or places a lien against a potential liability settlement.

(B) The date the services were provided or, in the case of inpatient hospital services, the date of discharge.

(ii) If the liability insurer does not pay within the 120-day period, the provider or supplier:

(A) Must withdraw its claim with the liability insurer and/or withdraw its lien against a potential liability settlement.

(B) May only bill Medicare for Medicare covered services.

(C) May bill the beneficiary only for applicable Medicare deductible and coinsurance amounts plus the amount of any charges that may be made to a beneficiary under 413.35 of this chapter (when cost limits are applied to these services) or under 489.32 of this chapter (when services are partially covered).

[54 FR 41734, Oct. 11, 1989, as amended at 68 FR 43942, July 25, 2003]

Subpart E—Limitations on Payment for Services Covered Under Group Health Plans: General Provisions

SOURCE: 60 FR 45362, Aug. 31, 1995, unless otherwise noted.

§ 411.100 Basis and scope.

(a) *Statutory basis.* (1) Section 1862(b) of the Act provides in part that Medicare is secondary payer, under specified conditions, for services covered under any of the following:

(i) Group health plans of employers that employ at least 20 employees and that cover Medicare beneficiaries age 65 or older who are covered under the plan by virtue of the individual's current employment status with an employer or the current employment status of a spouse of any age. (Section 1862(b)(1)(A))

(ii) Group health plans (without regard to the number of individuals employed and irrespective of current employment status) that cover individuals who have ESRD. Except as provided in § 411.163, group health plans

are always primary payers throughout the first 18 months of ESRD-based Medicare eligibility or entitlement. (Section 1862(b)(1)(C))

(iii) Large group health plans (that is, plans of employers that employ at least 100 employees) and that cover Medicare beneficiaries who are under age 65, entitled to Medicare on the basis of disability, and covered under the plan by virtue of the individual's or a family member's current employment status with an employer. (Section 1862(b)(1)(B))

(2) Sections 1862(b)(1)(A), (B), and (C) of the Act provide that group health plans and large group health plans may not take into account that the individuals described in paragraph (a)(1) of this section are entitled to Medicare on the basis of age or disability, or eligible for, or entitled to Medicare on the basis of ESRD.

(3) Section 1862(b)(1)(A)(i)(II) of the Act provides that group health plans of employers of 20 or more employees must provide to any employee or spouse age 65 or older the same benefits, under the same conditions, that it provides to employees and spouses under 65. The requirement applies regardless of whether the individual or spouse 65 or older is entitled to Medicare.

(4) Section 1862(b)(1)(C)(ii) of the Act provides that group health plans may not differentiate in the benefits they provide between individuals who have ESRD and other individuals covered under the plan on the basis of the existence of ESRD, the need for renal dialysis, or in any other manner. Actions that constitute ''differentiating'' are listed in §411.161(b).

(b) *Scope.* This subpart sets forth general rules pertinent to—

(1) Medicare payment for services that are covered under a group health plan and are furnished to certain beneficiaries who are entitled on the basis of ESRD, age, or disability.

(2) The prohibition against taking into account Medicare entitlement based on age or disability, or Medicare eligibility or entitlement based on ESRD.

(3) The prohibition against differentiation in benefits between individuals who have ESRD and other individuals covered under the plan.

(4) The requirement to provide to those 65 or over the same benefits under the same conditions as are provided to those under 65.

(5) The appeals procedures for group health plans that CMS determines are nonconforming plans.

§411.101 Definitions.

As used in this subpart and in subparts F through H of this part—

COBRA stands for Consolidated Omnibus Budget Reconciliation Act of 1985.

Days means calendar days.

Employee (subject to the special rules in §411.104) means an individual who—

(1) Is working for an employer; or

(2) Is not working for an employer but is receiving payments that are subject to FICA taxes, or would be subject to FICA taxes except that the employer is exempt from those taxes under the Internal Revenue Code.

Employer means, in addition to individuals (including self-employed persons) and organizations engaged in a trade or business, other entities exempt from income tax such as religious, charitable, and educational institutions, the governments of the United States, the individual States, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the District of Columbia, and the agencies, instrumentalities, and political subdivisions of these governments.

FICA stands for the Federal Insurance Contributions Act, the law that imposes social security taxes on employers and employees under section 21 of the Internal Revenue Code.

Group health plan (GHP) means any arrangement made by one or more employers or employee organizations to provide health care directly or through other methods such as insurance or reimbursement, to current or former employees, the employer, others associated or formerly associated with the employer in a business relationship, or their families, that—

(1) Is of, or contributed to by, one or more employers or employee organizations.

(2) If it involves more than one employer or employee organization, provides for common administration.

(3) Provides substantially the same benefits or the same benefit options to all those enrolled under the arrangement.

The term includes self-insured plans, plans of governmental entities (Federal, State and local), and employee organization plans; that is, union plans, employee health and welfare funds or other employee organization plans. The term also includes employee-pay-all plans, which are plans under the auspices of one or more employers or employee organizations but which receive no financial contributions from them. The term does not include a plan that is unavailable to employees; for example, a plan only for self-employed persons.

IRC stands for Internal Revenue Code.

IRS stands for Internal Revenue Service.

Large group health plan (LGHP) means a GHP that covers employees of either—

(1) A single employer or employee organization that employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year; or

(2) Two or more employers, or employee organizations, at least one of which employed at least 100 full-time or part-time employees on 50 percent or more of its regular business days during the previous calendar year.

MSP stands for Medicare secondary payer.

Multi-employer plan means a plan that is sponsored jointly by two or more employers (sometimes called a multiple-employer plan) or by employers and unions (sometimes under the Taft-Hartley law).

Self-employed person encompasses consultants, owners of businesses, and directors of corporations, and members of the clergy and religious orders who are paid for their services by a religious body or other entity.

Similarly situated individual means—

(1) In the case of employees, other employees enrolled or seeking to enroll in the plan; and

(2) In the case of other categories of individuals, other persons in any of those categories who are enrolled or seeking to enroll in the plan.

§ 411.102 Basic prohibitions and requirements.

(a) *ESRD.* (1) A group health plan of any size—(i) May not take into account the ESRD-based Medicare eligibility or entitlement of any individual who is covered or seeks to be covered under the plan; and

(ii) May not differentiate in the benefits it provides between individuals with ESRD and other individuals covered under the plan, on the basis of the existence of ESRD, or the need for dialysis, or in any other manner.

(2) The prohibitions of paragraph (a) of this section do not prohibit a plan from paying benefits secondary to Medicare after the first 18 months of ESRD-based eligibility or entitlement.

(b) *Age.* A GHP of an employer or employee organization of at least 20 employees—

(1) May not take into account the age-based Medicare entitlement of an individual or spouse age 65 or older who is covered (or seeks to be covered) under the plan by virtue of current employment status; and

(2) Must provide, to employees age 65 or older and to spouses age 65 or older of employees of any age, the same benefits under the same conditions as it provides to employees and spouses under age 65.

(c) *Disability.* A GHP of an employer or employee organization of at least 100 employees may not take into account the disability-based Medicare entitlement of any individual who is covered (or seeks to be covered) under the plan by virtue of current employment status.

§ 411.103 Prohibition against financial and other incentives.

(a) *General rule.* An employer or other entity (for example, an insurer) is prohibited from offering Medicare beneficiaries financial or other benefits as incentives not to enroll in, or to terminate enrollment in, a GHP that is, or would be, primary to Medicare. This prohibition precludes offering to Medicare beneficiaries an alternative to the

employer primary plan (for example, coverage of prescription drugs) unless the beneficiary has primary coverage other than Medicare. An example would be primary coverage through his own or a spouse's employer.

(b) *Penalty for violation.* (1) Any entity that violates the prohibition of paragraph (a) of this section is subject to a civil money penalty of up to $5,000 as adjusted annually under 45 CFR part 102 for each violation; and

(2) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to the civil money penalty of up to $5,000 as adjusted annually under 45 CFR part 102 in the same manner as the provisions apply to a penalty or proceeding under section 1128A(a).

[60 FR 45362, Aug. 31, 1995, as amended at 81 FR 61561, Sept. 6, 2016]

§ 411.104 Current employment status.

(a) *General rule.* An individual has current employment status if—

(1) The individual is actively working as an employee, is the employer (including a self-employed person), or is associated with the employer in a business relationship; or

(2) The individual is not actively working and—

(i) Is receiving disability benefits from an employer for up to 6 months (the first 6 months of employer disability benefits are subject to FICA taxes); or

(ii) Retains employment rights in the industry and has not had his employment terminated by the employer, if the employer provides the coverage (or has not had his membership in the employee organization terminated, if the employee organization provides the coverage), is not receiving disability benefits from an employer for more than 6 months, is not receiving disability benefits from Social Security, and has GHP coverage that is not pursuant to COBRA continuation coverage (26 U.S.C. 4980B; 29 U.S.C. 1161–1168; 42 U.S.C. 300bb–1 et seq.). Whether or not the individual is receiving pay during the period of nonwork is not a factor.

(b) *Persons who retain employment rights.* For purposes of paragraph (a)(2) of this section, persons who retain employment rights include but are not limited to—

(1) Persons who are furloughed, temporarily laid off, or who are on sick leave;

(2) Teachers and seasonal workers who normally do not work throughout the year; and

(3) Persons who have health coverage that extends beyond or between active employment periods; for example, based on an hours bank arrangement. (Active union members often have hours bank coverage.)

(c) *Coverage by virtue of current employment status.* An individual has coverage by virtue of current employment status with an employer if—

(1) the individual has GHP or LGHP coverage based on employment, including coverage based on a certain number of hours worked for that employer or a certain level of commissions earned from work for that employer at any time; and

(2) the individual has current employment status with that employer, as defined in paragraph (a) of this section.

(d) *Special rule: Self-employed person.* A self-employed individual is considered to have GHP or LGHP coverage by virtue of current employment status during a particular tax year only if, during the preceding tax year, the individual's net earnings, from work in that year related to the employer that offers the group health coverage, are at least equal to the amount specified in section 211(b)(2) of the Act, which defines ''self-employment income'' for social security purposes.

(e) *Special Rule: members of religious orders and members of clergy*—(1) *Members of religious orders who have not taken a vow of poverty.* A member of a religious order who has *not* taken a vow of poverty is considered to have current employment status with the religious order if—

(i) The religious order pays FICA taxes on behalf of that member; or

(ii) The individual is receiving cash remuneration from the religious order.

(2) *Members of religious orders who have taken a vow of poverty.* A member of a religious order whose members are required to take a vow of poverty is not considered to be employed by the order if the services he or she performs

as a member of the order are considered employment only because the order elects social security coverage under section 3121(r) of the IRC. This exemption applies retroactively to services performed as a member of the order, beginning with the effective dates of the MSP provisions for the aged and the disabled, respectively. The exemption does not apply to services performed for employers outside of the order.

(3) *Members of the clergy.* A member of the clergy is considered to have current employment status with a church or other religious organization if the individual is receiving cash remuneration from the church or other religious organization for services rendered.

(f) *Special rule: Delayed compensation subject to FICA taxes.* An individual who is not working is not considered an employee solely on the basis of receiving delayed compensation payments for previous periods of work even if those payments are subject to FICA taxes (or would be subject to FICA taxes if the employer were not exempt from paying those taxes). For example, an individual who is not working in 1993 and receives payments subject to FICA taxes for work performed in 1992 is not considered to be an employee in 1993 solely on the basis of receiving those payments.

§ 411.106 Aggregation rules.

The following rules apply in determining the number and size of employers, as required by the MSP provisions for the aged and disabled:

(a) All employers that are treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code (IRC) of 1986 (26 U.S.C. 52 (a) and (b)) are treated as a single employer.

(b) All employees of the members of an affiliated service group (as defined in section 414(m) of the IRC (26 U.S.C. 414m)) are treated as employed by a single employer.

(c) Leased employees (as defined in section 414(n)(2) of the IRC (26 U.S.C. 414(n)(2)) are treated as employees of the person for whom they perform services to the same extent as they are treated under section 414(n) of the IRC.

(d) In applying the IRC provisions identified in this section, CMS relies upon regulations and decisions of the Secretary of the Treasury respecting those provisions.

§ 411.108 Taking into account entitlement to Medicare.

(a) *Examples of actions that constitute ''taking into account''.* Actions by GHPs or LGHPs that constitute taking into account that an individual is entitled to Medicare on the basis of ESRD, age, or disability (or eligible on the basis of ESRD) include, but are not limited to, the following:

(1) Failure to pay primary benefits as required by subparts F, G, and H of this part 411.

(2) Offering coverage that is secondary to Medicare to individuals entitled to Medicare.

(3) Terminating coverage because the individual has become entitled to Medicare, except as permitted under COBRA continuation coverage provisions (26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); and 42 U.S.C. 300bb–2.(2)(D)).

(4) In the case of a LGHP, denying or terminating coverage because an individual is entitled to Medicare on the basis of disability without denying or terminating coverage for similarly situated individuals who are not entitled to Medicare on the basis of disability.

(5) Imposing limitations on benefits for a Medicare entitled individual that do not apply to others enrolled in the plan, such as providing less comprehensive health care coverage, excluding benefits, reducing benefits, charging higher deductibles or coinsurance, providing for lower annual or lifetime benefit limits, or more restrictive pre-existing illness limitations.

(6) Charging a Medicare entitled individual higher premiums.

(7) Requiring a Medicare entitled individual to wait longer for coverage to begin.

(8) Paying providers and suppliers less for services furnished to a Medicare beneficiary than for the same services furnished to an enrollee who is not entitled to Medicare.

(9) Providing misleading or incomplete information that would have the effect of inducing a Medicare entitled

individual to reject the employer plan, thereby making Medicare the primary payer. An example of this would be informing the beneficiary of the right to accept or reject the employer plan but failing to inform the individual that, if he or she rejects the plan, the plan will not be permitted to provide or pay for secondary benefits.

(10) Including in its health insurance cards, claims forms, or brochures distributed to beneficiaries, providers, and suppliers, instructions to bill Medicare first for services furnished to Medicare beneficiaries without stipulating that such action may be taken only when Medicare is the primary payer.

(11) Refusing to enroll an individual for whom Medicare would be secondary payer, when enrollment is available to similarly situated individuals for whom Medicare would not be secondary payer.

(b) *Permissible actions.* (1) If a GHP or LGHP makes benefit distinctions among various categories of individuals (distinctions unrelated to the fact that the individual is disabled, based, for instance, on length of time employed, occupation, or marital status), the GHP or LGHP may make the same distinctions among the same categories of individuals entitled to Medicare whose plan coverage is based on current employment status. For example, if a GHP or LGHP does not offer coverage to employees who have worked less than one year and who are *not* entitled to Medicare on the basis of disability or age, the GHP or LGHP is not required to offer coverage to employees who have worked less than one year and who *are* entitled to Medicare on the basis of disability or age.

(2) A GHP or LGHP may pay benefits secondary to Medicare for an aged or disabled beneficiary who has current employment status if the plan coverage is COBRA continuation coverage because of reduced hours of work. Medicare is primary payer for this beneficiary because, although he or she has current employment status, the GHP coverage is by virtue of the COBRA law rather than by virtue of the current employment status.

(3) A GHP may terminate COBRA continuation coverage of an individual who becomes entitled to Medicare on the basis of ESRD, when permitted under the COBRA provisions.

[60 FR 45362, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§411.110 Basis for determination of nonconformance.

(a) A ''determination of nonconformance'' is a CMS determination that a GHP or LGHP is a nonconforming plan as provided in this section.

(b) CMS makes a determination of nonconformance for a GHP or LGHP that, at any time during a calendar year, fails to comply with any of the following statutory provisions:

(1) The prohibition against taking into account that a beneficiary who is covered or seeks to be covered under the plan is entitled to Medicare on the basis of ESRD, age, or disability, or eligible on the basis of ESRD.

(2) The nondifferentiation clause for individuals with ESRD.

(3) The equal benefits clause for the working aged.

(4) The obligation to refund conditional Medicare primary payments.

(c) CMS may make a determination of nonconformance for a GHP or LGHP that fails to respond to a request for information, or to provide correct information, either voluntarily or in response to a CMS request, on the plan's primary payment obligation with respect to a given beneficiary, if that failure contributes to either or both of the following:

(1) Medicare erroneously making a primary payment.

(2) A delay or foreclosure of CMS's ability to recover an erroneous primary payment.

§411.112 Documentation of conformance.

(a) *Acceptable documentation.* CMS may require a GHP or LGHP to demonstrate that it has complied with the Medicare secondary payer provisions and to submit supporting documentation by an official authorized to act on behalf of the entity, under penalty of perjury. The following are examples of documentation that may be acceptable:

(1) A copy of the employer's plan or policy that specifies the services covered, conditions of coverage, benefit levels and limitations with respect to

persons entitled to Medicare on the basis of ESRD, age, or disability as compared to the provisions applicable to other enrollees and potential enrollees.

(2) An explanation of the plan's allegation that it does not owe CMS any amount CMS claims the plan owes as repayment for conditional or mistaken Medicare primary payments.

(b) *Lack of acceptable documentation.* If a GHP or LGHP fails to provide acceptable evidence or documentation that it has complied with the MSP prohibitions and requirements set forth in § 411.110, CMS may make a determination of nonconformance for both the year in which the services were furnished and the year in which the request for information was made.

§ 411.114 Determination of nonconformance.

(a) *Starting dates for determination of nonconformance.* CMS's authority to determine nonconformance of GHPs begins on the following dates:

(1) On January 1, 1987 for MSP provisions that affect the disabled.

(2) On December 20, 1989 for MSP provisions that affect ESRD beneficiaries and the working aged.

(3) On August 10, 1993 for failure to refund mistaken Medicare primary payments.

(b) *Special rule for failure to repay.* A GHP that fails to comply with § 411.110 (a)(1), (a)(2), or (a)(3) in a particular year is nonconforming for that year. If, in a subsequent year, that plan fails to repay the resulting mistaken primary payments (in accordance with § 411.110(a)(4)), the plan is also nonconforming for the subsequent year. For example, if a plan paid secondary for the working aged in 1991, that plan was nonconforming for 1991. If in 1994 CMS identifies mistaken primary payments attributable to the 1991 violation, and the plan refuses to repay, it is also nonconforming for 1994.

§ 411.115 Notice of determination of nonconformance.

(a) *Notice to the GHP or LGHP.* (1) If CMS determines that a GHP or an LGHP is nonconforming with respect to a particular calendar year, CMS mails to the plan written notice of the following:

(i) The determination.

(ii) The basis for the determination.

(iii) The right of the parties to request a hearing.

(iv) An explanation of the procedure for requesting a hearing.

(v) The tax that may be assessed by the IRS in accordance with section 5000 of the IRC.

(vi) The fact that if none of the parties requests a hearing within 65 days from the date of its notice, the determination is binding on all parties unless it is reopened in accordance with § 411.126.

(2) The notice also states that the plan must, within 30 days from the date on its notice, submit to CMS the names and addresses of all employers and employee organizations that contributed to the plan during the calendar year for which CMS has determined nonconformance.

(b) *Notice to contributing employers and employee organizations.* CMS mails written notice of the determination, including all the information specified in paragraph (a)(1) of this section, to all contributing employers and employee organizations already known to CMS or identified by the plan in accordance with paragraph (a)(2) of this section. Employers and employee organizations have 65 days from the date of their notice to request a hearing.

§ 411.120 Appeals.

(a) *Parties to the determination.* The parties to the determination are CMS, the GHP or LGHP for which CMS determined nonconformance, and any employers or employee organizations that contributed to the plan during the calendar year for which CMS determined nonconformance.

(b) *Request for hearing.* (1) A party's request for hearing must be in writing (not in facsimile or other electronic medium) and in the manner stipulated in the notice of nonconformance; it must be filed within 65 days from the date on the notice.

(2) The request may include rationale showing why the parties believe that CMS's determination is incorrect and supporting documentation.

(3) A request is considered filed on the date it is received by the appropriate office, as shown by the receipt date stamped on the request.

§411.121 Hearing procedures.

(a) *Nature of hearing.* (1) If any of the parties requests a hearing within 65 days from the date on the notice of the determination of nonconformance, the CMS Administrator appoints a hearing officer.

(2) If no party files a request within the 65-day period, the initial determination of nonconformance is binding upon all parties unless it is reopened in accordance with §411.126.

(3) If more than one party requests a hearing the hearing officer conducts a single hearing in which all parties may participate.

(4) *On the record review.* Ordinarily, the hearing officer makes a decision based upon review of the data and documents on which CMS based its determination of nonconformance and any other documentation submitted by any of the parties within 65 days from the date on the notice.

(5) *Oral hearing.* The hearing officer may provide for an oral hearing either on his or her own motion or in response to a party's request if the party demonstrates to the hearing officer's satisfaction that an oral hearing is necessary. Within 30 days of receipt of the request, the hearing officer gives all known parties written notice of the request and whether the request for oral hearing is granted.

(b) *Notice of time and place of oral hearing.* If the hearing officer provides an oral hearing, he or she gives all known parties written notice of the time and place of the hearing at least 30 days before the scheduled date.

(c) *Prehearing discovery.* (1) The hearing officer may permit prehearing discovery if it is requested by a party at least 10 days before the scheduled date of the hearing.

(2) If the hearing officer approves the request, he or she—

(i) Provides a reasonable time for inspection and reproduction of documents; and

(ii) In ruling on discovery matters, is guided by the Federal Rules of Civil Procedure. (28 U.S.C.A. Rules 26–37)

(3) The hearing officer's orders on all discovery matters are final.

(d) *Conduct of hearing.* The hearing officer determines the conduct of the hearing, including the order in which the evidence and the allegations are presented.

(e) *Evidence at hearing.* (1) The hearing officer inquires into the matters at issue and may receive from all parties documentary and other evidence that is pertinent and material, including the testimony of witnesses, and evidence that would be inadmissible in a court of law.

(2) Evidence may be received at any time before the conclusion of the hearing.

(3) The hearing officer gives the parties opportunity for submission and consideration of evidence and arguments and, in ruling on the admissibility of evidence, excludes irrelevant, immaterial, or unduly repetitious evidence.

(4) The hearing officer's ruling on admissibility of evidence is final and not subject to further review.

(f) *Subpoenas.* (1) The hearing officer may, either on his or her own motion or upon the request of any party, issue subpoenas for either or both of the following if they are reasonably necessary for full presentation of the case:

(i) The attendance and testimony of witnesses.

(ii) The production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(2) A party that wishes the issuance of a subpoena must, at least 10 days before the date fixed for the hearing, file with the hearing officer a written request that identifies the witnesses or documents to be produced and describes the address or location in sufficient detail to permit the witnesses or documents to be found.

(3) The request for a subpoena must state the pertinent facts that the party expects to establish by the witnesses or documents and whether those facts could be established by other evidence without the use of a subpoena.

(4) The hearing officer issues the subpoenas at his or her discretion, and CMS assumes the cost of the issuance

and the fees and mileage of any subpoenaed witness, in accordance with section 205(d) of the Act (42 U.S.C. 405(d)).

(g) *Witnesses.* Witnesses at the hearing testify under oath or affirmation, unless excused by the hearing officer for cause. The hearing officer may examine the witnesses and shall allow the parties to examine and cross-examine witnesses.

(h) *Record of hearing.* A complete record of the proceedings at the hearing is made and transcribed in all cases. It is made available to the parties upon request. The record is not closed until a decision has been issued.

(i) *Sources of hearing officer's authority.* In the conduct of the hearing, the hearing officer complies with all the provisions of title XVIII of the Act and implementing regulations, as well as with CMS Rulings issued under § 401.108 of this chapter. The hearing officer gives great weight to interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS.

§ 411.122 Hearing officer's decision.

(a) *Timing.* (1) If the decision is based on a review of the record, the hearing officer mails the decision to all known parties within 120 days from the date of receipt of the request for hearing.

(2) If the decision is based on an oral hearing, the hearing officer mails the decision to all known parties within 120 days from the conclusion of the hearing.

(b) *Basis, content, and distribution of hearing decision.* (1) The written decision is based on substantial evidence and contains findings of fact, a statement of reasons, and conclusions of law.

(2) The hearing officer mails a copy of the decision to each of the parties, by certified mail, return receipt requested, and includes a notice that the administrator may review the hearing decision at the request of a party or on his or her own motion.

(c) *Effect of hearing decision.* The hearing officer's decision is the final Departmental decision and is binding upon all parties unless the Administrator chooses to review that decision in accordance with § 411.124 or it is reopened by the hearing officer in accordance with § 411.126.

§ 411.124 Administrator's review of hearing decision.

(a) *Request for review.* A party's request for review of a hearing officer's decision must be in writing (not in facsimile or other electronic medium) and must be received by the Administrator within 25 days from the date on the decision.

(b) *Office of the Attorney Advisor responsibility.* The Office of the Attorney Advisor examines the hearing officer's decision, the requests made by any of the parties or CMS, and any submission made in accordance with the provisions of this section in order to assist the Administrator in deciding whether to review the decision.

(c) *Administrator's discretion.* The Administrator may—

(1) Review or decline to review the hearing officer's decision;

(2) Exercise this discretion on his or her own motion or in response to a request from any of the parties; and

(3) Delegate review responsibility to the Deputy Administrator. (As used in this section, the term ''Administrator'' includes ''Deputy Administrator'' if review responsibility has been delegated.)

(d) *Basis for decision to review.* In deciding whether to review a hearing officer's decision, the Administrator considers—

(1) Whether the decision—

(i) Is based on a correct interpretation of law, regulation, or CMS Ruling;

(ii) Is supported by substantial evidence;

(iii) Presents a significant policy issue having a basis in law and regulations;

(iv) Requires clarification, amplification, or an alternative legal basis for the decision; and

(v) Is within the authority provided by statute, regulation, or CMS Ruling; and

(2) Whether review may lead to the issuance of a CMS Ruling or other directive needed to clarify a statute or regulation.

(e) *Notice of decision to review or not to review.* (1) The Administrator gives all

parties prompt written notice of his or her decision to review or not to review.

(2) The notice of a decision to review identifies the specific issues the Administrator will consider.

(f) *Response to notice of decision to review.* (1) Within 20 days from the date on a notice of the Administrator's decision to review a hearing officer's decision, any of the parties may file with the Administrator any or all of the following:

(i) Proposed findings and conclusions.

(ii) Supporting views or exceptions to the hearing officer's decision.

(iii) Supporting reasons for the proposed findings and exceptions.

(iv) A rebuttal to another party's request for review or to other submissions already filed with the Administrator.

(2) The submissions must be limited to the issues the Administrator has decided to review and confined to the record established by the hearing officer.

(3) All communications from the parties concerning a hearing officer's decision being reviewed by the Administrator must be in writing (not in facsimile or other electronic medium) and must include a certification that copies have been sent to all other parties.

(4) The Administrator does not consider any communication that does not meet the requirements of this paragraph.

(g) *Administrator's review decision.* (1) The Administrator bases his or her decision on the following:

(i) The entire record developed by the hearing officer.

(ii) Any materials submitted in connection with the hearing or under paragraph (f) of this section.

(iii) Generally known facts not subject to reasonable dispute.

(2) The Administrator mails copies of the review decision to all parties within 120 days from the date of the hearing officer's decision.

(3) The Administrator's review decision may affirm, reverse, or modify the hearing decision or may remand the case to the hearing officer.

(h) *Basis and effect of remand*—(1) *Basis.* The bases for remand do not include the following:

(i) Evidence that existed at the time of the hearing and that was known or could reasonably have been expected to be known.

(ii) A court case that was either not available at the time of the hearing or was decided after the hearing.

(iii) Change of the parties' representation.

(iv) An alternative legal basis for an issue in dispute.

(2) *Effect of remand.* (i) The Administrator may instruct the hearing officer to take further action with respect to the development of additional facts or new issues or to consider the applicability of laws or regulations other than those considered during the hearing.

(ii) The hearing officer takes the action in accordance with the Administrator's instructions in the remand notice and again issues a decision.

(iii) The Administrator may review or decline to review the hearing officer's remand decision in accordance with the procedures set forth in this section.

(i) *Finality of decision.* The Administrator's review decision, or the hearing officer's decision following remand, is the final Departmental decision and is binding on all parties unless the Administrator chooses to review the decision in accordance with this section, or the decision is reopened in accordance with §411.126.

§411.126 Reopening of determinations and decisions.

(a) A determination that a GHP or LGHP is a nonconforming GHP or the decision or revised decision of a hearing officer or of the CMS Administrator may be reopened within 12 months from the date on the notice of determination or decision or revised decision, for any reason by the entity that issued the determination or decision.

(b) The decision to reopen or not to reopen is not appealable.

§411.130 Referral to Internal Revenue Service (IRS).

(a) *CMS responsibility.* After CMS determines that a plan has been a nonconforming GHP in a particular year, it refers its determination to the IRS,

but only after the parties have exhausted all CMS appeal rights with respect to the determination.

(b) *IRS responsibility*. The IRS administers section 5000 of the IRC, which imposes a tax on employers (other than governmental entities) and employee organizations that contribute to a nonconforming GHP. The tax is equal to 25 percent of the employer's or employee organization's expenses, incurred during the calendar year in which the plan is a nonconforming GHP, for each GHP, both conforming and nonconforming, to which the employer or employee organization contributes.

Subpart F—Special Rules: Individuals Eligible or Entitled on the Basis of ESRD, Who Are Also Covered Under Group Health Plans

§ 411.160 Scope.

This subpart sets forth special rules that apply to individuals who are eligible for, or entitled to, Medicare on the basis of ESRD. (Section 406.13 of this chapter contains the rules for eligibility and entitlement based on ESRD.)

[60 FR 45367, Aug. 31, 1995]

§ 411.161 Prohibition against taking into account Medicare eligibility or entitlement or differentiating benefits.

(a) *Taking into account*—(1) *Basic rule*. A GHP may not take into account that an individual is eligible for or entitled to Medicare benefits on the basis of ESRD during the coordination period specified in § 411.162(b) and (c). Examples of actions that constitute taking into account Medicare entitlement are listed in § 411.108(a).

(2) *Applicability*. This prohibition applies for ESRD-based Medicare eligibility to the same extent as for ESRD-based Medicare entitlement. An individual who has ESRD but who has not filed an application for entitlement to Medicare on that basis is eligible for Medicare based on ESRD for purposes of paragraphs (b)(2) and (c)(2) through (c)(4) of § 411.162 if the individual meets the other requirements of § 406.13 of this chapter.

(3) *Relation to COBRA continuation coverage*. This rule does not prohibit the termination of GHP coverage under title X of COBRA when termination of that coverage is expressly permitted, upon entitlement to Medicare, under 26 U.S.C. 4980B(f)(2)(B)(iv); 29 U.S.C. 1162.(2)(D); or 42 U.S.C. 300bb–2.(2)(D).[1] (Situations in which Medicare is secondary to COBRA continuation coverage are set forth in § 411.162(a)(3).)

(b) *Nondifferentiation*. (1) A GHP may not differentiate in the benefits it provides between individuals who have ESRD and others enrolled in the plan, on the basis of the existence of ESRD, or the need for renal dialysis, or in any other manner.

(2) GHP actions that constitute differentiation in plan benefits (and that may also constitute ''taking into account'' Medicare eligibility or entitlement) include, but are not limited to the following:

(i) Terminating coverage of individuals with ESRD, when there is no basis for such termination unrelated to ESRD (such as failure to pay plan premiums) that would result in termination for individuals who do not have ESRD.

(ii) Imposing on persons who have ESRD, but not on others enrolled in the plan, benefit limitations such as less comprehensive health plan coverage, reductions in benefits, exclusions of benefits, a higher deductible or coinsurance, a longer waiting period, a lower annual or lifetime benefit limit,

[1] COBRA requires that certain group health plans offer continuation of plan coverage for 18 to 36 months after the occurrence of certain ''qualifying events,'' including loss of employment or reduction of employment hours. Those are events that otherwise would result in loss of group health plan coverage unless the individual is given the opportunity to elect, and does so elect, to continue plan coverage at his or her own expense. With one exception, the COBRA amendments expressly permit termination of continuation coverage upon entitlement to Medicare. The exception is that the plan may not terminate continuation coverage of an individual (and his or her qualified dependents) if the individual retires on or before the date the employer substantially eliminates regular plan coverage by filing for Chapter 11 bankruptcy (26 U.S.C. 4980B(g)(1)(D) and 29 U.S.C. 1167.(3)(C)).

or more restrictive preexisting illness limitations.

(iii) Charging individuals with ESRD higher premiums.

(iv) Paying providers and suppliers less for services furnished to individuals who have ESRD than for the same services furnished to those who do not have ESRD, such as paying 80 percent of the Medicare rate for renal dialysis on behalf of a plan enrollee who has ESRD and the usual, reasonable and customary charge for renal dialysis on behalf of an enrollee who does not have ESRD.

(v) Failure to cover routine maintenance dialysis or kidney transplants, when a plan covers other dialysis services or other organ transplants.

(c) *Uniform Limitations on particular services permissible.* A plan is not prohibited from limiting covered utilization of a particular service as long as the limitation applies uniformly to all plan enrollees. For instance, if a plan limits its coverage of renal dialysis sessions to 30 per year for all plan enrollees, the plan would not be differentiating in the benefits it provides between plan enrollees who have ESRD and those who do not.

(d) *Benefits secondary to Medicare.* (1) The prohibition against differentiation of benefits does not preclude a plan from paying benefits secondary to Medicare after the expiration of the coordination period described in §411.162(b) and (c), but a plan may not otherwise differentiate, as described in paragraph (b) of this section, in the benefits it provides.

(2) Example—

Mr. Smith works for employer A, and he and his wife are covered through employer A's GHP (Plan A). Neither is eligible for Medicare nor has ESRD. Mrs. Smith works for employer B, and is also covered by employer B's plan (Plan B). Plan A is more comprehensive than Plan B and covers certain items and services which Plan B does not cover, such as prescription drugs. If Mrs. Smith obtains a medical service, Plan B pays primary and Plan A pays secondary. That is, Plan A covers Plan B copayment amounts and items and services that Plan A covers but that Plan B does not.

Mr. Jones also works for employer A, and he and his wife are covered by Plan A. Mrs. Jones does not have other GHP coverage. Mrs. Jones develops ESRD and becomes entitled to Medicare on that basis. Plan A pays primary to Medicare during the first 18 months of Medicare entitlement based on ESRD. When Medicare becomes the primary payer, the plan converts Mrs. Jones' coverage to a Medicare supplement policy. That policy pays Medicare deductible and coinsurance amounts but does not pay for items and services not covered by Medicare, which plan A would have covered. That conversion is impermissible because the plan is providing a lower level of coverage for Mrs. Jones, who has ESRD, than it provides for Mrs. Smith, who does not. In other words, if Plan A pays secondary to primary payers other than Medicare, it must provide the same level of secondary benefits when Medicare is primary in order to comply with the nondifferentiation provision.

[60 FR 45368, Aug. 31, 1995]

§411.162 Medicare benefits secondary to group health plan benefits.

(a) *General provisions*—(1) *Basic rule.* Except as provided in §411.163 (with respect to certain individuals who are also entitled on the basis of age or disability), Medicare is secondary to any GHP (including a retirement plan), with respect to benefits that are payable to an individual who is entitled to Medicare on the basis of ESRD, for services furnished during any coordination period determined in accordance with paragraphs (b) and (c) of this section. (No Medicare benefits are payable on behalf of an individual who is eligible but not yet entitled.)

(2) *Medicare benefits secondary without regard to size of employer and beneficiary's employment status.* The size of employer and employment status requirements of the MSP provisions for the aged and disabled do not apply with respect to ESRD beneficiaries.

(3) *COBRA continuation coverage.* Medicare is secondary payer for benefits that a GHP—

(i) Is required to keep in effect under COBRA continuation requirements (as explained in the footnote to §411.161(a)(3)), even after the individual becomes entitled to Medicare; or

(ii) Voluntarily keeps in effect after the individual becomes entitled to Medicare on the basis of ESRD, even though not obligated to do so under the COBRA provisions.

(4) *Medicare payments during the coordination period.* During the coordination period, CMS makes Medicare payments as follows:

(i) Primary payments only for Medicare covered services that are—

(A) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(B) Not covered under the plan;[1]

(C) Covered under the plan but not available to particular enrollees because they have exhausted their benefits; or

(D) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement.

(ii) Secondary payments, within the limits specified in §§ 411.32 and 411.33, to supplement the amount paid by the GHP if that plan pays only a portion of the charge for the services.

(b) *Beginning of coordination period.* (1) For individuals who start a course of maintenance dialysis or who receive a kidney transplant before December 1989, the coordination period begins with the earlier of—

(i) The month in which the individual initiated a regular course of renal dialysis; or

(ii) In the case of an individual who received a kidney transplant, the first month in which the individual became entitled to Medicare, or, if earlier, the first month for which the individual would have been entitled to Medicare benefits if he or she had filed an application for such benefits.

(2) For individuals other than those specified in paragraph (b)(1) of this section, the coordination period begins with the earlier of—

(i) The first month in which the individual becomes entitled to Medicare part A on the basis of ESRD; or

(ii) The first month the individual would have become entitled to Medicare part A on the basis of ESRD if he or she had filed an application for such benefits.

(c) *End of coordination period.* (1) For individuals who start a regular course of renal dialysis or who receive a kidney transplant before December 1989, the coordination period ends with the earlier of the end of the 12th month of dialysis or the end of the 12th month of a transplant. The 12th month of dialysis may be any time from the 9th month through the 12th month of Medicare entitlement, depending on the extent to which the individual was subject to a waiting period before becoming entitled to Medicare.

(2) The coordination period for the following individuals ends with the earlier of the 12th month of eligibility or the 12th month of entitlement to Medicare part A:

(i) Individuals, other than those specified in paragraph (c)(1) of this section, who became entitled to Medicare part A solely on the basis of ESRD during December 1989 and January 1990.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could have become entitled to Medicare Part A solely on the basis of ESRD during December 1989 and January 1990 if they had filed an application.

(iii) Individuals who become entitled to Medicare part A on the basis of ESRD after September 1997.

(iv) Individuals who can become entitled to Medicare part A on the basis of ESRD after September 1997.

(3) The coordination period for the following individuals ends with the earlier of the end of the 18th month of eligibility or the 18th month of entitlement to Medicare part A:

(i) Individuals, other than those specified in paragraph (c)(1) of this section, who become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997.

(ii) Individuals, other than those specified in paragraph (c)(1) of this section, who could become entitled to Medicare part A on the basis of ESRD from February 1990 through April 1997 if they would file an application.

(4) The coordination periods for the following individuals ends September 30, 1998:

(i) Individuals who become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997.

(ii) Individuals who could become entitled to Medicare part A on the basis of ESRD from May 1997, through September 1997, if they would file an application.

[1] CMS does not pay if noncoverage of services constitutes differentiation as prohibited by § 411.161(b).

(d) *Examples.* Based on the rules specified in paragraphs (b) and (c) of this section and the rules specified in §406.13 of this subchapter, the following examples illustrate how to determine, in different situations, the number of months during which Medicare is secondary payer.

(1) An individual began dialysis on November 4, 1989. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on February 1, 1990. Since this individual began dialysis before December 1989, the 12-month period began with the first month of dialysis, November 1989, and ended October 31, 1990. The coordination period in this case is 9 months, February 1990 through October 1990.

(2) An individual began dialysis on January 29, 1990. He did not initiate a course in self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on April 1, 1990. Since the individual began dialysis after November 1989, and became entitled to Medicare after January 1990, the coordination period began with the first month of entitlement, April 1990, and ended September 30, 1991, the end of the 18th month of entitlement.

(3) An individual began a regular course of maintenance dialysis on February 10, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare on May 1, 1990. Medicare is secondary payer from May 1, 1990 through October 1991, a total of 18 months.

(4) The same facts exist as in the example under paragraph (d)(3), except that the individual began a course of self-dialysis training during the first 3 calendar months of dialysis. Thus, the effective date of his Medicare entitlement is February 1, 1990, and Medicare is secondary payer from February 1, 1990 through July 1991, a total of 18 months.

(5) An individual began dialysis on September 15, 1990. He did not initiate a course of self-dialysis training nor did he receive a kidney transplant during the first 3 calendar months of dialysis. Thus, he became entitled to Medicare effective December 1, 1990. Medicare is secondary payer from December 1, 1990 through May 1992, a total of 18 months.

(6) An individual began dialysis on November 17, 1990. He initiates a course of self-dialysis training in January 1991, and thus becomes entitled to Medicare effective November 1, 1990. Medicare is secondary payer from November 1, 1990, through April 1992, a total of 18 months.

(7) An individual began a regular course of dialysis on December 10, 1990. He does not initiate a course of self-dialysis training nor does he receive a kidney transplant. He decides to delay his enrollment in Medicare because his employer group health plan pays charges in full and he does not wish to incur part B premiums at this time. However, in March 1992, he files for part A and part B Medicare entitlement, and stipulates that he wants his Medicare entitlement to be effective March 1, 1992 (one year later than he could have become entitled). Since this individual could have been entitled to Medicare as early as March 1, 1991, Medicare is secondary payer only from March 1, 1992, through August 1992, a period of 6 months.

(While Medicare is secondary payer for only the last 6 months of this period, the Medicare program is effectively secondary payer for the full coordination period, due to the fact that the individual delayed his Medicare enrollment on account of his employer plan coverage and Medicare made no payments at all during the deferred period.)

(8) The same facts exist as in the example under paragraph (d)(7) of this section, except that the individual defers Medicare entitlement beyond August 1992. (For purposes of this example, Medicare entitlement is not retroactive, but rather takes effect after August 1992.) There would be no period during which Medicare is secondary payer in this situation. This is because Medicare entitlement does not begin until after the 18-month period expires as specified in paragraph (c)(3)(ii) of this section. Medicare would become

primary payer as of the effective date of Medicare entitlement. The employer plan is required to pay primary from December 1, 1990, through August 1992, a total of 21 months.

(9) An individual becomes entitled to Medicare on December 1, 1997. The employer plan is primary payer, and Medicare is secondary payer, from December 1, 1997, through November 30, 1998, a period of 12 months. Medicare becomes primary payer on December 1, 1998, because the extension of the coordination period from 12 to 18 months applies only to items and services furnished before October 1, 1998.

(10) An individual becomes entitled to Medicare on August 1, 1997. Medicare is secondary payer from August 1, 1997, through September 30, 1998, a period of 14 months. Medicare becomes primary payer on October 1, 1998, because the coordination period has expired.

(e) [Reserved]

(f) *Determinations for subsequent periods of ESRD eligibility.* If an individual has more than one period of eligibility based on ESRD, a coordination period will be determined for each period of eligibility in accordance with this section.

[57 FR 36015, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992. Redesignated and amended at 60 FR 45362, 45368, Aug. 31, 1995]

§ 411.163 Coordination of benefits: Dual entitlement situations.

(a) *Basic rule.* Coordination of benefits is governed by this section if an individual is eligible for or entitled to Medicare on the basis of ESRD and also entitled on the basis of age or disability.

(b) *Specific rules.*[1] (1) *Coordination period ended before August 1993.* If the first 18 months of ESRD-based eligibility or entitlement ended before August 1993, Medicare was primary payer from the first month of dual eligibility or entitlement, regardless of when dual eligibility or entitlement began.

(2) *First month of ESRD-based eligibility or entitlement and first month of dual eligibility/entitlement after February 1992 and before August 10, 1993.* Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-based eligibility or entitlement and first month of dual eligibility/entitlement were after February 1992 and before August 10, 1993, Medicare—

(i) Is primary payer from the first month of dual eligibility/entitlement through August 9, 1993;

(ii) Is secondary payer from August 10, 1993, through the 18th month of ESRD-based eligibility or entitlement; and

(iii) Again becomes primary payer after the 18th month of ESRD-based eligibility or entitlement.

(3) *First month of ESRD-based eligibility or entitlement after February 1992 and first month of dual eligibility/entitlement after August 9, 1993.* Except as provided in paragraph (b)(4) of this section, if the first month of ESRD-based eligibility or entitlement is after February 1992, and the first month of dual eligibility/entitlement is after August 9, 1993, the rules of § 411.162(b) and (c) apply; that is, Medicare—

(i) Is secondary payer during the first 18 months of ESRD-based eligibility or entitlement; and

(ii) Becomes primary after the 18th month of ESRD-based eligibility or entitlement.

(4) *Medicare continues to be primary after an aged or disabled beneficiary becomes eligible on the basis of ESRD.* (i) *Applicability of the rule.* Medicare remains the primary payer when an individual becomes eligible for Medicare based on ESRD if all of the following conditions are met:

(A) The individual is already entitled on the basis of age or disability when he or she becomes eligible on the basis of ESRD.

(B) The MSP prohibition against ''taking into account'' age-based or disability-based entitlement does not apply because plan coverage was not

[1] A lawsuit was filed in United States District Court for the District of Columbia on May 5, 1995 (*National Medical Care, Inc.* v. *Shalala,* Civil Action No. 95–0860), challenging the implementation of one aspect of the OBRA '93 provisions with respect to group health plan retirement coverage. The court issued a preliminary injunction order on June 6, 1995, which enjoins the Secretary from applying the rule contained in § 411.163(b)(4) for items and services furnished between August 10, 1993 and April 24, 1995, pending the court's decision on the merits. CMS will modify the rules, if required, based on the final ruling by the court.

''by virtue of current employment status'' or the employer had fewer than 20 employees (in the case of the aged) or fewer than 100 employees (in the case of the disabled).

(C) The plan is paying secondary to Medicare because the plan had justifiably taken into account the age-based or disability-based entitlement.

(ii) *Effect of the rule.* The plan may continue to pay benefits secondary to Medicare under paragraph (b)(4)(i) of this section. However, the plan may not differentiate in the services covered and the payments made between persons who have ESRD and those who do not.

(c) *Examples.* (1) (Rule (b)(1).) Mr. A, who is covered by a GHP, became entitled to Medicare on the basis of ESRD in January 1992. On December 20, 1992, Mr. A attained age 65 and became entitled on the basis of age. Since prior law was still in effect (OBRA '93 amendment was effective in August 1993), Medicare became primary payer as of December 1992, when dual entitlement began.

(2) (Rule (b)(2).) Miss B, who has GHP coverage, became entitled to Medicare on the basis of ESRD in July 1992, and also entitled on the basis of disability in June 1993. Medicare was primary payer from June 1993 through August 9, 1993, because the plan permissibly took into account the ESRD-based entitlement (ESRD was not the ''sole'' basis of Medicare entitlement); secondary payer from August 10, 1993, through December 1993, the 18th month of ESRD-based entitlement (the plan is no longer permitted to take into account ESRD-based entitlement that is not the ''sole'' basis of Medicare entitlement); and again became primary payer beginning January 1994.

(3) (Rule (b)(3).) Mr. C, who is 67 years old and entitled to Medicare on the basis of age, has GHP coverage by virtue of current employment status. Mr. C is diagnosed as having ESRD and begins a course of maintenance dialysis on June 27, 1993. Effective September 1, 1993, Mr. C. is eligible for Medicare on the basis of ESRD. Medicare, which was secondary because Mr. C's GHP coverage was by virtue of current employment, continues to be secondary payer through February 1995, the 18th month of ESRD-based eligibility, and becomes primary payer beginning March 1995.

(4) (Rule (b)(3).) Mr. D retired at age 62 and maintained GHP coverage as a retiree. In January 1994, at the age of 64, Mr. D became entitled to Medicare based on ESRD. Seven months into the 18-month coordination period (July 1994) Mr. D turned age 65. The coordination period continues without regard to age-based entitlement, with the retirement plan continuing to pay primary benefits through June 1995, the 18th month of ESRD-based entitlement. Thereafter, Medicare becomes the primary payer.

(5) (Rule (b)(3).) Mrs. E retired at age 62 and maintained GHP coverage as a retiree. In July 1994, she simultaneously became eligible for Medicare based on ESRD (maintenance dialysis began in April 1994) and entitled based on age. The retirement plan must pay benefits primary to Medicare from July 1994 through December 1995, the first 18 months of ESRD-based eligibility. Thereafter, Medicare becomes the primary payer.

(6) (Rule (b)(3).) Mr. F, who is 67 years of age, is working and has GHP coverage because of his employment status, subsequently develops ESRD, and begins a course of maintenance dialysis in October 1994. He becomes eligible for Medicare based on ESRD effective January 1, 1995. Under the working aged provision, the plan continues to pay primary to Medicare through December 1994. On January 1, 1995, the working aged provision ceases to apply and the ESRD MSP provision takes effect. In September 1995, Mr. F retires. The GHP must ignore Mr. F's retirement status and continue to pay primary to Medicare through June 1996, the end of the 18-month coordination period.

(7) (Rule (b)(4).) Mrs. G, who is 67 years of age, is retired. She has GHP retirement coverage through her former employer. Her plan permissibly took into account her age-based Medicare entitlement when she retired and is paying benefits secondary to Medicare. Mrs. G subsequently develops ESRD and begins a course of maintenance dialysis in October 1995. She automatically becomes eligible for

Medicare based on ESRD effective January 1, 1996. The plan continues to be secondary on the basis of Mrs. G's age-based entitlement as long as the plan does not differentiate in the services it provides to Mrs. G and does not do anything else that would constitute ''taking into account'' her ESRD-based eligibility.

[60 FR 45369, Aug. 31, 1995; 60 FR 53876, Oct. 18, 1995]

§ 411.165 Basis for conditional Medicare payments.

(a) *General rule.* Except as specified in paragraph (b) of this section, the Medicare intermediary or carrier may make a conditional payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment files a proper claim under the group health plan and the plan denies the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, fails to file a proper claim.

(b) *Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The group health plan limits its payments when the individual is entitled to Medicare.

(iii) Failure to file a proper claim if that failure is for any reason other than the physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[57 FR 36015, Aug. 12, 1992. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

Subpart G—Special Rules: Aged Beneficiaries and Spouses Who Are Also Covered Under Group Health Plans

§ 411.170 General provisions.

(a) *Basis.* (1) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(i) Individuals who are entitled to Medicare on the basis of age; and

(ii) GHPs of at least one employer of 20 or more employees that cover those individuals.

(2) Under these provisions, the following rules apply:

(i) An employer is considered to employ 20 or more employees if the employer has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(ii) The plan may not take into account the Medicare entitlement of—

(A) An individual age 65 or older who is covered or seeks to be covered under the plan by virtue of current employment status; or

(B) The spouse, including divorced or common-law spouse age 65 or older of an individual (of any age) who is covered or seeks to be covered by virtue of current employment status. (Section 411.108 gives examples of actions that constitute ''taking into account.'')

(iii) Regardless of whether entitled to Medicare, employees and spouses age 65 or older, including divorced or common-law spouses of employees of any age, are entitled to the same plan benefits under the same conditions as employees and spouses under age 65.

(b) [Reserved]

(c) *Determination of ''aged''.* (1) An individual attains a particular age on the day preceding the anniversary of his or her birth.

(2) The period during which an individual is considered to be ''aged'' begins on the first day of the month in which that individual attains age 65.

(3) For services furnished before May 1986, the period during which an individual is considered ''aged'' ends as follows:

(i) For services furnished before July 18, 1984, it ends on the last day of the month in which the individual attains age 70.

(ii) For services furnished between July 18, 1984 and April 30, 1986, it ends on the last day of the month *before* the month the individual attains age 70.

(4) For services furnished on or after May 1, 1986, the period has no upper age limit.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995]

§411.172 Medicare benefits secondary to group health plan benefits.

(a) *Conditions that the individual must meet.* Medicare Part A and Part B benefits are secondary to benefits payable by a GHP for services furnished during any month in which the individual—

(1) Is aged;

(2) Is entitled to Medicare Part A benefits under §406.10 of this chapter; and

(3) Meets one of the following conditions:

(i) Is covered under a GHP of an employer that has at least 20 employees (including a multi-employer plan in which at least one of the participating employers meets that condition), and coverage under the plan is by virtue of the individual's current employment status.

(ii) Is the aged spouse (including a divorced or common-law spouse) of an individual (of any age) who is covered under a GHP described in paragraph (a)(3)(i) of this section by virtue of the individual's current employment status.

(b) *Special rule for multi-employer plans.* The requirements and limitations of paragraph (a) of this section and of (a)(2)(iii) of §411.170 do not apply with respect to individuals enrolled in a multi-employer plan if—

(1) The individuals are covered by virtue of current employment status with an employer that has fewer than 20 employees; and

(2) The plan requests an exception and identifies the individuals for whom it requests the exception as meeting the conditions specified in paragraph (b)(1) of this section.

(c) *Refusal to accept group health plan coverage.* An employee or spouse may refuse the health plan offered by the employer. If the employee or spouse refuses the plan—

(1) Medicare is primary payer for that individual; and

(2) The plan may not offer that individual coverage complementary to Medicare.

(d) *Reemployed retiree or annuitant.* A reemployed retiree or annuitant who is covered by a GHP and who performs sufficient services to qualify for coverage on that basis (that is, other employees in the same category are provided health benefits) is considered covered ''by reason of current employment status'' even if:

(1) The employer provides the same GHP coverage to retirees; or

(2) The premiums for the plan are paid from a retirement or pension fund.

(e) *Secondary payments.* Medicare pays secondary benefits, within the limitations specified in §§411.32 and 411.33, to supplement the primary benefits paid by the group health plan if that plan pays only a portion of the charge for the services.

(f) *Disabled aged individuals who are considered employed.* (1) For services furnished on or after November 12, 1985, and before July 17, 1987, a disabled, nonworking individual age 65 or older was considered employed if he or she—

(i) Was receiving, from an employer, disability payments that were subject to tax under the Federal Insurance Contributions Act (FICA); and

(ii) For the month before the month of attainment of age 65, was not entitled to disability benefits under title II of the Act and 20 CFR 404.315 of the SSA regulations.

(2) For services furnished on or after July 17, 1987, an individual is considered employed if he or she receives, from an employer, disability benefits that are subject to tax under FICA, even if he or she was entitled to Social Security disability benefits before attaining age 65.

(g) *Individuals entitled to Medicare on the basis of age who are also eligible for or entitled to Medicare on the basis of ESRD.* If an aged individual is, or could upon filing an application become, entitled to Medicare on the basis of ESRD, the coordination of benefits rules of subpart F of this part apply.

[54 FR 41734, Oct. 11, 1989, as amended at 55 FR 1820, Jan. 19, 1990. Redesignated and amended at 60 FR 45362, 45370, Aug. 31, 1995; 60 FR 53877, Oct. 18, 1995]

§ 411.175 Basis for Medicare primary payments.

(a) *General rule.* CMS makes Medicare primary payments for covered services that are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered by the plan for any individuals or spouses who are enrolled by virtue of the individual's current employment status;

(3) Covered under the plan but not available to particular individuals or spouses enrolled by virtue of current employment status because they have exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional Medicare payments: Basic rule.* Except as provided in paragraph (c) of this section, Medicare may make a conditional primary payment if—

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim under the group health plan and the plan has denied the claim in whole or in part; or

(2) The beneficiary, because of physical or mental incapacity, failed to file proper claim.

(c) *Conditional primary payments: Exception.* Medicare does not make conditional primary payments under either of the following circumstances:

(1) The claim is denied for one of the following reasons:

(i) It is alleged that the group health plan is secondary to Medicare.

(ii) The plan limits its payments when the individual is entitled to Medicare.

(iii) The plan covers the services for individuals or spouses who are enrolled in the plan by virtue of current employment status and are under age 65 but not for individuals and spouses who are enrolled on the same basis but are age 65 or older.

(iv) Failure to file a proper claim if that failure is for any reason other than physical or mental incapacity of the beneficiary.

(2) The group health plan fails to furnish information requested by CMS and necessary to determine whether the employer plan is primary to Medicare.

[54 FR 41734, Oct. 11, 1989. Redesignated and amended at 60 FR 45362, 45371, Aug. 31, 1995]

Subpart H—Special Rules: Disabled Beneficiaries Who Are Also Covered Under Large Group Health Plans

SOURCE: 60 FR 45371, Aug. 31, 1995, unless otherwise noted.

§ 411.200 Basis.

(a) This subpart is based on certain provisions of section 1862(b) of the Act, which impose specific requirements and limitations with respect to—

(1) Individuals who are entitled to Medicare on the basis of disability; and

(2) Large group health plans (LGHPs) that cover those individuals.

(b) Under these provisions, the LGHP may not take into account the Medicare entitlement of a disabled individual who is covered (or seeks to be covered) under the plan by virtue of his or her own current employment status or that of a member of his or her family. (§ 411.108 gives examples of actions that constitute taking into account.)

§ 411.201 Definitions.

As used in this subpart—

Entitled to Medicare on the basis of disability means entitled or deemed entitled on the basis of entitlement to social security disability benefits or railroad retirement disability benefits. (§ 406.12 of this chapter explains the requirements an individual must meet in order to be entitled or deemed to be entitled to Medicare on the basis of disability.)

Family member means a person who is enrolled in an LGHP based on another person's enrollment; for example, the enrollment of the named insured individual. Family members may include a spouse (including a divorced or common-law spouse), a natural, adopted, foster, or stepchild, a parent, or a sibling.

§ 411.204 Medicare benefits secondary to LGHP benefits.

(a) Medicare benefits are secondary to benefits payable by an LGHP for services furnished during any month in which the individual—

(1) Is entitled to Medicare Part A benefits under § 406.12 of this chapter;

(2) Is covered under an LGHP; and

(3) Has LGHP coverage by virtue of his or her own or a family member's current employment status.

(b) *Individuals entitled to Medicare on the basis of disability who are also eligible for, or entitled to, Medicare on the basis of ESRD.* If a disabled individual is, or could upon filing an application become, entitled to Medicare on the basis of ESRD, the coordination of benefits rules of subpart F of this part apply.

§ 411.206 Basis for Medicare primary payments and limits on secondary payments.

(a) *General rule.* CMS makes Medicare primary payments for services furnished to disabled beneficiaries covered under the LGHP by virtue of their own or a family member's current employment status if the services are—

(1) Furnished to Medicare beneficiaries who have declined to enroll in the GHP;

(2) Not covered under the plan for the disabled individual or similarly situated individuals;

(3) Covered under the plan but not available to particular disabled individuals because they have exhausted their benefits under the plan;

(4) Furnished to individuals whose COBRA continuation coverage has been terminated because of the individual's Medicare entitlement; or

(5) Covered under COBRA continuation coverage notwithstanding the individual's Medicare entitlement.

(b) *Conditional primary payments: Basic rule.* Except as provided in paragraph (c) of this section, CMS may make a conditional Medicare primary payment for any of the following reasons:

(1) The beneficiary, the provider, or the supplier that has accepted assignment has filed a proper claim with the LGHP and the LGHP has denied the claim in whole or in part.

(2) The beneficiary, because of physical or mental incapacity, failed to file a proper claim.

(c) *Conditional primary payments: Exceptions.* CMS does not make conditional Medicare primary payments if—

(1) The LGHP denies the claim in whole or in part for one of the following reasons:

(i) It is alleged that the LGHP is secondary to Medicare.

(ii) The LGHP limits its payments when the individual is entitled to Medicare.

(iii) The LGHP does not provide the benefits to individuals who are entitled to Medicare on the basis of disability and covered under the plan by virtue of current employment status but does provide the benefits to other similarly situated individuals enrolled in the plan.

(iv) The LGHP takes into account entitlement to Medicare in any other way.

(v) There was failure to file a proper claim for any reason other than physical or mental incapacity of the beneficiary.

(2) The LGHP, an employer or employee organization, or the beneficiary fails to furnish information that is requested by CMS and that is necessary to determine whether the LGHP is primary to Medicare.

(d) *Limit on secondary payments.* The provisions of § 411.172(e) also apply to services furnished to the disabled under this subpart.

Subpart I [Reserved]

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

SOURCE: 69 FR 16126, Mar. 26, 2004, unless otherwise noted.

§ 411.350 Scope of subpart.

(a) This subpart implements section 1877 of the Act, which generally prohibits a physician from making a referral under Medicare for designated health services to an entity with which

the physician or a member of the physician's immediate family has a financial relationship.

(b) This subpart does not provide for exceptions or immunity from civil or criminal prosecution or other sanctions applicable under any State laws or under Federal law other than section 1877 of the Act. For example, although a particular arrangement involving a physician's financial relationship with an entity may not prohibit the physician from making referrals to the entity under this subpart, the arrangement may nevertheless violate another provision of the Act or other laws administered by HHS, the Federal Trade Commission, the Securities and Exchange Commission, the Internal Revenue Service, or any other Federal or State agency.

(c) This subpart requires, with some exceptions, that certain entities furnishing covered services under Medicare report information concerning ownership, investment, or compensation arrangements in the form, in the manner, and at the times specified by CMS.

(d) This subpart does not alter an individual's or entity's obligations under—

(1) The rules regarding reassignment of claims (§ 424.80 of this chapter);

(2) The rules regarding purchased diagnostic tests (§ 414.50 of this chapter);

(3) The rules regarding payment for services and supplies incident to a physician's professional services (§ 410.26 of this chapter); or

(4) Any other applicable Medicare laws, rules, or regulations.

[85 FR 77656, Dec. 2, 2020]

§ 411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

Centralized building means all or part of a building, including, for purposes of this subpart only, a mobile vehicle, van, or trailer that is owned or leased on a full-time basis (that is, 24 hours per day, 7 days per week, for a term of not less than 6 months) by a group practice and that is used exclusively by the group practice. Space in a building or a mobile vehicle, van, or trailer that is shared by more than one group practice, by a group practice and one or more solo practitioners, or by a group practice and another provider or supplier (for example, a diagnostic imaging facility) is not a centralized building for purposes of this subpart. This provision does not preclude a group practice from providing services to other providers or suppliers (for example, purchased diagnostic tests) in the group practice's centralized building. A group practice may have more than one centralized building.

Clinical laboratory services means the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings, including procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body, as specifically identified by the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are clinical laboratory services for purposes of this subpart. Any service not specifically identified as a clinical laboratory service on the List of CPT/HCPCS Codes is not a clinical laboratory service for purposes of this subpart.

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

Consultation means a professional service furnished to a patient by a physician if the following conditions are satisfied:

(1) The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.

(2) The request and need for the consultation are documented in the patient's medical record.

(3) After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.

(4) With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:

(1)(i) Clinical laboratory services.

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

(iii) Radiology and certain other imaging services.

(iv) Radiation therapy services and supplies.

(v) Durable medical equipment and supplies.

(vi) Parenteral and enteral nutrients, equipment, and supplies.

(vii) Prosthetics, orthotics, and prosthetic devices and supplies.

(viii) Home health services.

(ix) Outpatient prescription drugs.

(x) Inpatient and outpatient hospital services.

(2) Except as otherwise noted in this subpart, the term ''designated health services'' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are paid by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable under a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems (PPS):

(i) Acute Care Hospital Inpatient (IPPS);

(ii) Inpatient Rehabilitation Facility (IRF PPS);

(iii) Inpatient Psychiatric Facility (IPF PPS); or

(iv) Long-Term Care Hospital (LTCH PPS).

Does not violate the anti-kickback statute, as used in this subpart only, means that the particular arrangement—

(1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, ''Exceptions'';

(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, ''Advisory Opinions by the OIG''; or

(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—

(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under §1001.952 of this title; or

(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement.

Downstream contractor means a ''first tier contractor'' as defined at §1001.952(t)(2)(iii) of this title or a

''downstream contractor'' as defined at § 1001.952(t)(2)(i) of this title.

Durable medical equipment (DME) and supplies has the meaning given in section 1861(n) of the Act and § 414.202 of this chapter.

Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

Employee means any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity. (Application of these common law rules is discussed in 20 CFR 404.1007 and 26 CFR 31.3121(d)–1(c).)

Entity means—

(1) A physician's sole practice or a practice of multiple physicians or any other person, sole proprietorship, public or private agency or trust, corporation, partnership, limited liability company, foundation, nonprofit corporation, or unincorporated association that furnishes DHS. An entity does not include the referring physician himself or herself, but does include his or her medical practice. A person or entity is considered to be furnishing DHS if it—

(i) Is the person or entity that has performed services that are billed as DHS; or

(ii) Is the person or entity that has presented a claim to Medicare for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned in accordance with § 424.80(b)(1) (employer) or (b)(2) (payment under a contractual arrangement) of this chapter (other than a health care delivery system that is a health plan (as defined at § 1001.952(l) of this title), and other than any managed care organization (MCO), provider-sponsored organization (PSO), or independent practice association (IPA) with which a health plan contracts for services provided to plan enrollees).

(2) A health plan, MCO, PSO, or IPA that employs a supplier or operates a facility that could accept reassignment from a supplier under § 424.80(b)(1) and (b)(2) of this chapter, with respect to any DHS provided by that supplier.

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9.

Fair market value means—

(1) *General.* The value in an arm's-length transaction, consistent with the general market value of the subject transaction.

(2) *Rental of equipment.* With respect to the rental of equipment, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space.* With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

(1) *Assets.* With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of *bona fide* bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) *Compensation.* With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of *bona fide* bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) *Rental of equipment or office space.* With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of *bona fide* bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Home health services means the services described in section 1861(m) of the Act and part 409, subpart E of this chapter.

Hospital means any entity that qualifies as a ''hospital'' under section 1861(e) of the Act, as a ''psychiatric hospital'' under section 1861(f) of the Act, or as a ''critical access hospital'' under section 1861(mm)(1) of the Act, and refers to any separate legally organized operating entity plus any subsidiary, related entity, or other entities that perform services for the hospital's patients and for which the hospital bills. However, a ''hospital'' does not include entities that perform services for hospital patients ''under arrangements'' with the hospital.

HPSA means, for purposes of this subpart, an area designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act for primary medical care professionals (in accordance with the criteria specified in part 5 of this title).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

''*Incident to*'' *services* or *services* ''*incident to*'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, §410.26 of this chapter, and Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4.

Inpatient hospital services means those services defined in section 1861(b) of the Act and §409.10(a) and (b) of this chapter and include inpatient psychiatric hospital services listed in section 1861(c) of the Act and inpatient critical access hospital services, as defined in section 1861(mm)(2) of the Act. ''Inpatient hospital services'' do not include emergency inpatient services provided by a hospital located outside of the U.S. and covered under the authority in section 1814(f)(2) of the Act and part 424, subpart H of this chapter, or emergency inpatient services provided by a nonparticipating hospital within the U.S., as authorized by section 1814(d) of the Act and described in part 424, subpart G of this chapter. ''Inpatient hospital services'' also do not include dialysis furnished by a hospital that is not certified to provide end-stage renal dialysis (ESRD) services under subpart U of part 405 of this chapter. ''Inpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Inpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists and qualified psychologists if Medicare reimburses the services independently and not as part of the inpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Interoperable means—

(1) Able to securely exchange data with and use data from other health information technology; and

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

Isolated financial transaction—(1) Isolated financial transaction means a one-time transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third

party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).

Laboratory means an entity furnishing biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Entities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually and posted on the CMS website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes*.

Locum tenens physician (or substitute physician) means a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11.

Member of the group or member of a group practice means, for purposes of this subpart, a direct or indirect physician owner of a group practice (including a physician whose interest is held by his or her individual professional corporation or by another entity), a physician employee of the group practice (including a physician employed by his or her individual professional corporation that has an equity interest in the group practice), a *locum tenens* physician (as defined in this section), or an on-call physician while the physician is providing on-call services for members of the group practice. A physician is a member of the group during the time he or she furnishes ''patient care services'' to the group as defined in this section. An independent contractor or a leased employee is not a member of the group (unless the leased employee meets the definition of an ''employee'' under this section).

Outpatient hospital services means the therapeutic, diagnostic, and partial hospitalization services listed under sections 1861(s)(2)(B) and (s)(2)(C) of the Act; outpatient services furnished by a psychiatric hospital, as defined in section 1861(f) of the Act; and outpatient critical access hospital services, as defined in section 1861(mm)(3) of the Act. ''Outpatient hospital services'' do not include emergency services furnished by nonparticipating hospitals and covered under the conditions described in section 1835(b) of the Act and subpart G of part 424 of this chapter. ''Outpatient hospital services'' include services that are furnished either by the hospital directly or under arrangements made by the hospital with others. ''Outpatient hospital services'' do not include professional services performed by physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and qualified psychologists if Medicare reimburses the services independently and not as part of the outpatient hospital service (even if they are billed by a hospital under an assignment or reassignment).

Outpatient prescription drugs means all drugs covered by Medicare Part B or D, except for those drugs that are ''covered ancillary services,'' as defined at § 416.164(b) of this chapter, for which separate payment is made to an ambulatory surgical center.

Parenteral and enteral nutrients, equipment, and supplies means the following

services (including all HCPCS level 2 codes for these services):

(1) *Parenteral nutrients, equipment, and supplies,* meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies,* meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2.

Patient care services means any task(s) performed by a physician in the group practice that address the medical needs of specific patients or patients in general, regardless of whether they involve direct patient encounters or generally benefit a particular practice. Patient care services can include, for example, the services of physicians who do not directly treat patients, such as time spent by a physician consulting with other physicians or reviewing laboratory tests, or time spent training staff members, arranging for equipment, or performing administrative or management tasks.

Physical therapy, occupational therapy, and outpatient speech-language pathology services means those particular services so identified on the List of CPT/HCPCS Codes. All services so identified on the List of CPT/HCPCS Codes are physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this subpart. Any service not specifically identified as physical therapy, occupational therapy or outpatient speech-language pathology on the List of CPT/HCPCS Codes is not a physical therapy, occupational therapy, or outpatient speech-language pathology service for purposes of this subpart. The list of codes identifying physical therapy, occupational therapy, and outpatient speech-language pathology services for purposes of this regulation includes the following:

(1) *Physical therapy services,* meaning those outpatient physical therapy services described in section 1861(p) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Assessments, function tests, and measurements of strength, balance, endurance, range of motion, and activities of daily living;

(ii) Therapeutic exercises, massage, and use of physical medicine modalities, assistive devices, and adaptive equipment; or

(iii) Establishment of a maintenance therapy program for an individual whose restoration potential has been reached; however, maintenance therapy itself is not covered as part of these services.

(2) *Occupational therapy services,* meaning those services described in section 1861(g) of the Act that are covered under Medicare Part A or Part B, regardless of who provides them, if the services include—

(i) Teaching of compensatory techniques to permit an individual with a physical or cognitive impairment or limitation to engage in daily activities;

(ii) Evaluation of an individual's level of independent functioning;

(iii) Selection and teaching of task-oriented therapeutic activities to restore sensory-integrative function; or

(iv) Assessment of an individual's vocational potential, except when the assessment is related solely to vocational rehabilitation.

(3) *Outpatient speech-language pathology services,* meaning those services as described in section 1861(ll)(2) of the Act that are for the diagnosis and treatment of speech, language, and cognitive disorders that include swallowing and other oral-motor dysfunctions.

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation

of which he or she is a sole owner are the same for purposes of this subpart.

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment rules in § 424.80(b)(2) of this chapter (*see* also Pub. L. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.

Physician organization means a physician, a physician practice, or a group practice that complies with the requirements of § 411.352.

Plan of care means the establishment by a physician of a course of diagnosis or treatment (or both) for a particular patient, including the ordering of services.

Professional courtesy means the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.

Prosthetics, Orthotics, and Prosthetic Devices and Supplies means the following services (including all HCPCS level 2 codes for these items and services that are covered by Medicare):

(1) *Orthotics,* meaning leg, arm, back, and neck braces, as listed in section 1861(s)(9) of the Act.

(2) *Prosthetics,* meaning artificial legs, arms, and eyes, as described in section 1861(s)(9) of the Act.

(3) *Prosthetic devices,* meaning devices (other than a dental device) listed in section 1861(s)(8) of the Act that replace all or part of an internal body organ, including colostomy bags, and one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.

(4) *Prosthetic supplies,* meaning supplies that are necessary for the effective use of a prosthetic device (including supplies directly related to colostomy care).

Radiation therapy services and supplies means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and § 410.35 of this chapter.

Radiology and certain other imaging services means those particular services so identified on the List of CPT/HCPCS Codes. All services identified on the List of CPT/HCPCS Codes are radiology and certain other imaging services for purposes of this subpart. Any service not specifically identified as radiology and certain other imaging services on the List of CPT/HCPCS Codes is not a radiology or certain other imaging service for purposes of this subpart. The list of codes identifying radiology and certain other imaging services includes the professional and technical components of any diagnostic test or procedure using x-rays, ultrasound, computerized axial tomography, magnetic resonance imaging, nuclear medicine (effective January 1, 2007), or

other imaging services. All codes identified as radiology and certain other imaging services are covered under section 1861(s)(3) of the Act and §§410.32 and 410.34 of this chapter, but do not include—

(1) X-ray, fluoroscopy, or ultrasound procedures that require the insertion of a needle, catheter, tube, or probe through the skin or into a body orifice;

(2) Radiology or certain other imaging services that are integral to the performance of a medical procedure that is not identified on the list of CPT/HCPCS codes as a radiology or certain other imaging service and is performed—

(i) Immediately prior to or during the medical procedure; or

(ii) Immediately following the medical procedure when necessary to confirm placement of an item placed during the medical procedure.

(3) Radiology and certain other imaging services that are ''covered ancillary services,'' as defined at §416.164(b), for which separate payment is made to an ASC.

Referral—

(1) Means either of the following:

(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.

(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—

(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and

(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

(3) Can be in any form, including, but not limited to, written, oral, or electronic.

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

Referring physician means a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made by another person or entity. A referring physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:

(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;

(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of referrals.

Rural area means an area that is not an urban area as defined at § 412.64(b) of this chapter.

Rural emergency hospital has the meaning set forth in section 1861(kkk)(2) of the Act and § 419.91 of this chapter.

Same building means a structure with, or combination of structures that share, a single street address as assigned by the U.S. Postal Service, excluding all exterior spaces (for example, lawns, courtyards, driveways, parking lots) and interior loading docks or parking garages. For purposes of this section, the ''same building'' does not include a mobile vehicle, van, or trailer.

Specialty hospital means:

(1) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act) that is primarily or exclusively engaged in the care and treatment of one of the following:

(i) Patients with a cardiac condition;

(ii) Patients with an orthopedic condition;

(iii) Patients receiving a surgical procedure; or

(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital.

(2) A ''specialty hospital'' does not include any hospital—

(i) Determined by the Secretary to be in operation before or under development as of November 18, 2003;

(ii) For which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) For which the type of categories described above is no different at any time on or after such date than the type of such categories as of such date;

(iv) For which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) That meets such other requirements as the Secretary may specify.

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Transaction means an instance of two or more persons or entities doing business.

Value-based activity means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

(1) The provision of an item or service;

(2) The taking of an action; or

(3) The refraining from taking an action.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are—

(1) The value-based enterprise and one or more of its VBE participants; or

(2) VBE participants in the same value-based enterprise.

Value-based enterprise (VBE) means two or more VBE participants—

(1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means any of the following:

(1) Coordinating and managing the care of a target patient population;

(2) Improving the quality of care for a target patient population;

(3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or

(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE participant means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65667, Nov. 19, 2021; 87 FR 72285, Nov. 23, 2022]

§ 411.352 Group practice.

For purposes of this subpart, a group practice is a physician practice that meets the following conditions:

(a) *Single legal entity*. The group practice must consist of a single legal entity operating primarily for the purpose of being a physician group practice in any organizational form recognized by the State in which the group practice achieves its legal status, including, but not limited to, a partnership, professional corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar association. The single legal entity may be organized by any party or parties, including, but not limited to, physicians, health care facilities, or other persons or entities (including, but not limited to, physicians individually incorporated as professional corporations). The single legal entity may be organized or owned (in whole or in part) by another medical practice, provided that the other medical practice is not an operating physician practice (and regardless of whether the medical practice meets the conditions for a group practice under this section). For purposes of this subpart, a single legal entity does not include informal affiliations of physicians formed substantially to share profits from referrals, or separate group practices under common ownership or control through a physician practice management company, hospital, health system, or other entity or organization. A group practice that is otherwise a single legal entity may itself own subsidiary entities. A group practice operating in more than one State will be considered to be a single legal entity notwithstanding that it is composed of multiple legal entities, provided that—

(1) The States in which the group practice is operating are contiguous (although each State need not be contiguous to every other State);

(2) The legal entities are absolutely identical as to ownership, governance, and operation; and

(3) Organization of the group practice into multiple entities is necessary to comply with jurisdictional licensing laws of the States in which the group practice operates.

(b) *Physicians.* The group practice must have at least two physicians who are members of the group (whether employees or direct or indirect owners), as defined at § 411.351.

(c) *Range of care.* Each physician who is a member of the group, as defined at § 411.351, must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(d) *Services furnished by group practice members.* (1) Except as otherwise provided in paragraphs (d)(3) through (6) of this section, substantially all of the patient care services of the physicians who are members of the group (that is, at least 75 percent of the total patient care services of the group practice members) must be furnished through the group and billed under a billing number assigned to the group, and the amounts received must be treated as receipts of the group. *Patient care services* must be measured by one of the following:

(i) The total time each member spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries). (For example, if a physician practices 40 hours a week and spends 30 hours a week on patient care services for a group practice, the physician has spent 75 percent of his or her time providing patient care services for the group.)

(ii) Any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented.

(2) The data used to calculate compliance with this *substantially all* test and related supportive documentation must be made available to the Secretary upon request.

(3) The *substantially all* test set forth in paragraph (d)(1) of this section does not apply to any group practice that is located solely in a HPSA, as defined at § 411.351.

(4) For a group practice located outside of a HPSA (as defined at § 411.351), any time spent by a group practice member providing services in a HPSA should not be used to calculate whether the group practice has met the *substantially all* test, regardless of whether the member's time in the HPSA is spent in a group practice, clinic, or office setting.

(5) During the *start up* period (not to exceed 12 months) that begins on the date of the initial formation of a new group practice, a group practice must make a reasonable, good faith effort to ensure that the group practice complies with the *substantially all* test requirement set forth in paragraph (d)(1) of this section as soon as practicable, but no later than 12 months from the date of the initial formation of the group practice. This paragraph (d)(5) does not apply when an existing group practice admits a new member or reorganizes.

(6)(i) If the addition to an existing group practice of a new member who would be considered to have relocated his or her medical practice under § 411.357(e)(2) would result in the existing group practice not meeting the *substantially all* test set forth in paragraph (d)(1) of this section, the group practice will have 12 months following the addition of the new member to come back into full compliance, provided that—

(A) For the 12-month period the group practice is fully compliant with the *substantially all* test if the new member is not counted as a member of the group for purposes of § 411.352; and

(B) The new member's employment with, or ownership interest in, the group practice is documented in writing no later than the beginning of his or her new employment, ownership, or investment.

(ii) This paragraph (d)(6) does not apply when an existing group practice reorganizes or admits a new member who is not relocating his or her medical practice.

(e) *Distribution of expenses and income.* The overhead expenses of, and income from, the practice must be distributed according to methods that are determined before the receipt of payment

for the services giving rise to the overhead expense or producing the income. Nothing in this section prevents a group practice from adjusting its compensation methodology prospectively, subject to restrictions on the distribution of revenue from DHS under paragraph (i) of this section.

(f) *Unified business.* (1) The group practice must be a unified business having at least the following features:

(i) Centralized decision-making by a body representative of the group practice that maintains effective control over the group's assets and liabilities (including, but not limited to, budgets, compensation, and salaries); and

(ii) Consolidated billing, accounting, and financial reporting.

(2) Location and specialty-based compensation practices are permitted with respect to revenues derived from services that are not DHS and may be permitted with respect to revenues derived from DHS under paragraph (i) of this section.

(g) *Volume or value of referrals.* No physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in paragraph (i) of this section.

(h) *Physician-patient encounters.* Members of the group must personally conduct no less than 75 percent of the physician-patient encounters of the group practice.

(i) *Special rules for profit shares and productivity bonuses*—(1) *Overall profits.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals.

(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided per capita (for example, per member of the group or per physician in the group).

(B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services ''incident to'' such personally performed services, that is not directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of the physician's referrals if the referrals are for services ''incident to'' the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician.

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation.* Notwithstanding paragraph (g) of this

section, profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined at § 411.351, may be distributed to the participating physician.

(4) *Supporting documentation.* Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

[85 FR 77656, 76682, Dec. 2, 2020]

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

(a) *Prohibition on referrals.* Except as provided in this subpart, a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral to that entity for the furnishing of DHS for which payment otherwise may be made under Medicare. A physician's prohibited financial relationship with an entity that furnishes DHS is not imputed to his or her group practice or its members or its staff. However, a referral made by a physician's group practice, its members, or its staff may be imputed to the physician if the physician directs the group practice, its members, or its staff to make the referral or if the physician controls referrals made by his or her group practice, its members, or its staff.

(b) *Limitations on billing.* An entity that furnishes DHS pursuant to a referral that is prohibited by paragraph (a) of this section may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.

(c) *Denial of payment for services furnished under a prohibited referral.* (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

(2) When payment for a designated health service is denied on the basis that the service was furnished pursuant to a prohibited referral, and such payment denial is appealed—

(i) The ultimate burden of proof (burden of persuasion) at each level of appeal is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral); and

(ii) The burden of production on each issue at each level of appeal is initially on the claimant, but may shift to CMS or its contractors during the course of the appellate proceeding, depending on the evidence presented by the claimant.

(d) *Refunds.* An entity that collects payment for a designated health service that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis, as defined at § 1003.110 of this title.

(e) *Exception for certain entities.* Payment may be made to an entity that submits a claim for a designated health service if—

(1) The entity did not have actual knowledge of, and did not act in reckless disregard or deliberate ignorance of, the identity of the physician who made the referral of the designated health service to the entity; and

(2) The claim otherwise complies with all applicable Federal and State laws, rules, and regulations.

(f) *Exception for certain arrangements involving temporary noncompliance.* (1) Except as provided in paragraphs (f)(2) through (4) of this section, an entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, 411.356, or 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception; and

(ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance.

(2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception.

(3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) Paragraph (f)(1) does not apply if the exception with which the financial relationship previously complied was §411.357(k) or (m).

(g) [Reserved]

(h) *Special rule for reconciling compensation.* An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if—

(1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and

(2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement fully complies with an applicable exception in this subpart.

[85 FR 77656, Dec. 2, 2020, as amended at 88 FR 59328, Aug. 28, 2023]

§411.354 Financial relationship, compensation, and ownership or investment interest.

(a) *Financial relationships*—(1) *Financial relationship* means—

(i) A direct or indirect ownership or investment interest (as defined in paragraph (b) of this section) in any entity that furnishes DHS; or

(ii) A direct or indirect compensation arrangement (as defined in paragraph (c) of this section) with an entity that furnishes DHS.

(2) *Types of financial relationships.* (i) A *direct* financial relationship exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family).

(ii) An *indirect* financial relationship exists under the conditions described in paragraphs (b)(5) and (c)(2) of this section.

(b) *Ownership or investment interest.* An ownership or investment interest in the entity may be through equity, debt, or other means, and includes an interest in an entity that holds an ownership or investment interest in any entity that furnishes DHS.

(1) An ownership or investment interest includes, but is not limited to, stock, stock options other than those described in paragraph (b)(3)(ii) of this section, partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) An ownership or investment interest in a subsidiary company is neither an ownership or investment interest in the parent company, nor in any other subsidiary of the parent, unless the subsidiary company itself has an ownership or investment interest in the parent or such other subsidiaries. It may, however, be part of an indirect financial relationship.

(3) Ownership and investment interests do not include, among other things—

(i) An interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity;

(ii) Stock options and convertible securities received as compensation until the stock options are exercised or the convertible securities are converted to

equity (before this time the stock options or convertible securities are compensation arrangements as defined in paragraph (c) of this section);

(iii) An unsecured loan subordinated to a credit facility (which is a compensation arrangement as defined in paragraph (c) of this section);

(iv) An ''under arrangements'' contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS ''under arrangements'' with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section);

(v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section);

(vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(4) An ownership or investment interest that meets an exception set forth in § 411.355 or § 411.356 need not also meet an exception for compensation arrangements set forth in § 411.357 with respect to profit distributions, dividends, or interest payments on secured obligations.

(5)(i) An *indirect ownership or investment interest* exists if—

(A) Between the referring physician (or immediate family member) and the entity furnishing DHS there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(B) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the entity furnishing the DHS.

(ii) An indirect ownership or investment interest exists even though the entity furnishing DHS does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

(iii) Notwithstanding anything in this paragraph (b)(5), common ownership or investment in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor.

(iv) An indirect ownership or investment interest requires an unbroken chain of ownership interests between the referring physician and the entity furnishing DHS such that the referring physician has an indirect ownership or investment interest *in* the entity furnishing DHS.

(c) *Compensation arrangement.* A compensation arrangement is any arrangement involving remuneration, direct or indirect, between a physician (or a member of a physician's immediate family) and an entity. An ''under arrangements'' contract between a hospital and an entity providing DHS ''under arrangements'' to the hospital creates a compensation arrangement for purposes of these regulations. A compensation arrangement does not include the portion of any business arrangement that consists solely of the remuneration described in section 1877(h)(1)(C) of the Act and in paragraphs (1) through (3) of the definition of the term ''remuneration'' at § 411.351. (However, any other portion of the arrangement may still constitute a compensation arrangement.)

(1)(i) A direct compensation arrangement exists if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities.

(ii) Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to ''stand in the shoes'' of his or her physician organization and

have a direct compensation arrangement with an entity furnishing DHS if—

(A) The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and

(B) The physician has an ownership or investment interest in the physician organization.

(iii) A physician (other than a physician described in paragraph (c)(1)(ii)(B) of this section) is permitted to ''stand in the shoes'' of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the entity furnishing DHS is his or her physician organization.

(2) An *indirect compensation arrangement* exists if all of the conditions of paragraphs (c)(2)(i) through (iii) of this section exist:

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link).

(ii)(A)(*1*) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS; and

(*2*) The amount of compensation that the physician (or immediate family member) receives per individual unit—

(*i*) Is not fair market value for items or services actually provided;

(*ii*) Could increase as the number or value of the physician's referrals to the entity furnishing DHS increases, or could decrease as the number or value of the physician's referrals to the entity decreases;

(*iii*) Could increase as the amount or value of the other business generated by the physician for the entity furnishing DHS increases, or could decrease as the amount or value of the other business generated by the physician for the entity furnishing DHS decreases; or

(*iv*) Is payment for the lease of office space or equipment or for the use of premises or equipment.

(B) For purposes of applying paragraph (c)(2)(ii)(A)(*2*) of this section, the individual unit is:

(*1*) Item, if the physician (or immediately family member) is compensated solely per item provided.

(*2*) Service, if the physician (or immediate family member) is compensated solely per service provided, which includes arrangements where the ''service'' provided includes both items and services.

(*3*) Time, if the conditions of paragraph (c)(2)(ii)(B)(1) or (*2*) of this section are not met.

(C) If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the nonownership or noninvestment interest closest to the referring physician (or immediate family member) is used to determine whether the aggregate compensation varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and whether the amount of compensation that the physician (or immediate family member) receives per individual unit meets the conditions in paragraph (c)(2)(ii)(A)(*2*) of this section. (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii).

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives

aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

(iv)(A) For purposes of paragraph (c)(2)(i) of this section, except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to ''stand in the shoes'' of his or her physician organization if the physician has an ownership or investment interest in the physician organization.

(B) For purposes of paragraph (c)(2)(i) of this section, a physician (other than a physician described in paragraph (c)(2)(iv)(A) of this section) is permitted to ''stand in the shoes'' of his or her physician organization.

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in §§ 411.355 and 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the ''parties to the arrangements'' are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who ''stands in the shoes'' of the physician organization as required under paragraph (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

(ii) The provisions of paragraphs (c)(1)(ii) and (c)(2)(iv)(A) of this section—

(A) Need not apply during the original term or current renewal term of an arrangement that satisfied the requirements of § 411.357(p) as of September 5, 2007 (see 42 CFR parts 400–413, revised as of October 1, 2007);

(B) Do not apply to an arrangement that satisfies the requirements of § 411.355(e); and

(C) Do not apply to a physician whose ownership or investment interest is titular only. A titular ownership or investment interest is an ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment.

(iii) An arrangement structured to comply with an exception in § 411.357 (other than § 411.357(p)), but which would otherwise qualify as an indirect compensation arrangement under this paragraph as of August 19, 2008, need not be restructured to satisfy the requirements of § 411.357(p) until the expiration of the original term or current renewal term of the arrangement.

(4)(i) *Exceptions applicable to indirect compensation arrangements—General.* Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§ 411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving a MCO or IPA and a referring physician.* Only the exceptions at §§ 411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS described in paragraph (c)(2)(i) of this section is a MCO or IPA.

(iii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined at § 411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party—

(A) Only the exceptions at §§ 411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is not a MCO or IPA; and

(B) Only the exceptions at §§ 411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is a MCO or IPA.

(d) *Special rules on compensation.* The following special rules apply only to

compensation under section 1877 of the Act and subpart J of this part:

(1) *Set in advance.* (i) Compensation is deemed to be ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

(ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is ''set in advance'' if all of the following conditions are met:

(A) All requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the modified compensation (or the formula for determining the modified compensation).

(B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.

(C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).

(2) *Unit-based compensation and the volume or value standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. This paragraph (d)(2) does not apply for purposes of paragraphs (d)(5)(i) and (6)(i) of this section.

(3) *Unit-based compensation and the other business generated standard.* Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered ''other business generated'' by the referring physician). This paragraph (d)(3) does not apply for purposes of paragraphs (d)(5)(ii) and (d)(6)(ii) of this section.

(4) *Directed referral requirement.* If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at §411.355 or §411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the

patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

(5) *Compensation to a physician.* (i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if the formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at § 411.357(m), (s), (u), (v), (w), and (bb).

(6) *Compensation from a physician.* (i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if the formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.

(iv) This paragraph (d)(6) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of

this section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).

(e) *Special rule on compensation arrangements*—(1) *Application.* This paragraph (e) applies only to compensation arrangements as defined in section 1877 of the Act and this subpart.

(2) *Writing requirement.* In the case of any requirement in this subpart for a compensation arrangement to be in writing, such requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

(3) *Signature requirement.* In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

(4) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65667, Nov. 19, 2021]

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

The prohibition on referrals set forth in §411.353 does not apply to the following types of services:

(a) *Physician services.* (1) Physician services as defined at §410.20(a) of this chapter that are furnished—

(i) Personally by another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician; or

(ii) Under the supervision of another physician who is a member of the referring physician's group practice or is a physician in the same group practice (as defined at §411.351) as the referring physician, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the physician services.

(2) For purposes of this paragraph (a), ''physician services'' include only those ''incident to'' services (as defined at §411.351) that are physician services under §410.20(a) of this chapter.

(b) *In-office ancillary services.* Services (including certain items of durable medical equipment (DME), as defined in paragraph (b)(4) of this section, and infusion pumps that are DME (including external ambulatory infusion pumps), but excluding all other DME and parenteral and enteral nutrients, equipment, and supplies (such as infusion pumps used for PEN)), that meet the following conditions:

(1) *Individual who furnishes the service.* They are furnished personally by one of the following individuals:

(i) The referring physician.

(ii) A physician who is a member of the same group practice as the referring physician.

(iii) An individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

(2) *Location where service is furnished.* They are furnished in one of the following locations:

(i) The same building (as defined at §411.351), but not necessarily in the same space or part of the building, in which all of the conditions of paragraph (b)(2)(i)(A), (b)(2)(i)(B), *or* (b)(2)(i)(C) of this section are satisfied:

(A)(*1*) The referring physician or his or her group practice (if any) has an office that is normally open to the physician's or group's patients for medical services at least 35 hours per week; and

(*2*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 30 hours per week. The 30 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(B)(*1*) The patient receiving the DHS usually receives physician services from the referring physician or members of the referring physician's group practice (if any);

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS; or

(C)(*1*) The referring physician is present and orders the DHS during a patient visit on the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section *or* the referring physician or a member of the referring physician's group practice (if any) is present while the DHS is furnished during occupancy of the premises as set forth in paragraph (b)(2)(i)(C)(*2*) of this section;

(*2*) The referring physician or the referring physician's group practice owns or rents an office that is normally open to the physician's or group's patients for medical services at least 8 hours per week; and

(*3*) The referring physician or one or more members of the referring physician's group practice regularly practices medicine and furnishes physician services to patients at least 6 hours per week. The 6 hours must include some physician services that are unrelated to the furnishing of DHS payable by Medicare, any other Federal health care payer, or a private payer, even though the physician services may lead to the ordering of DHS.

(ii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services.

(iii) A centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).

(3) *Billing of the service.* They are billed by one of the following:

(i) The physician performing or supervising the service.

(ii) The group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice.

(iii) The group practice if the supervising physician is a ''physician in the group practice'' (as defined at § 411.351) under a billing number assigned to the group practice.

(iv) An entity that is wholly owned by the performing or supervising physician or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice.

(v) An independent third party billing company acting as an agent of the physician, group practice, or entity specified in paragraphs (b)(3)(i) through (iv) of this section under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of § 424.80(b)(5) of this chapter. For purposes of this paragraph (b)(3), a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.

(4) *Durable Medical Equipment.* For purposes of this paragraph (b), DME covered by the in-office ancillary services exception means canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors, that meet the following conditions:

(i) The item is one that a patient requires for the purpose of ambulating, a patient uses in order to depart from the physician's office, or is a blood glucose monitor (including one starter set of test strips and lancets, consisting of no more than 100 of each). A blood glucose monitor may be furnished only by a physician or employee of a physician or group practice that also furnishes outpatient diabetes self-management training to the patient.

(ii) The item is furnished in a building that meets the ''same building'' requirements in the in-office ancillary services exception as part of the treatment for the specific condition for which the patient-physician encounter occurred.

(iii) The item is furnished personally by the physician who ordered the DME, by another physician in the group practice, or by an employee of the physician or the group practice.

(iv) A physician or group practice that furnishes the DME meets all DME supplier standards set forth in §424.57(c) of this chapter.

(v) [Reserved]

(vi) All other requirements of the in-office ancillary services exception in this paragraph (b) are met.

(5) *Furnishing a service.* A designated health service is ''furnished'' for purposes of this paragraph (b) in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

(6) *Special rule for home care physicians.* In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the ''same building'' requirements of paragraph (b)(2)(i) of this section are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a designated health service provided by the referring physician to the patient in the patient's private home. For purposes of paragraph (b)(5) of this section only, a private home does not include a nursing, long-term care, or other facility or institution, except that a patient may have a private home in an assisted living or independent living facility.

(7) *Disclosure requirement for certain imaging services.* (i) With respect to magnetic resonance imaging, computed tomography, and positron emission tomography services identified as ''radiology and certain other imaging services'' on the List of CPT/HCPCS Codes, the referring physician must provide written notice to the patient at the time of the referral that the patient may receive the same services from a person other than one described in paragraph (b)(1) of this section. Except as set forth in paragraph (b)(7)(ii) of this section, the written notice must include a list of at least 5 other suppliers (as defined at §400.202 of this chapter) that provide the services for which the individual is being referred and which are located within a 25-mile radius of the referring physician's office location at the time of the referral. The notice should be written in a manner sufficient to be reasonably understood by all patients and should include for each supplier on the list, at a minimum, the supplier's name, address, and telephone number.

(ii) If there are fewer than 5 other suppliers located within a 25-mile radius of the physician's office location at the time of the referral, the physician must list all of the other suppliers of the imaging service that are present within a 25-mile radius of the referring physician's office location. Provision of the written list of alternate suppliers will not be required if no other suppliers provide the services for which the individual is being referred within the 25-mile radius.

(c) *Services furnished by an organization (or its contractors or subcontractors) to enrollees.* Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans (not including services provided to enrollees in any other plan or line of business offered or administered by the same organization):

(1) An HMO or a CMP in accordance with a contract with CMS under section 1876 of the Act and part 417, subparts J through M of this chapter.

(2) A health care prepayment plan in accordance with an agreement with CMS under section 1833(a)(1)(A) of the Act and part 417, subpart U of this chapter.

(3) An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project under section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1) or under section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b–1 note).

(4) A qualified HMO (within the meaning of section 1310(d) of the Public Health Service Act).

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(6) A MCO contracting with a State under section 1903(m) of the Act.

(7) A prepaid inpatient health plan (PIHP) or prepaid ambulance health plan (PAHP) contracting with a State under part 438 of this chapter.

(8) A health insuring organization (HIO) contracting with a State under part 438, subpart D of this chapter.

(9) An entity operating under a demonstration project under sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

(d) [Reserved]

(e) *Academic medical centers.* (1) Services provided by an academic medical center if all of the following conditions are met:

(i) The referring physician—

(A) Is a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. (A ''component'' of an academic medical center means an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, departmental professional corporation, or nonprofit support organization whose primary purpose is supporting the teaching mission of the academic medical center.) The components need not be separate legal entities;

(B) Is licensed to practice medicine in the State(s) in which he or she practices medicine;

(C) Has a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital (as defined at § 411.355(e)(3)); and

(D) Provides either substantial academic services or substantial clinical teaching services (or a combination of academic services and clinical teaching services) for which the faculty member receives compensation as part of his or her employment relationship with the academic medical center. Parties should use a reasonable and consistent method for calculating a physician's academic services and clinical teaching services. A physician will be deemed to meet this requirement if he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services). A physician who does not spend at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services (or a combination of academic services or clinical teaching services) is not precluded from qualifying under this paragraph (e)(1)(i)(D).

(ii) The compensation paid to the referring physician must meet all of the following conditions:

(A) The total compensation paid by each academic medical center component to the referring physician is set in advance.

(B) In the aggregate, the compensation paid by all academic medical center components to the referring physician does not exceed fair market value for the services provided.

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(iii) The academic medical center must meet all of the following conditions:

(A) All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service.

(B) The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. If the academic medical center is one legal entity, this requirement will be satisfied if transfers of funds between components of the academic medical center are reflected in the routine financial reports covering the components.

(C) All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

(2) The ''academic medical center'' for purposes of this section consists of—

(i) An accredited medical school (including a university, when appropriate) or an accredited academic hospital (as defined at paragraph (e)(3) of this section);

(ii) One or more faculty practice plans affiliated with the medical school, the affiliated hospital(s), or the accredited academic hospital; and

(iii) One or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members and a majority of all hospital admissions is made by physicians who are faculty members. The hospital for purposes of this paragraph (e)(2)(iii) may be the same hospital that satisfies the requirement of paragraph (e)(2)(i) of this section. For purposes of this paragraph (e)(2)(iii), a faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. In meeting this paragraph (e)(2)(iii), faculty from any affiliated medical school or accredited academic hospital education program may be aggregated, and residents and non-physician professionals need not be counted. Any faculty member may be counted, including courtesy and volunteer faculty. For purposes of determining whether the majority of physicians on the medical staff consists of faculty members, the affiliated hospital must include or exclude all individual physicians with the same class of privileges at the affiliated hospital (for example, physicians holding courtesy privileges).

(3) An accredited academic hospital for purposes of this section means a hospital or a health system that sponsors four or more approved medical education programs.

(f) *Implants furnished by an ASC.* Implants furnished by an ASC, including, but not limited to, cochlear implants, intraocular lenses, and other implanted prosthetics, implanted prosthetic devices, and implanted DME that meet the following conditions:

(1) The implant is implanted by the referring physician or a member of the referring physician's group practice in an ASC that is certified by Medicare under part 416 of this chapter and with which the referring physician has a financial relationship.

(2) The implant is implanted in the patient during a surgical procedure paid by Medicare to the ASC as an ASC procedure under §416.65 of this chapter.

(3) [Reserved]

(4) [Reserved]

(5) The exception set forth in this paragraph (f) does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished to, and implanted in, the patient.

(g) *EPO and other dialysis-related drugs.* EPO and other dialysis-related drugs that meet the following conditions:

(1) The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph (g)(1), ''EPO and other dialysis-related drugs'' means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes; and ''furnished'' means that the EPO or dialysis-related drugs are administered

to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.

(2) [Reserved]

(3) [Reserved]

(4) The exception set forth in this paragraph (g) does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(h) *Preventive screening tests and vaccines.* (1) Preventive screening tests and vaccines that meet the following conditions:

(i) The preventive screening test or vaccine is listed on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

(ii) The preventive screening test or vaccine is covered by Medicare.

(iii) The preventive screening test or vaccine is subject to a CMS-mandated frequency limit.

(2) During such period as the vaccine is not subject to a CMS-mandated frequency limit, paragraph (h)(1)(iii) of this section does not apply to a COVID–19 vaccine identified on the List of CPT/HCPCS Codes as a code to which the exception in this paragraph is applicable.

(i) *Eyeglasses and contact lenses following cataract surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery that meet the following conditions:

(1) The eyeglasses or contact lenses are provided in accordance with the coverage and payment provisions set forth in §§ 410.36(a)(2)(ii) and 414.228 of this chapter, respectively.

(2) [Reserved]

(j) *Intra-family rural referrals.* (1) Services provided pursuant to a referral from a referring physician to his or her immediate family member or to an entity furnishing DHS with which the immediate family member has a financial relationship, if all of the following conditions are met:

(i) The patient who is referred resides in a rural area as defined at § 411.351 of this subpart;

(ii) Except as provided in paragraph (j)(1)(iii) of this section, in light of the patient's condition, no other person or entity is available to furnish the services in a timely manner within 25 miles of or 45 minutes transportation time from the patient's residence;

(iii) In the case of services furnished to patients where they reside (for example, home health services or DME), no other person or entity is available to furnish the services in a timely manner in light of the patient's condition; and

(2) The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. However, neither the referring physician nor the immediate family member has any obligation to inquire as to the availability of persons or entities located farther than 25 miles of or 45 minutes transportation time from (whichever test the referring physician utilized for purposes of paragraph (j)(1)(ii)) the patient's residence.

[85 FR 77656, Dec. 2, 2020, as amended at 86 FR 65668, Nov. 19 2021]

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

For purposes of § 411.353, the following ownership or investment interests do not constitute a financial relationship:

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (2) of this section.

(1) They are either—

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent.

(2) They are in a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years. ''Stockholder equity'' is the difference in value between a corporation's total assets and total liabilities.

(b) *Mutual funds.* Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75 million.

(c) *Specific providers.* Ownership or investment interest in the following entities, for purposes of the services specified:

(1) A rural provider, in the case of DHS furnished in a rural area (as defined at §411.351 of this part) by the provider. A ''rural provider'' is an entity that furnishes substantially all (not less than 75 percent) of the DHS that it furnishes to residents of a rural area and, for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), is not a specialty hospital, and in the case where the entity is a hospital, the hospital meets the requirements of §411.362 no later than September 23, 2011.

(2) A hospital that is located in Puerto Rico, in the case of DHS furnished by such a hospital.

(3) A hospital that is located outside of Puerto Rico, in the case of DHS furnished by such a hospital, if—

(i) The referring physician is authorized to perform services at the hospital;

(ii) Effective for the 18-month period beginning on December 8, 2003 (or such other period as Congress may specify), the hospital is not a specialty hospital;

(iii) The ownership or investment interest is in the entire hospital and not merely in a distinct part or department of the hospital; and

(iv) The hospital meets the requirements described in §411.362 not later than September 23, 2011.

[85 FR 77656, Dec. 2, 2020]

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

For purposes of §411.353, the following compensation arrangements do not constitute a financial relationship:

(a) *Rental of office space.* Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) *Rental of equipment.* Payments made by a lessee to a lessor for the use of equipment under the following conditions:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

(3) The duration of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of this paragraph (b) if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) *Bona fide employment relationships.* Any amount paid by an employer to a physician (or immediate family member) who has a *bona fide* employment relationship with the employer for the

provision of services if the following conditions are met:

(1) The employment is for identifiable services.

(2) The amount of the remuneration under the employment is—

(i) Consistent with the fair market value of the services; and

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

(4) Paragraph (c)(2)(ii) of this section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician).

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(d) *Personal service arrangements*—(1) *General.* Remuneration from an entity under an arrangement or multiple arrangements to a physician or his or her immediate family member, or to a group practice, including remuneration for specific physician services furnished to a nonprofit blood center, if the following conditions are met:

(i) Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.

(ii) Except for services provided under an arrangement that satisfies all of the conditions of paragraph (z) of this section, the arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member may ''furnish'' services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice).

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The duration of each arrangement is at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at §411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(vi) The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

(viii) If remuneration to the physician is conditioned on the physician's

referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

(i) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.

(ii) Upon request of the Secretary, the entity provides the Secretary with access to information regarding the plan (including any downstream contractor plans), in order to permit the Secretary to determine whether the plan is in compliance with paragraph (d)(2) of this section.

(iii) In the case of a plan that places a physician or a physician group at substantial financial risk as defined at § 422.208, the entity or any downstream contractor (or both) complies with the requirements concerning physician incentive plans set forth in §§ 422.208 and 422.210 of this chapter.

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(e) *Physician recruitment.* (1) Remuneration provided by a hospital to recruit a physician that is paid directly to the physician and that is intended to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by both parties;

(ii) The arrangement is not conditioned on the physician's referral of patients to the hospital;

(iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

(2)(i) *Geographic area served by the hospital—defined.* The ''geographic area served by the hospital'' is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. The geographic area served by the hospital may include one or more zip codes from which the hospital draws no inpatients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the hospital draws at least 75 percent of its inpatients.

(ii) *Noncontiguous zip codes.* With respect to a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' will be deemed to be the area composed of all of the contiguous zip codes from which the hospital draws its inpatients.

(iii) *Special optional rule for rural hospitals.* In the case of a hospital located in a rural area (as defined at § 411.351), the ''geographic area served by the hospital'' may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients. If the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, the ''geographic area served by the hospital'' may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the hospital's inpatients resides, and continuing to add noncontiguous zip codes in decreasing order of percentage of inpatients.

(iv) *Relocation of medical practice.* A physician will be considered to have relocated his or her medical practice if the medical practice was located outside the geographic area served by the hospital and—

(A) The physician moves his or her medical practice at least 25 miles and into the geographic area served by the hospital; or

(B) The physician moves his medical practice into the geographic area served by the hospital, and the physician's new medical practice derives at least 75 percent of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years, measured on an annual basis (fiscal or calendar year). For the initial ''start up'' year of the recruited physician's practice, the 75 percent test in the preceding sentence will be satisfied if there is a reasonable expectation that the recruited physician's medical practice for the year will derive at least 75 percent of its revenues from professional services furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

(3) The recruited physician will not be subject to the relocation requirement of this paragraph (e), provided that he or she establishes his or her medical practice in the geographic area served by the recruiting hospital, if—

(i) He or she is a resident or physician who has been in practice 1 year or less;

(ii) He or she was employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by one of the following (and did not maintain a private practice in addition to such full-time employment):

(A) A Federal or State bureau of prisons (or similar entity operating one or more correctional facilities) to serve a prison population;

(B) The Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or

(C) A facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service; or

(iii) The Secretary has deemed in an advisory opinion issued under section 1877(g) of the Act that the physician does not have an established medical practice that serves or could serve a significant number of patients who are or could become patients of the recruiting hospital.

(4) In the case of remuneration provided by a hospital to a physician either indirectly through payments made to another physician practice, or directly to a physician who joins a physician practice, the following additional conditions must be met:

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

(ii) Except for actual costs incurred by the physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician.

(iii) In the case of an income guarantee of any type made by the hospital to a recruited physician who joins a physician practice, the costs allocated by the physician practice to the recruited physician do not exceed the actual additional incremental costs attributable to the recruited physician. With respect to a physician recruited to join a physician practice located in a rural area or HPSA, if the physician is recruited to replace a physician who, within the previous 12-month period, retired, relocated outside of the geographic area served by the hospital, or died, the costs allocated by the physician practice to the recruited physician do not exceed either—

(A) The actual additional incremental costs attributable to the recruited physician; or

(B) The lower of a *per capita* allocation or 20 percent of the practice's aggregate costs.

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years

and made available to the Secretary upon request.

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

(vi) The physician practice may not impose on the recruited physician practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.

(5) Recruitment of a physician by a hospital located in a rural area (as defined at § 411.351) to an area outside the geographic area served by the hospital is permitted under this exception if the Secretary determines in an advisory opinion issued under section 1877(g) of the Act that the area has a demonstrated need for the recruited physician and all other requirements of this paragraph (e) are met.

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center, rural health clinic, or rural emergency hospital is the area composed of the lowest number of contiguous or noncontiguous zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients, as determined on an encounter basis. The geographic area served by the federally qualified health center, rural health clinic, or rural emergency hospital may include one or more zip codes from which the federally qualified health center, rural health clinic, or rural emergency hospital draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described in the preceding sentence from which the federally qualified health center, rural health clinic, or rural emergency hospital draws at least 90 percent of its patients.

(f) *Isolated transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, or a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute, if all of the following conditions are met:

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

(3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in §§ 411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

(4) An isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a *bona fide* dispute is not part of the compensation arrangement giving rise to the *bona fide* dispute.

(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as ''unrelated,'' remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it—

(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;

(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or

(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group practice arrangements with a hospital.* An arrangement between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital if the following conditions are met:

(1) With respect to services furnished to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1861(b)(3) of the Act.

(2) The arrangement began before, and has continued in effect without interruption since, December 19, 1989.

(3) With respect to the DHS covered under the arrangement, at least 75 percent of these services furnished to patients of the hospital are furnished by the group under the arrangement.

(4) The arrangement is in accordance with a written agreement that specifies the services to be furnished by the parties and the compensation for services furnished under the agreement.

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(6) The compensation is provided in accordance with an agreement that would be commercially reasonable even if no referrals were made to the entity.

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).

(i) *Payments by a physician.* Payments made by a physician (or his or her immediate family member)—

(1) To a laboratory in exchange for the provision of clinical laboratory services; or

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), ''services'' means services of any kind (not merely those defined as ''services'' for purposes of the Medicare program in §400.202 of this chapter).

(j) *Charitable donations by a physician.* *Bona fide* charitable donations made by a physician (or immediate family member) to an entity if all of the following conditions are satisfied:

(1) The charitable donation is made to an organization exempt from taxation under the Internal Revenue Code (or to a supporting organization);

(2) The donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity; and

(k) *Nonmonetary compensation.* (1) Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of $300 per calendar year, as adjusted for inflation in accordance with paragraph (k)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

(ii) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

(3) Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the limit (as set forth in paragraph (k)(1) of this section), such compensation is deemed to be within the limit if—

(i) The value of the excess nonmonetary compensation is no more than 50 percent of the limit; and

(ii) The physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the excess nonmonetary compensation) by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.

(iii) This paragraph (k)(3) may be used by an entity only once every 3 years with respect to the same referring physician.

(4) In addition to nonmonetary compensation up to the limit described in paragraph (k)(1) of this section, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the limit in paragraph (k)(1).

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services or for the lease of office space or equipment by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. The writing specifies—

(i) The items, services, office space, or equipment covered under the arrangement;

(ii) The compensation that will be provided under the arrangement; and

(iii) The timeframe for the arrangement.

(2) An arrangement may be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year.

(3) The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act).

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on

one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.

(m) *Medical staff incidental benefits.* Compensation in the form of items or services (not including cash or cash equivalents) from a hospital to a member of its medical staff when the item or service is used on the hospital's campus, if all of the following conditions are met:

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m).

(4) The compensation is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital.

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

(6) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) [Reserved]

(8) Other facilities and health care clinics (including, but not limited to, federally qualified health centers) that have *bona fide* medical staffs may provide compensation under this paragraph (m) on the same terms and conditions applied to hospitals under this paragraph (m).

(n) *Risk-sharing arrangements.* Compensation paid directly or indirectly by a MCO or an IPA to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) for services provided by the physician to enrollees of a health plan. For purposes of this paragraph (n), ''health plan'' and ''enrollees'' have the meanings set forth in §1001.952(l) of this title.

(o) *Compliance training.* Compliance training provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area, provided that the training is held in the local community or service area. For purposes of this paragraph (o), ''compliance training'' means training regarding the basic elements of a compliance program (for example, establishing policies and procedures, training of staff, internal monitoring, or reporting); specific training regarding the requirements of Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal, State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided. For purposes of this paragraph, ''compliance training'' includes programs that offer continuing medical education credit, provided that

compliance training is the primary purpose of the program.

(p) *Indirect compensation arrangements.* Indirect compensation arrangements, as defined at § 411.354(c)(2), if all of the following conditions are satisfied:

(1)(i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) [Reserved]

(4) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in § 411.354(c)(2)(ii) satisfies the conditions of § 411.354(d)(4).

(q) *Referral services.* Remuneration that meets all of the conditions set forth in § 1001.952(f) of this title.

(r) *Obstetrical malpractice insurance subsidies.* Remuneration that meets all of the conditions of paragraph (r)(1) or (2) of this section.

(1) Remuneration that meets all of the conditions set forth in § 1001.952(o) of this title.

(2) A payment from a hospital, federally qualified health center, rural health clinic, or rural emergency hospital that is used to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice, if all of the following conditions are met:

(i)(A) The physician's medical practice is located in a rural area, a primary care HPSA, or an area with demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's obstetrical patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The arrangement is set out in writing, is signed by the physician and the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment, and specifies the payment to be made by the hospital, federally qualified health center, rural health clinic, or rural emergency hospital and the terms under which the payment is to be provided.

(iii) The arrangement is not conditioned on the physician's referral of patients to the hospital, federally qualified health center, rural health clinic, or rural emergency hospital providing the payment.

(iv) The hospital, federally qualified health center, rural health clinic, or rural emergency hospital does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), rural health clinic(s), or rural emergency hospital(s) and to refer business

to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with §411.354(d)(4)).

(vi) The payment is made to a person or organization (other than the physician) that is providing malpractice insurance (including a self-funded organization).

(vii) The physician treats obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(viii) The insurance is a *bona fide* malpractice insurance policy or program, and the premium, if any, is calculated based on a *bona fide* assessment of the liability risk covered under the insurance.

(ix)(A) For each coverage period (not to exceed 1 year), at least 75 percent of the physician's obstetrical patients treated under the coverage of the obstetrical malpractice insurance during the prior period (not to exceed 1 year)—

(*1*) Resided in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Were part of a medically underserved population.

(B) For the initial coverage period (not to exceed 1 year), the requirements of paragraph (r)(2)(ix)(A) of this section will be satisfied if the physician certifies that he or she has a reasonable expectation that at least 75 percent of the physician's obstetrical patients treated under the coverage of the malpractice insurance will—

(*1*) Reside in a rural area, HPSA, medically underserved area, or an area with a demonstrated need for the physician's obstetrical services as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(*2*) Be part of a medically underserved population.

(3) For purposes of paragraph (r)(2) of this section, *costs of malpractice insurance premiums* means:

(i) For physicians who engage in obstetrical practice on a full-time basis, any costs attributable to malpractice insurance; or

(ii) For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs attributable exclusively to the obstetrical portion of the physician's malpractice insurance, and related exclusively to obstetrical services provided—

(A) In a rural area, primary care HPSA, or an area with demonstrated need for the physician's obstetrical services, as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) In any area, provided that at least 75 percent of the physician's obstetrical patients treated in the coverage period (not to exceed 1 year) resided in a medically underserved area or were part of a medically underserved population.

(s) *Professional courtesy*. Professional courtesy (as defined at §411.351) offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff if all of the following conditions are met:

(1) The professional courtesy is offered to all physicians on the entity's bona fide medical staff or in such entity's local community or service area, and the offer does not take into account the volume or value of referrals or other business generated between the parties;

(2) The health care items and services provided are of a type routinely provided by the entity;

(3) The entity has a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body; and

(4) The professional courtesy is not offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need.

(t) *Retention payments in underserved areas*—(1) *Bona fide written offer*. Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in

paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician has a *bona fide* firm, written recruitment offer or offer of employment from a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that is not related to the hospital making the payment, and the offer specifies the remuneration being offered and requires the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by the hospital making the retention payment.

(ii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iii) Any retention payment is subject to the same obligations and restrictions, if any, on repayment or forgiveness of indebtedness as the written recruitment offer or offer of employment.

(iv) The retention payment does not exceed the lower of—

(A) The amount obtained by subtracting the physician's current income from physician and related services from the income the physician would receive from comparable physician and related services in the written recruitment or employment offer, provided that the respective incomes are determined using a reasonable and consistent methodology, and that they are calculated uniformly over no more than a 24-month period; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this setion are satisfied.

(2) *Written certification from physician.* Remuneration provided by a hospital directly to a physician on the hospital's medical staff to retain the physician's medical practice in the geographic area served by the hospital (as defined in paragraph (e)(2) of this section), if all of the following conditions are met:

(i) The physician furnishes to the hospital before the retention payment is made a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center (as defined at §411.355(e)), or physician organization (as defined at §411.351) that requires the physician to move the location of his or her medical practice at least 25 miles and outside the geographic area served by the hospital. The certification contains at least the following—

(A) Details regarding the steps taken by the physician to effectuate the employment opportunity;

(B) Details of the physician's employment opportunity, including the identity and location of the physician's future employer or employment location or both, and the anticipated income and benefits (or a range for income and benefits);

(C) A statement that the future employer is not related to the hospital making the payment;

(D) The date on which the physician anticipates relocating his or her medical practice outside of the geographic area served by the hospital; and

(E) Information sufficient for the hospital to verify the information included in the written certification.

(ii) The hospital takes reasonable steps to verify that the physician has a *bona fide* opportunity for future employment that requires the physician to relocate outside the geographic area served by the hospital.

(iii) The requirements of paragraphs (e)(1)(i) through (iv) of this section are satisfied.

(iv) The retention payment does not exceed the lower of—

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

(B) The reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital to join the medical staff of the hospital to replace the retained physician.

(v) The requirements of paragraph (t)(3) of this section are satisfied.

(3) *Additional requirements.* Remuneration provided under paragraph (t)(1) or (2) of this section must meet the following additional requirements:

(i)(A) The physician's current medical practice is located in a rural area or HPSA (regardless of the physician's specialty) or is located in an area with demonstrated need for the physician as determined by the Secretary in an advisory opinion issued in accordance with section 1877(g)(6) of the Act; or

(B) At least 75 percent of the physician's patients reside in a medically underserved area or are members of a medically underserved population.

(ii) The hospital does not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years.

(iii) The amount and terms of the retention payment are not altered during the term of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(4) *Waiver of relocation requirement.* The Secretary may waive the relocation requirement of paragraphs (t)(1) and (t)(2) of this section for payments made to physicians practicing in a HPSA or an area with demonstrated need for the physician through an advisory opinion issued in accordance with section 1877(g)(6) of the Act, if the retention payment arrangement otherwise complies with all of the conditions of this paragraph (t).

(5) Application to other entities. This paragraph (t) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital. For purposes of this paragraph (t), the geographic area served by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(u) *Community-wide health information systems.* Items or services of information technology provided by an entity to a physician that allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community's overall health, provided that—

(1) The items or services are available as necessary to enable the physician to participate in a community-wide health information system, are principally used by the physician as part of the community-wide health information system, and are not provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician;

(2) The community-wide health information systems are available to all providers, practitioners, and residents of the community who desire to participate; and

(v) *Electronic prescribing items and services.* Nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital or rural emergency hospital to a physician who is a member of its medical staff;

(ii) Group practice (as defined at §411.352) to a physician who is a member of the group (as defined at §411.351); or

(iii) PDP sponsor or MA organization to a prescribing physician.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(5) Neither the physician nor the physician's practice (including employees

and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

(1) The items and services are provided to a physician by an entity (as defined at § 411.351) that is not a laboratory company.

(2) The software is interoperable (as defined at § 411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) [Reserved]

(4)(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services.

(ii) Except as provided in paragraph (w)(4)(i) of this section, with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals.

(iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.

(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);

(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the physician practices medicine;

(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the physician; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.

(8) [Reserved]

(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.

(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.

(x) *Assistance to compensate a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by—

(*1*) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), ''nonphysician practitioner'' means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined at § 410.71(d) of this subchapter.

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) ''NPP patient care services'' means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) ''NPP referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, ''geographic area served by the hospital'' has the meaning set forth in paragraph (e)(2) of this section.

(6) For purposes of paragraph (x)(1) of this section, a ''compensation arrangement'' between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, rural health clinic, or rural emergency hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician

stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center, rural health clinic, or rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center, rural health clinic, or rural emergency hospital has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The arrangement is between a physician (or the physician organization in whose shoes the physician stands under §411.354(c)) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) [Reserved]

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

(10) This paragraph (y) applies to remuneration provided by a rural emergency hospital in the same manner as it applies to remuneration provided by a hospital.

(z) *Limited remuneration to a physician.* (1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $5,000 per calendar year, as adjusted for inflation in accordance with paragraph (z)(3) of this

section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.

(vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of § 411.354(d)(4).

(2) A physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians (as defined at § 411.351, except that the regular physician need not be a member of a group practice).

(3) The annual aggregate remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new remuneration limit on the physician self-referral website at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp*.

(aa) *Arrangements that facilitate value-based health care delivery and payment*—(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined at § 411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's

best medical interests in the physician's judgment.

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), ''full financial risk'' means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), ''prospective basis'' means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), ''meaningful downside financial risk'' means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.

(3) *Value-based arrangements*. Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The outcome measures against which the recipient of the remuneration is assessed, if any.

(ii) The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support.

(iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

(iv) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(vi) The arrangement is commercially reasonable.

(vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

(*1*) Whether the parties have furnished the value-based activities required under the arrangement;

(*2*) Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and

(3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—

(*1*) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or

(*2*) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

(viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(ix) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(x) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(xi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(xii) For purposes of this paragraph (aa)(3), ''outcome measure'' means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

(bb) *Cybersecurity technology and related services.* (1) Nonmonetary remuneration (consisting of technology and

services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met:

(i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(ii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iii) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), ''technology'' means any software or other types of information technology.

[85 FR 77656, Dec. 2, 2020, as amended at 87 FR 72285, Nov. 23, 2022; 88 FR 59328, Aug. 28, 2023]

§411.361 Reporting requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, all entities furnishing services for which payment may be made under Medicare must submit information to CMS or to the Office of Inspector General (OIG) concerning their reportable financial relationships (as defined in paragraph (d) of this section), in the form, manner, and at the times that CMS or OIG specifies.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to entities that furnish 20 or fewer Part A and Part B services during a calendar year, or to any Medicare covered services furnished outside the United States.

(c) *Required information.* The information requested by CMS or OIG can include the following:

(1) The name and unique physician identification number (UPIN) or the national provider identifier (NPI) of each physician who has a reportable financial relationship with the entity.

(2) The name and UPIN or NPI of each physician who has an immediate family member (as defined at §411.351) who has a reportable financial relationship with the entity.

(3) The covered services furnished by the entity.

(4) With respect to each physician identified under paragraphs (c)(1) and (c)(2) of this section, the nature of the financial relationship (including the extent or value of the ownership or investment interest or the compensation arrangement) as evidenced in records that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain to comply with the rules of the Internal Revenue Service and the Securities and Exchange Commission and other rules of the Medicare and Medicaid programs.

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at §411.354(b) or any compensation arrangement, as defined at §411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in §411.356(a) or §411.356(b) regarding publicly traded securities and mutual funds.

(e) *Form and timing of reports.* Entities that are subject to the requirements of this section must submit the required information, upon request, within the time period specified by the request. Entities are given at least 30 days from the date of the request to provide the information. Entities must retain the information, and documentation sufficient to verify the information, for the length of time specified by the applicable regulatory requirements for the information, and, upon request, must make that information and documentation available to CMS or OIG.

(f) *Consequences of failure to report.* Any person who is required, but fails, to submit information concerning his or her financial relationships in accordance with this section is subject to a civil money penalty of up to $10,000 as adjusted annually under 45 CFR part 102 for each day following the deadline established under paragraph (e) of this section until the information is submitted. Assessment of these penalties will comply with the applicable provisions of part 1003 of this title.

(g) *Public disclosure.* Information furnished to CMS or OIG under this section is subject to public disclosure in accordance with the provisions of part 401 of this chapter.

[72 FR 51098, Sept. 5, 2007, as amended at 80 FR 71378, Nov. 16, 2015; 81 FR 61561, Sept. 6, 2016]

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) *Definitions.* For purposes of this section—

Ownership or investment interest means for purposes of this section, a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

Physician owner or investor means a physician (or immediate family member of the physician) with a direct or an indirect ownership or investment interest in the hospital.

Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) *General requirements.* (1) *Physician ownership and provider agreement.* The hospital had physician ownership or investment on December 31, 2010; and a provider agreement under section 1866 of the Act in effect on that date.

(2) *Prohibition on facility expansion.* The hospital may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital is licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of this date, but does have a provider agreement in effect on December 31, 2010, the effective date of such agreement), unless an exception is approved under § 411.363.

(3) *Disclosure of conflicts of interest.* (i) At such time and in such manner as specified by CMS, the hospital must submit an annual report to CMS containing a detailed description of the identity of each owner or investor in the hospital and the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital must—

(A) Require each referring physician owner or investor who is a member of the hospital's medical staff to agree, as a condition of continued medical staff membership or admitting privileges, to provide written disclosure of his or her ownership or investment interest in the hospital (and, if applicable, the ownership or investment interest of any treating physician) to all patients whom the physician refers to the hospital. Disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.

(B) Not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

(4) *Ensuring bona fide investment.* The hospital satisfies the following criteria:

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(5) *Patient safety.* The hospital satisfies the following criteria:

(i) If the hospital does not have a physician available on the premises to provide services during all hours in which the hospital is providing services to the patient, the hospital must disclose this information to the patient. Before providing services to the patient, the hospital must receive a signed acknowledgment from the patient stating that the patient understands that a physician may not be present during all hours services are furnished to the patient.

(ii) The hospital must have the capacity to provide assessment and initial treatment for all patients, and the ability to refer and transfer patients to hospitals with the capability to treat the needs of the patient that the hospital is unable to address. For purposes of this paragraph, the hospital inpatient stay or outpatient visit begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or an outpatient service.

(6) *Prohibition on conversion from an ambulatory surgery center.* The hospital must not have been converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

[75 FR 72260, Nov. 24, 2010, as amended at 76 FR 74581, Nov. 30, 2011; 79 FR 67029, Nov. 10, 2014; 80 FR 71378, Nov. 16, 2015; 85 FR 86299, Dec. 29, 2020; 88 FR 59328, Aug. 28, 2023]

§411.363 Process for requesting an exception from the prohibition on facility expansion.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure

rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

External data source means a data source that—

(i) Is generated, maintained, or under the control of a State Medicaid agency;

(ii) Is reliable and transparent;

(iii) Maintains data that, for purposes of the process described in this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(iv) Maintains or generates data that, for purposes of the process described in this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means ''campus'' as defined at § 413.65(a)(2) of this chapter.

Procedure room has the meaning set forth at § 411.362(a).

(b) *CMS consideration of requests for an exception from the prohibition on facility expansion.* (1) CMS will not consider a request for an exception from the prohibition on facility expansion from a hospital that is not eligible to request the exception.

(2) A hospital that meets the criteria for an applicable hospital or a high Medicaid facility is eligible to request an exception from the prohibition on facility expansion for consideration by CMS, provided that—

(i) CMS has not previously approved a request for an exception from the prohibition on facility expansion that would allow the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed to reach 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds if the full expansion is utilized; and

(ii) It has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent request for an exception from the prohibition on facility expansion.

(c) *Criteria for an applicable hospital.* An applicable hospital is a hospital that meets the following criteria:

(1) *Population increase.* The hospital is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(2) *Medicaid inpatient admissions.* The hospital has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph (c)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from the Healthcare Cost Report Information System (HCRIS) or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and

are located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Average bed capacity.* The hospital is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity.

(i) CMS will provide on its website State average bed capacities and the national average bed capacity.

(ii) For purposes of this paragraph (c)(4), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(4) would not materially change after additional hospital data are reported.

(5) *Average bed occupancy.* The hospital has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate.

(i) A hospital must use filed hospital cost report data from HCRIS to determine its average bed occupancy rate.

(ii) CMS will provide on its website State average bed occupancy rates. For purposes of this paragraph (c)(5), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(5) would not materially change after additional hospital data are reported.

(6) *Hospital location.* For purposes of this paragraph (c), a hospital is located in the county and State in which the main campus of the hospital is located.

(d) *Criteria for a high Medicaid facility.* A high Medicaid facility is a hospital that meets all of the following criteria:

(1) *Sole hospital.* The hospital is not the sole hospital in the county in which the hospital is located.

(2) *Medicaid inpatient admissions.* With respect to each of the three most recent 12-month periods for which data are available as of the date the hospital submits its request, the hospital has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located. For purposes of this paragraph (d)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from HCRIS or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percentage of

total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Hospital location.* For purposes of this paragraph (d), a hospital is located in the county in which the main campus of the hospital is located.

(e) *Procedure for submitting a request for an exception from the prohibition on facility expansion.* (1) A hospital must submit the request for an exception from the prohibition on facility expansion and the signed certification set forth in paragraph (e)(3) of this section electronically to CMS according to the instructions specified on the CMS website.

(2) For a hospital's request for an exception from the prohibition on facility expansion to be considered by CMS, the request must include all of the following information:

(i) The name, address, national provider identification number(s) (NPI), tax identification number (TIN), and CMS certification number (CCN) for the hospital.

(ii)(A) The name of the county in which the main campus is located; and

(B) The names of any counties in which the hospital provides inpatient or outpatient hospital services.

(iii) The name, title, daytime telephone number, electronic mail address, and hard copy mail address for the contact person who will be available to discuss the request with CMS on behalf of the hospital.

(iv)(A) A statement identifying the hospital as an applicable hospital or high Medicaid facility; and

(B) A detailed explanation with supporting documentation regarding whether and how the hospital meets each of the criteria for an applicable hospital or high Medicaid facility.

(v) A statement and supporting documentation, if available, explaining how the hospital satisfies the criterion in paragraph (c)(3) or (d)(3) of this section that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(vi) Documentation supporting—

(A) The hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds;

(B) The number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception;

(C) Whether and how the hospital has used any expansion facility capacity approved in a prior request; and

(D) The additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(3) A hospital may submit other information with respect to the request, including but not limited to information regarding—

(i) Whether the hospital plans to use expansion facility capacity to provide specialty services (for example, maternity, psychiatric services, or substance use disorder care) if the request is approved; and

(ii) The current or future need, if any, for additional operating rooms, procedure rooms, and beds—

(A) For the hospital to serve Medicaid, uninsured, and underserved populations;

(B) In the county in which the main campus of the hospital is located; and

(C) In any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(4) A request for an exception from the prohibition on facility expansion must include the following certification signed by an authorized representative of the hospital: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.'' An authorized representative is the chief executive officer, chief financial officer, or other

individual who is authorized by the hospital to make the request.

(f) *Community input.* (1) Upon submitting a request for an exception from the prohibition on facility expansion and until the hospital receives a CMS decision on the request, the hospital must disclose on any public website for the hospital that it is requesting an exception from the prohibition on facility expansion.

(2) A hospital submitting a request for an exception from the prohibition on facility expansion must provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2) and (d)(2) of this section.

(3)(i) Individuals and entities in the hospital's community may provide input with respect to the hospital's request for an exception from the prohibition on facility expansion, including, but not limited to, input regarding whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility and the factors listed in paragraph (i)(2) of this section that CMS will consider in deciding whether to approve or deny a hospital's request.

(ii) The hospital's community includes the geographic area served by the hospital (as defined at §411.357(e)(2)) and all of the following:

(A) The county in which the hospital's main campus is located.

(B) The counties in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(iii) Community input must be—

(A) In the form of written comments;

(B) Submitted according to the instructions in the FEDERAL REGISTER notice of the hospital's request; and

(C) Received no later than 60 days after CMS publishes notice of the hospital's request in the FEDERAL REGISTER.

(iv) If CMS receives written comments from the community, the hospital has 60 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(g) *Timing of complete request.* (1) If only filed Medicare hospital cost report data from HCRIS are used in the hospital's request for an exception from the prohibition on facility expansion, the written comments, and the hospital's rebuttal statement, a request will be deemed complete no later than 90 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(2) If data from an external data source are used in the hospital's request for an exception from the prohibition on facility expansion, the written comments, or the hospital's rebuttal statement, a request will be deemed complete no later than 180 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(h) *Determination that the hospital is an applicable hospital or a high Medicaid facility.* Based on the information described in paragraph (e) of this section and the community input described in paragraph (f) of this section, if any, CMS will first determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility.

(i) *CMS decision to approve or deny a request for an exception from the prohibition on facility expansion*—(1) *Data and information for consideration by CMS.* In reviewing a request for an exception from the prohibition on facility expansion, CMS—

(i) Will consider data and information provided by the hospital in its request, included in the community input, if any, and provided by the hospital in its rebuttal statement, if any; and

(ii) May also consider any other data and information relevant to its decision.

(2) *Factors considered by CMS.* Factors that CMS will consider in deciding whether to approve or deny a hospital's

request for an exception from the prohibition on facility expansion include but are not limited to the following:

(i) The specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request.

(ii) Program integrity or quality of care concerns related to the hospital.

(iii) Whether the hospital has a need for additional operating rooms, procedure rooms, or beds.

(iv) Whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located or in any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(j) *Permitted increase in facility capacity.* (1) Except as provided in paragraph (j)(2) of this section, a permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(2) The limitations of paragraph (j)(1) of this section do not apply to an increase in facility capacity approved by CMS with respect to a request for an exception from the prohibition on facility expansion submitted by a high Medicaid facility between January 1, 2021, and September 30, 2023.

(k) *Publication of final determination and decision.* Not later than 60 days after receiving a complete request—

(1) If CMS determines that the hospital does not meet the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the FEDERAL REGISTER notice of such determination; or

(2) If CMS determines that the hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the FEDERAL REGISTER notice of such determination and its decision regarding the hospital's request for an exception from the prohibition on facility expansion.

(l) *Limitation on review.* There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the process under this section (including the establishment of such process and any CMS determination or decision under such process).

[88 FR 59328, Aug. 28, 2023]

§ 411.370 Advisory opinions relating to physician referrals.

(a) *Period during which CMS accepts requests.* The provisions of § 411.370 through § 411.389 apply to requests for advisory opinions that are submitted to CMS during any time period in which CMS is required by law to issue the advisory opinions described in this subpart.

(b) *Matters that qualify for advisory opinions and who may request one.* Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to designated health services (other than clinical laboratory services) is prohibited under section 1877 of the Act. In the advisory opinion, CMS will determine whether a business arrangement described by the parties to that arrangement appears to constitute a ''financial relationship'' (as defined in section 1877(a)(2) of the Act) that could potentially restrict a physician's referrals, and whether the arrangement or the designated health services at issue appear to qualify for any of the exceptions to the referral prohibition described in section 1877 of the Act.

(1) The request must relate to an existing arrangement or one into which the requestor, in good faith, specifically plans to enter. The planned arrangement may be contingent upon the party or parties receiving a favorable advisory opinion. CMS does not consider, for purposes of an advisory opinion, requests that involve the activities of third parties.

(2) The requestor must be a party to the existing or proposed arrangement.

(c) *Matters not subject to advisory opinions.* CMS will not address through an advisory opinion—

(1) Whether the fair market value was, or will be, paid or received for any goods, services, or property; and

(2) Whether an individual is a *bona fide* employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(d) *Facts subject to advisory opinions.* The requestor must include in the advisory opinion request a complete description of the arrangement that the requestor is undertaking, or plans to undertake, as described in §411.372.

(e) *Acceptance of requests.* (1) CMS does not accept an advisory opinion request or issue an advisory opinion if—

(i) The request is not related to a named individual or entity;

(ii) The request does not describe the arrangement at issue with a level of detail sufficient for CMS to issue an opinion, and the requestor does not timely respond to CMS requests for additional information;

(iii) CMS is aware, after consultation with OIG and DOJ, that the same course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency;

(iv) CMS believes that it cannot make an informed opinion or could only make an informed opinion after extensive investigation, clinical study, testing, or collateral inquiry; or

(v) CMS determines that the arrangement or course of conduct at issue is or would be in violation of applicable State or Federal law or regulation.

(2) CMS may elect not to accept an advisory opinion request if it determines, after consultation with OIG and DOJ:

(i) The course of action described is substantially similar to a course of conduct that is under investigation or the subject of a proceeding involving the Department or other law enforcement agencies; and

(ii) Issuing an advisory opinion could interfere with the investigation or proceeding.

(f) *Effects of an advisory opinion on other Governmental authority.* Nothing in this part limits the investigatory or prosecutorial authority of the OIG, the Department of Justice, or any other agency of the Government. In addition, in connection with any request for an advisory opinion, CMS, the OIG, or the Department of Justice may conduct whatever independent investigation it believes appropriate.

[69 FR 57227, Sept. 24, 2004, as amended at 72 FR 51098, Sept. 5, 2007; 84 FR 63191, Nov. 15, 2019]

§411.372 Procedure for submitting a request.

(a) *Format for a request.* A party or parties must submit a request for an advisory opinion to CMS according to the instructions specified on the CMS Web site.

(b) *Information CMS requires with all submissions.* The request must include the following:

(1) The name, address, telephone number, and Taxpayer Identification Number of the requestor.

(2) The names and addresses, to the extent known, of all other actual and potential parties to the arrangement that is the subject of the request.

(3) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requestor.

(4) A complete and specific description of all relevant information bearing on the arrangement, including—

(i) A complete description of the arrangement that the requestor is undertaking, or plans to undertake, including:

(A) The purpose of the arrangement; the nature of each party's (including each entity's) contribution to the arrangement; the direct or indirect relationships between the parties, with an emphasis on the relationships between physicians involved in the arrangement (or their immediate family members who are involved); and

(B) Any entities that provide designated health services; the types of services for which a physician wishes to refer, and whether the referrals will involve Medicare or Medicaid patients;

(ii) Complete copies of all relevant documents or relevant portions of documents that affect or could affect the arrangement, such as personal service or employment contracts, leases, deeds, pension or insurance plans, or financial statements (or, if these relevant documents do not yet exist, a complete description, to the best of the

requestor's knowledge, of what these documents are likely to contain);

(iii) Detailed statements of all collateral or oral understandings, if any; and

(iv) Descriptions of any other arrangements or relationships that could affect CMS's analysis.

(5) The identity of all entities involved either directly or indirectly in the arrangement, including their names, addresses, legal form, ownership structure, nature of the business (products and services) and, if relevant, their Medicare and Medicaid provider numbers. The requestor must also include a brief description of any other entities that could affect the outcome of the opinion, including those with which the requestor, the other parties, or the immediate family members of involved physicians, have any financial relationships (either direct or indirect, and as defined in section 1877(a)(2) of the Act and § 411.354), or in which any of the parties holds an ownership or control interest as defined in section 1124(a)(3) of the Act.

(6) At the option of the requestor, a discussion of the specific issues or questions to be addressed by CMS including, if possible, a discussion of why the requestor believes the referral prohibition in section 1877 of the Act might or might not be triggered by the arrangement and which, if any, exceptions the requestor believes might apply. The requestor should attempt to designate which facts are relevant to each issue or question raised in the request and should cite the provisions of law under which each issue or question arises.

(7) An indication of whether the parties involved in the request have also asked for or are planning to ask for an advisory opinion on the arrangement in question from the OIG under section 1128D(b) of the Act (42 U.S.C. 1320a–7d(b)) and whether the arrangement is or is not, to the best of the requestor's knowledge, the subject of an investigation.

(8) The certification(s) described in § 411.373. The certification(s) must be signed by—

(i) The requestor, if the requestor is an individual;

(ii) The chief executive officer, or other authorized officer, of the requestor, if the requestor is a corporation;

(iii) The managing partner of the requestor, if the requestor is a partnership; or

(iv) A managing member, if the requestor is a limited liability company.

(c) *Additional information CMS might require.* If the request does not contain all of the information required by paragraph (b) of this section, or, if either before or after accepting the request, CMS believes it needs more information in order to render an advisory opinion, it may request whatever additional information or documents it deems necessary. Additional information must be provided in writing, signed by the same person who signed the initial request (or by an individual in a comparable position), and be certified as described in § 411.373.

(d) *Requests for expedited review.* Parties may seek expedited review of arrangements under § 411.380(c)(1)(i) for a determination as to whether the arrangement or course of conduct is indistinguishable in all material aspects from an arrangement or course of conduct that was the subject of a prior advisory opinion. Parties seeking such expedited review must identify the relevant advisory opinion and provide an explanation of why the subject arrangement is indistinguishable from the arrangement that was the subject of the prior relevant advisory opinion. Requestors should clearly and prominently indicate in their submission to CMS that they are seeking expedited review.

[69 FR 57227, Sept. 24, 2004, as amended at 81 FR 80553, Nov. 15, 2016; 84 FR 63191, Nov. 15, 2019]

§ 411.373 Certification.

(a) Every request must include the following signed certification: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, in addition to the certification required by paragraph (a) of this section, the following certification must be included and signed by the requestor: ''The arrangement described in this request for an advisory opinion is one into which [the requestor], in good faith, plans to enter.'' This statement may be made contingent on a favorable advisory opinion, in which case the requestor should add one of the following phrases to the certification:

(1) ''if CMS issues a favorable advisory opinion.''

(2) ''if CMS and the OIG issue favorable advisory opinions.''

[69 FR 57227, Sept. 24, 2004]

§411.375 Fees for the cost of advisory opinions.

(a) *Hourly rate.* CMS will charge an hourly rate of $220. Parties may request an estimate from CMS after submitting a complete request. Before issuing the advisory opinion, CMS will calculate the final fee for responding to the request.

(b) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (c)(3) of this section, to pay all costs the Department incurs in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If CMS estimates that the costs of processing the advisory opinion request have reached or are likely to exceed the designated triggering dollar amount, CMS notifies the requestor.

(3) If CMS notifies the requestor that the actual or estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, CMS stops processing the request until the requestor makes a written request for CMS to continue. If CMS is delayed in processing the request for an advisory opinion because of this procedure, the time within which CMS must issue an advisory opinion is suspended until the requestor asks CMS to continue working on the request.

(4) If the requestor chooses not to pay for CMS to complete an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs CMS has identified as costs it incurred in processing the request for an advisory opinion, up to that point.

(5) If the costs CMS has incurred in responding to the request are greater than the amount the requestor has paid, CMS, before issuing the advisory opinion, notifies the requestor of any additional amount that is due. CMS does not issue an advisory opinion until the requestor has paid the full amount that is owed. Once the requestor has paid CMS the total amount due for the costs of processing the request, CMS issues the advisory opinion. The time period CMS has for issuing advisory opinions is suspended from the time CMS notifies the requestor of the amount owed until the time CMS receives full payment.

(c) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §411.377.

(2) The time period for issuing an advisory opinion is suspended from the time that CMS notifies the requestor that it needs an outside expert opinion until the time CMS receives that opinion.

[69 FR 57228, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§411.377 Expert opinions from outside sources.

(a) CMS may request expert advice from qualified sources if CMS believes that the advice is necessary to respond to a request for an advisory opinion. For example, CMS may require the use of accountants or business experts to assess the structure of a complex business arrangement or to ascertain a physician's or immediate family member's financial relationship with entities that provide designated health services.

(b) If CMS determines that it needs to obtain expert advice in order to issue a requested advisory opinion, CMS notifies the requestor of that fact and provides the identity of the appropriate expert and an estimate of the

costs of the expert advice. As indicated in § 411.375(d), the requestor must pay the estimated cost of the expert advice.

(c) Once CMS has received payment for the estimated cost of the expert advice, CMS arranges for the expert to provide a prompt review of the issue or issues in question. CMS considers any additional expenses for the expert advice, beyond the estimated amount, as part of the costs CMS has incurred in responding to the request, and the responsibility of the requestor, as described in § 411.375(c).

[69 FR 57229, Sept. 24, 2004]

§ 411.378 Withdrawing a request.

The party requesting an advisory opinion may withdraw the request before CMS issues a formal advisory opinion. This party must submit the withdrawal in writing to the same address as the request, as indicated in § 411.372(a). Even if the party withdraws the request, the party must pay the costs the Department has expended in processing the request, as discussed in § 411.375. CMS reserves the right to keep any request for an advisory opinion and any accompanying documents and information, and to use them for any governmental purposes permitted by law.

[69 FR 57229, Sept. 24, 2004]

§ 411.379 When CMS accepts a request.

(a) Upon receiving a request for an advisory opinion, CMS promptly makes an initial determination of whether the request contains a level of detail sufficient for CMS to process the request.

(b) If CMS determines that the request submitted lacks details necessary for CMS to process the request, CMS will provide notification to the requestor within 15 working days of receiving the request.

(c) If the requestor provides the additional information CMS has requested, or otherwise resubmits the request, CMS processes the resubmission in accordance with paragraphs (a) and (b) of this section as if it were an initial request for an advisory opinion.

(d) CMS formally accepts a request when CMS determines that the request (inclusive of any supplemental submissions) describes the arrangement at issue with sufficient detail and that the grounds for rejection of a request listed at § 411.370(e) do not apply. Upon accepting the request, CMS notifies the requestor by regular U.S. mail of the date that CMS formally accepts the request.

(e) The applicable time period that CMS has to issue an advisory opinion set forth in § 411.380(c) does not begin until CMS formally accepts the request for an advisory opinion.

[69 FR 57229, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§ 411.380 When CMS issues a formal advisory opinion.

(a) CMS considers an advisory opinion to be issued once it has received payment and once the opinion has been dated, numbered, and signed by an authorized CMS official.

(b) An advisory opinion contains a description of the material facts known to CMS that relate to the arrangement that is the subject of the advisory opinion, and states CMS's opinion about the subject matter of the request based on those facts. If necessary, CMS includes in the advisory opinion material facts that could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1095.

(c)(1) Except as set forth in paragraph (c)(2) of this section, CMS issues an advisory opinion in accordance with the provisions of this part within 60 working days after the date on which it formally accepts the advisory opinion request.

(i) In the case of a request for a determination that an arrangement or course of conduct is indistinguishable in all material aspects from another arrangement or course of conduct that was the subject of a prior opinion, CMS issues an advisory opinion within 30 working days after the date on which it formally accepts the advisory opinion request.

(ii) In the case of a request that CMS determines, in its discretion, involves complex legal issues or highly complicated fact patterns, CMS issues an advisory opinion within a reasonable time period after the date on which it formally accepts the advisory opinion request.

(iii) If the last day of the 60-working day or 30-working day time period falls on a Saturday, Sunday, or Federal holiday, CMS may issue the advisory opinion at the close of business on the first business day following the weekend or holiday.

(2) The applicable time period for issuing an advisory opinion is suspended from the time CMS;

(i) Notifies the requestor that the costs have reached or are likely to exceed the triggering amount as described in §411.375(c)(2) until CMS receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until CMS receives the additional information;

(iii) Notifies the requestor of the full amount due until CMS receives payment of this amount; and

(iv) Notifies the requestor of the need for expert advice until CMS receives the expert advice.

(d) After CMS has notified the requestor of the full amount owed and has received full payment of that amount, CMS issues the advisory opinion and promptly mails it to the requestor by regular first class U.S. mail.

[69 FR 57229, Sept. 24, 2004, as amended at 84 FR 63192, Nov. 15, 2019]

§411.382 CMS' right to rescind advisory opinions.

(a)(1) Any advice CMS gives in an advisory opinion does not prejudice its right to reconsider the questions involved in the opinion, and CMS may rescind or revoke the opinion if it determines that there is good cause to rescind or revoke the opinion.

(2) Good cause shall exist where—

(i) There is a material change in the law that affects the conclusions reached in an opinion; or

(ii) A party that has received a negative advisory opinion seeks reconsideration based on new facts or law.

(b) CMS provides advance notice to the requestor and to the public of its decision to rescind or revoke the opinion so that the requestor and other parties may discontinue any course of action they have taken in accordance with, or in good faith reliance on, the advisory opinion.

(c) CMS does not proceed against the requestor with respect to any action the requestor and the involved parties have taken in good faith reliance upon CMS' advice under this part, provided—

(1) The requestor presented to CMS a full, complete and accurate description of all the relevant facts; and

(2) The parties promptly discontinue the action upon receiving notice that CMS had rescinded or revoked its approval, or discontinue the action within a reasonable ''wind down'' period, as determined by CMS.

[84 FR 63193, Nov. 15, 2019]

§411.384 Disclosing advisory opinions and supporting information.

(a) Advisory opinions that CMS issues and releases in accordance with the procedures set forth in this subpart are available to the public.

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion on the CMS Web site.

(c) Any predecisional document, or part of such predecisional document, that is prepared by CMS, the Department of Justice, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part is exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to CMS in connection with a request for an advisory opinion are available to the public to the extent they are required to be made available by 5 U.S.C. 552, through procedures set forth in 45 CFR part 5.

(e) Nothing in this section limits CMS's obligation, under applicable laws, to publicly disclose the identity of the requesting party or parties, and the nature of the action CMS has taken in response to the request.

[69 FR 57230, Sept. 24, 2004, as amended at 80 FR 71379, Nov. 16, 2015; 84 FR 63193, Nov. 15, 2019]

§411.386 CMS's advisory opinions as exclusive.

The procedures described in this subpart constitute the only method by which any individuals or entities can

obtain a binding advisory opinion on the subject of a physician's referrals, as described in § 411.370. CMS has not and does not issue a binding advisory opinion on the subject matter in § 411.370, in either oral or written form, except through written opinions it issues in accordance with this subpart.

[69 FR 57230, Sept. 24, 2004]

§ 411.387 Effect of an advisory opinion.

(a) An advisory opinion is binding on the Secretary, and a favorable advisory opinion shall preclude imposition of sanctions under section 1877(g) of the Act with respect to:

(1) The individuals or entities requesting the opinion; and

(2) Individuals or entities that are parties to the specific arrangement with respect to which such advisory opinion has been issued.

(b) The Secretary will not pursue sanctions under section 1877(g) of the Act against any party to an arrangement that CMS determines is indistinguishable in all its material aspects from an arrangement with respect to which CMS issued a favorable advisory opinion.

(c) Individuals and entities may rely on an advisory opinion as non-binding guidance that illustrates the application of the physician self-referral law and regulations to the specific facts and circumstances described in the advisory opinion.

[84 FR 63193, Nov. 15, 2019]

§ 411.388 When advisory opinions are not admissible evidence.

The failure of a party to seek or to receive an advisory opinion may not be introduced into evidence to prove that the party either intended or did not intend to violate the provisions of sections 1128, 1128A or 1128B of the Act.

[69 FR 57230, Sept. 24, 2004]

§ 411.389 Range of the advisory opinion.

(a) An advisory opinion states only CMS's opinion regarding the subject matter of the request. If the subject of an advisory opinion is an arrangement that must be approved by or is regulated by any other agency, CMS's advisory opinion cannot be read to indicate CMS's views on the legal or factual issues that may be raised before that agency.

(b) An advisory opinion that CMS issues under this part does not bind or obligate any agency other than the Department. It does not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[69 FR 57230, Sept. 24, 2004]

Subpart K—Payment for Certain Excluded Services

§ 411.400 Payment for custodial care and services not reasonable and necessary.

(a) *Conditions for payment.* Notwithstanding the exclusions set forth in § 411.15 (g) and (k). Medicare pays for ''custodial care'' and ''services not reasonable and necessary'' if the following conditions are met:

(1) The services were funished by a provider or by a practitioner or supplier that had accepted assignment of benefits for those services.

(2) Neither the beneficiary nor the provider, practitioner, or supplier knew, or could reasonably have been expected to know, that the services were excluded from coverage under § 411.15 (g) or (k).

(b) *Time limits on payment*—(1) *Basic rule.* Except as provided in paragraph (b)(2) of this section, payment may not be made for inpatient hospital care, posthospital SNF care, or home health services furnished after the earlier of the following:

(i) The day on which the beneficiary has been determined, under § 411.404, to have knowledge, actual or imputed, that the services were excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(ii) The day on which the provider has been determined, under § 411.406 to have knowledge, actual or imputed, that the services are excluded from coverage by reason of § 411.15(g) or § 411.15(k).

(2) *Exception.* Payment may be made for services furnished during the first day after the limit established in paragraph (b)(1) of this section, if the QIO

or the intermediary determines that the additional period of one day is necessary for planning post-discharge care. It the QIO or the intermediary determines that yet another day is necessary for planning post-discharge care, payment may be made for services furnished during the second day after the limit established in paragraph (b)(1) of this section.

§411.402 Indemnification of beneficiary.

(a) *Conditions for indemnification.* If Medicare payment is precluded because the conditions of §411.400(a)(2) are not met. Medicare indemnifies the beneficiary (and recovers from the provider, practitioner, or supplier), if the following conditions are met:

(1) The beneficiary paid the provider, practitioner, or supplier some or all of the charges for the excluded services.

(2) The beneficiary did not know and could not reasonably have been expected to know that the services were not covered.

(3) The provider, practitioner, or supplier knew, or could reasonably have been expected to know that the services were not covered.

(4) The beneficiary files a proper request for indemnification before the end of the sixth month after whichever of the following is later:

(i) The month is which the beneficiary paid the provider, practitioner, or supplier.

(ii) The month in which the intermediary or carrier notified the beneficiary (or someone on his or her behalf) that the beneficiary would not be liable for the services.

For good cause shown by the beneficiary, the 6-month period may be extended.

(b) *Amount of indemnification.*[1] The amount of indemnification is the total that the beneficiary paid the provider, practitioner, or supplier.

(c) *Effect of indemnification.* The amount of indemnification is considered an overpayment to the provider, practitioner, or supplier, and as such is recoverable under this part or in accordance with other applicable provisions of law.

§411.404 Criteria for determining that a beneficiary knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A beneficiary who receives services that constitute custodial care under §411.15(g) or that are not reasonable and necessary under §411.15(k), is considered to have known that the services were not covered if the criteria of paragraphs (b) and (c) of this section are met.

(b) *Written notice.* (1) Written notice is given to the beneficiary, or to someone acting on his or her behalf, that the services were not covered because they did not meet Medicare coverage guidelines.

(2) A notice concerning similar or reasonably comparable services furnished on a previous occasion also meets this criterion.

(3) After a beneficiary is notified that there is no Medicare payment for a service that is not covered by Medicare, he or she is presumed to know that there is no Medicare payment for any form of subsequent treatment for the non-covered condition.

(c) *Source of notice.* The notice was given by one of the following:

(1) The QIO, intermediary, or carrier.

(2) The group or committee responsible for utilization review for the provider that furnished the services.

(3) The provider, practitioner, or supplier that furnished the service.

[54 FR 41734, Oct. 11, 1989, as amended at 69 FR 66423, Nov. 15, 2004]

§411.406 Criteria for determining that a provider, practitioner, or supplier knew that services were excluded from coverage as custodial care or as not reasonable and necessary.

(a) *Basic rule.* A provider, practitioner, or supplier that furnished services which constitute custodial care under §411.15(g) or that are not reasonable and necessary under §411.15(k) is considered to have known that the services were not covered if any one of the conditions specified in paragraphs (b) through (e) of this section is met.

[1] For services furnished before 1988, the indemnification amount was reduced by any deductible or coinsurance amounts that would have been applied if the services had been covered.

(b) *Notice from the QIO, intermediary or carrier.* The QIO, intermediary, or carrier had informed the provider, practitioner, or supplier that the services furnished were not covered, or that similar or reasonably comparable services were not covered.

(c) *Notice from the utilization review committee or the beneficiary's attending phyician.* The utilization review group or committee for the provider or the beneficiary's attending physician had informed the provider that these services were not covered.

(d) *Notice from the provider, practitioner, or supplier to the beneficiary.* Before the services were furnished, the provider, practitioner or supplier informed the beneficiary that—

(1) The services were not covered; or

(2) The beneficiary no longer needed covered services.

(e) *Knowledge based on experience, actual notice, or constructive notice.* It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to preadmission review by a QIO.

(2) FEDERAL REGISTER publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

[54 FR 41734, Oct. 11, 1989, as amended at 60 FR 48425, Sept. 19, 1995]

§ 411.408 Refunds of amounts collected for physician services not reasonable and necessary, payment not accepted on an assignment-related basis.

(a) *Basic rule.* Except as provided in paragraph (d) of this section, a physician who furnishes a beneficiary services for which the physician does not undertake to claim payment on an assignment-related basis must refund any amounts collected from the beneficiary for services otherwise covered if Medicare payment is denied because the services are found to be not reasonable and necessary under § 411.15(k).

(b) *Time limits for making refunds.* A timely refund of any incorrectly collected amounts of money must be made to the beneficiary to whom the services were furnished. A refund is timely if—

(1) A physician who does not request a review within 30 days after receipt of the denial notice makes the refund within that time period; or

(2) A physician who files a request for review within 30 days after receipt of the denial notice makes the refund within 15 days after receiving notice of an initial adverse review determination, whether or not the physician further appeals the initial adverse review determination.

(c) *Notices and appeals.* If payment is denied for nonassignment-related claims because the services are found to be not reasonable and necessary, a notice of denial will be sent to both the physician and the beneficiary. The physician who does not accept assignment will have the same rights as a physician who submits claims on an assignment-related basis, as detailed in subpart H of part 405 and subpart B of part 473, to appeal the determination, and will be subject to the same time limitations.

(d) *When a refund is not required.* A refund of any amounts collected for services not reasonable and necessary is not required if—

(1) The physician did not know, and could not reasonably have been expected to know, that Medicare would not pay for the service; or

(2) Before the service was provided—

(i) The physician informed the beneficiary, or someone acting on the beneficiary's behalf, in writing that the physician believed Medicare was likely to deny payment for the specific service; and

(ii) The beneficiary (or someone eligible to sign for the beneficiary under § 424.36(b) of this chapter) signed a statement agreeing to pay for that service.

(e) *Criteria for determining that a physician knew that services were excluded as not reasonable and necessary.* A physician will be determined to have known that furnished services were excluded from coverage as not reasonable and necessary if one or more of the conditions in §411.406 of this subpart are met.

(f) *Acceptable evidence of prior notice to a beneficiary that Medicare was likely to deny payment for a particular service.* To qualify for waiver of the refund requirement under paragraph (d)(2) of this section, the physician must inform the beneficiary (or person acting on his or her behalf) that the physician believes Medicare is likely to deny payment.

(1) The notice must—

(i) Be in writing, using approved notice language;

(ii) Cite the particular service or services for which payment is likely to be denied; and

(iii) Cite the physician's reasons for believing Medicare payment will be denied.

(2) The notice is not acceptable evidence if—

(i) The physician routinely gives this notice to all beneficiaries for whom he or she furnishes services; or

(ii) The notice is no more than a statement to the effect that there is a possibility that Medicare may not pay for the service.

(g) *Applicability of sanctions to physicians who fail to make refunds under this section.* A physician who knowingly and willfully fails to make refunds as required by this section may be subject to sanctions as provided for in chapter V, parts 1001, 1002, and 1003 of this title.

[55 FR 24568, June 18, 1990; 55 FR 35142, 35143, Aug. 28, 1990]

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

Subpart A—General Provisions

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

AUTHORITY: 42 U.S.C. 1302 and 1395hh.

SOURCE: 50 FR 12741, Mar. 29, 1985, unless otherwise noted.

Subpart A—General Provisions

§412.1 Scope of part.

(a) *Purpose.* (1) This part implements sections 1886(d) and (g) of the Act by establishing a 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, and a prospective payment system for the capital-related costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1991.

(i) Under these prospective payment systems, payment for the operating and capital-related costs of inpatient hospital services furnished by hospitals subject to the systems (generally, short-term, acute-care hospitals) is made on the basis of prospectively determined rates and applied on a per discharge basis.

(ii) Payment for other costs related to inpatient hospital services is made on a reasonable cost basis as follows:

(A) Organ acquisition costs incurred by hospitals with approved organ transplant programs.

(B) The costs of qualified nonphysician anesthetist's services, as described in §412.113(c).

(C) Direct costs of approved nursing and allied health educational programs.

(D) Costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in §412.113(e).

(iii) Payment for the direct costs of graduate medical education is made on a per resident amount basis in accordance with §§413.75 through 413.83 of this chapter.

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators, and for the additional resource costs for small, independent hospitals to establish and maintain access to buffer stocks of essential medicines.

(v) Under either prospective payment system, a hospital may keep the difference between its prospective payment rate and its operating or capital-related costs incurred in furnishing inpatient services, and the hospital is at risk for inpatient operating or inpatient capital-related costs that exceed its payment rate.

(2) This part implements section 124 of Public Law 106–113 by establishing a per diem prospective payment system for the inpatient operating and capital costs of hospital inpatient services furnished to Medicare beneficiaries by a psychiatric facility that meets the conditions of subpart N of this part.

(3) This part implements section 1886(j) of the Act by establishing a prospective payment system for the inpatient operating and capital costs of inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meets the conditions of § 412.604.

(4) This part implements the following regarding long-term care hospitals—

(i) Section 123 of Public Law 106–113, which provides for the establishment of a prospective payment system for the costs of inpatient hospital services furnished to Medicare beneficiaries by long-term care hospitals described in section 1886(d)(1)(B)(iv) of the Act, for cost reporting periods beginning on or after October 1, 2002.

(ii) The provisions of section 307(b) of Public Law 106–554, which state that the Secretary shall examine and may provide for appropriate adjustments to the long-term care hospital prospective payment system, including adjustments to diagnosis-related group (DRG) weights, area wage adjustments, geographic reclassification, outlier adjustments, updates, and disproportionate share adjustments consistent with section 1886(d)(5)(F) of the Act.

(iii) Section 114 of Public Law 110–173, which contains several provisions regarding long-term care hospitals, including the—

(A) Amendment of section 1886 of the Act to add a new subsection (m) that references section 123 of Public Law 106–113 and section 307(b) of Public Law 106–554 for the establishment and implementation of a prospective payment system for payments under title XVIII for inpatient hospital services furnished by a long-term care hospital described in section 1886(d)(1)(B)(iv) of the Act.

(B) Revision of the standard Federal rate for RY 2008.

(5) This part implements section 1886(q) of the Act, which provides that, effective for discharges from an ''applicable hospital'' beginning on or after October 1, 2012, payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions, under the Hospital Readmissions Reduction Program. This reduction will be made through an adjustment to the hospital's base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

(6) This part implements section 1886(o)(1)(B) of the Act, which directs the Secretary to begin to make value-based incentive payments under the Hospital Value-Based Purchasing Program to hospitals for discharges occurring on or after October 1, 2012, through an adjustment to the base operating DRG payment amounts under the prospective payment system for inpatient operating costs.

(7) This part implements section 1866(k) of the Act, which directs hospitals described in section 1886(d)(1)(B)(v) of the Act to submit data on quality measures to the Secretary.

(b) *Summary of content.* (1) This subpart describes the basis of payment for inpatient hospital services under the prospective payment systems specified in paragraph (a)(1) of this section and sets forth the general basis of these systems.

(2) Subpart B of this part sets forth all of the following:

(i)(A) The classifications of hospitals that are included in and excluded from the prospective payment systems specified in paragraph (a)(1) of this section.

(B) Requirements governing the inclusion or exclusion of hospitals in the systems as a result of changes in their classification.

(ii) Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

(3) Subpart C sets forth certain conditions that must be met for a hospital to receive payment under the prospective payment systems specified in paragraph (a)(1) of this section.

(4) Subpart D sets forth the basic methodology by which prospective payment rates for inpatient operating costs are determined under the prospective payment system specified in paragraph (a)(1) of this section.

(5) Subpart E describes the transition ratesetting methods that are used to determine transition payment rates for inpatient operating costs during the

first 4 years of the prospective payment system specified in paragraph (a)(1) of this section.

(6) Subpart F sets forth the methodology for determining payments for outlier cases under the prospective payment system specified in paragraph (a)(1) of this section.

(7) Subpart G sets forth rules for special treatment of certain facilities under the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs.

(8) Subpart H describes the types, amounts, and methods of payment to hospitals under the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs.

(9) Subpart K describes how the prospective payment system specified in paragraph (a)(1) of this section for inpatient operating costs is implemented for hospitals located in Puerto Rico.

(10) Subpart L sets forth the procedures and criteria concerning applications from hospitals to the Medicare Geographic Classification Review Board for geographic redesignation under the prospective payment systems specified in paragraph (a)(1) of this section.

(11) Subpart M describes how the prospective payment system specified in paragraph (a)(1) of this section for inpatient capital-related costs is implemented effective with reporting periods beginning on or after October 1, 1991.

(12) Subpart N describes the prospective payment system specified in paragraph (a)(2) of this section for inpatient psychiatric facilities and sets forth the general methodology for paying the operating and capital-related costs of inpatient hospital services furnished by inpatient psychiatric facilities effective with cost reporting periods beginning on or after January 1, 2005.

(13) Subpart O of this part describes the prospective payment system specified in paragraph (a)(4) of this section for long-term care hospitals and sets forth the general methodology for paying for the operating and capital-related costs of inpatient hospital services furnished by long-term care hospitals, effective with cost reporting periods beginning on or after October 1, 2002.

(14) Subpart P describes the prospective payment system specified in paragraph (a)(3) of this section for rehabilitation hospitals and rehabilitation units and sets forth the general methodology for paying for the operating and capital-related costs of inpatient hospital services furnished by rehabilitation hospitals and rehabilitation units effective with cost reporting periods beginning on or after January 1, 2002.

[66 FR 41385, Aug. 7, 2001, as amended at 67 FR 56048, Aug. 30, 2002; 69 FR 66976, Nov. 15, 2004; 70 FR 47484, Aug. 12, 2005; 73 FR 24879, May 6, 2008; 77 FR 53673, Aug. 31, 2012; 85 FR 59020, Sept. 18, 2020; 86 FR 45518, Aug. 13, 2021; 86 FR 73510, Dec. 27, 2021; 87 FR 72286, Nov. 23, 2022; 89 FR 69909, Aug. 28, 2024]

§412.2 Basis of payment.

(a) *Payment on a per discharge basis.* Under both the inpatient operating and inpatient capital-related prospective payment systems, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to Medicare beneficiaries. The prospective payment rate for each discharge (as defined in §412.4) is determined according to the methodology described in subpart D, E, or G of this part, as appropriate, for operating costs, and according to the methodology described in subpart M of this part for capital-related costs. An additional payment is made for both inpatient operating and inpatient capital-related costs, in accordance with subpart F of this part, for cases that are extraordinarily costly to treat.

(b) *Payment in full.* (1) The prospective payment amount paid for inpatient hospital services is the total Medicare payment for the inpatient operating costs (as described in paragraph (c) of this section) and the inpatient capital-related costs (as described in paragraph (d) of this section) incurred in furnishing services covered by the Medicare program.

(2) The full prospective payment amount, as determined under subpart D, E, or G and under subpart M of this part, is made for each stay during which there is at least one Medicare payable day of care. Payable days of care, for purposes of this paragraph include the following:

(i) Limitation of liability days payable under the payment procedures for custodial care and services that are not reasonable and necessary as specified in § 411.400 of this chapter.

(ii) Guarantee of payment days, as authorized under § 409.68 of this chapter, for inpatient hospital services furnished to an individual whom the hospital has reason to believe is entitled to Medicare benefits at the time of admission.

(3) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at § 412.23(e) to be paid as a LTCH, during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Medicare will not make payment under subpart H for any part of the hospitalization. Payment for the entire patient stay (days prior to and after the designation of LTCH status) will be made in accordance with the requirements specified in § 412.521. The requirements of this paragraph (b)(3) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004.

(c) *Inpatient operating costs.* The prospective payment system provides a payment amount for inpatient operating costs, including—

(1) Operating costs for routine services (as described in § 413.53(b) of this chapter), such as the costs of room, board, and routine nursing services;

(2) Operating costs for ancillary services, such as radiology and laboratory services furnished to hospital inpatients;

(3) Special care unit operating costs (intensive care type unit services, as described in § 413.53(b) of this chapter);

(4) Malpractice insurance costs related to services furnished to inpatients; and

(5) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the 3 calendar days immediately preceding the date of the beneficiary's admission to the hospital that meet the condition specified in paragraph (c)(5)(i) of this section and at least one of the conditions specified in paragraphs (c)(5)(ii) through (c)(5)(iv).

(i) The services are furnished by the hospital or by an entity wholly owned or operated by the hospital. An entity is wholly owned by the hospital if the hospital is the sole owner of the entity. An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the hospital also has policymaking authority over the entity.

(ii) For services furnished after January 1, 1991, the services are diagnostic (including clinical diagnostic laboratory tests).

(iii) For services furnished on or after October 1, 1991, through June 24, 2010, the services are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient and are not the following:

(A) Ambulance services.

(B) Maintenance renal dialysis.

(iv) Nondiagnostic services furnished on or after June 25, 2010, other than ambulance services and maintenance renal dialysis services, that are furnished on the date of the beneficiary's inpatient admission or on the first, second, or third calendar day immediately preceding the date of the beneficiary's inpatient admission and the hospital does not attest that such services are unrelated to the beneficiary's inpatient admission.

(d) *Inpatient capital-related costs.* For cost reporting periods beginning on or after October 1, 1991, the capital prospective payment system provides a payment amount for inpatient hospital capital-related costs as described in part 413, subpart G of this chapter.

(e) *Excluded costs.* The following inpatient hospital costs are excluded from the prospective payment amounts and are paid for on a reasonable cost basis:

(1) Capital-related costs for cost reporting periods beginning before October 1, 1991, and an allowance for return on equity, as described in §§ 413.130 and 413.157, respectively, of this chapter.

(2) Direct medical education costs for approved nursing and allied health education programs as described in § 413.85 of this chapter.

(3) Costs for direct medical and surgical services of physicians in teaching hospitals exercising the election in § 405.521 of this chapter.

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplant programs.

(5) The costs of qualified nonphysician anesthetists' services, as described in § 412.113(c).

(6) For cost reporting periods beginning on or after October 1, 2020, the costs of allogenic hematopoietic stem cell acquisition, as described in § 412.113(e), for the purpose of an allogeneic hematopoietic stem cell transplant.

(f) *Additional payments to hospitals.* In addition to payments based on the prospective payment system rates for inpatient operating and inpatient capital-related costs, hospitals receive payments for the following:

(1) Outlier cases, as described in subpart F of this part.

(2) The indirect costs of graduate medical education, as specified in subparts F and G of this part and in § 412.105 for inpatient operating costs and in § 412.322 for inpatient capital-related costs.

(3) Costs excluded from the prospective payment rates under paragraph (e) of this section, as provided in § 412.115.

(4) Bad debts of Medicare beneficiaries, as provided in § 412.115(a).

(5) ESRD beneficiary discharges if such discharges are ten percent or more of the hospital's total Medicare discharges, as provided in § 412.104.

(6) Serving a disproportionate share of low-income patients, as provided in § 412.106 for inpatient operating costs and § 412.320 for inpatient capital-related costs.

(7) The direct graduate medical education costs for approved residency programs in medicine, osteopathy, dentistry, and podiatry as described in §§ 413.75–413.83 of this chapter.

(8) For discharges on or after June 19, 1990, and before October 1, 1994, and for discharges on or after October 1, 1997, a payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia. For discharges occurring on or after October 1, 2005, the additional payment is made based on the average sales price methodology specified in subpart K, part 414 of this subchapter and the furnishing fee specified in § 410.63 of this subchapter.

(9) Special additional payment for certain new technology as specified in §§ 412.87 and 412.88 of subpart F.

(10) A payment adjustment for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators as specified in § 412.113.

(11) A payment adjustment for small, independent hospitals for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines as specified in § 412.113.

(g) *Payment adjustment for certain replaced devices.* CMS makes a payment adjustment for certain replaced devices, as provided under § 412.89.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.3 Admissions.

(a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and §§ 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. In addition, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622.

(b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition. The practitioner may not delegate the decision (order) to another individual who is not

authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

(c) The physician order must be furnished at or before the time of the inpatient admission.

(d)(1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

(ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2020 are exempt from certain medical review activities.

(i) For those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

(ii) For those services and procedures removed on or after January 1, 2021, the exemption in this paragraph (d)(2) will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

(3) Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

[78 FR 50965, Aug. 19, 2013, as amended at 79 FR 67030, Nov. 10, 2014; 80 FR 70602, Nov. 13, 2015; 83 FR 41700, Aug. 17, 2018; 85 FR 86300, Dec. 29, 2020; 86 FR 63992, Nov. 16, 2021]

§ 412.4 Discharges and transfers.

(a) *Discharges.* Subject to the provisions of paragraphs (b) and (c) of this section, a hospital inpatient is considered discharged from a hospital paid under the prospective payment system when—

(1) The patient is formally released from the hospital; or

(2) The patient dies in the hospital.

(b) *Acute care transfers.* A discharge of a hospital inpatient is considered to be a transfer for purposes of payment under this part if the patient is readmitted the same day (unless the readmission is unrelated to the initial discharge) to another hospital that is—

(1) Paid under the prospective payment system described in subparts A through M of this part;

(2) Excluded from being paid under the prospective payment system described in subparts A through M of this part because of participation in an approved statewide cost control program as described in subpart C of part 403 of this chapter;

(3) An acute care hospital that would otherwise be eligible to be paid under the IPPS, but does not have an agreement to participate in the Medicare program; or

(4) A critical access hospital.

(c) *Postacute care transfers.* A discharge of a hospital inpatient is considered to be a transfer for purposes of this part when the patient's discharge is assigned, as described in §412.60(c), to one of the qualifying diagnosis-related groups (DRGs) listed in paragraph (d) of this section and the discharge is made under any of the following circumstances:

(1) To a hospital or distinct part hospital unit excluded from the prospective payment system described in subparts A through M of this part under subpart B of this part.

(2) To a skilled nursing facility.

(3) To home under a written plan of care for the provision of home health services from a home health agency and those services begin within 3 days after the date of discharge.

(4) For discharges occurring on or after October 1, 2018, to hospice care provided by a hospice program.

(d) *Qualifying DRGs.* (1) For a fiscal year prior to FY 2006, for purposes of paragraph (c) of this section, and subject to the provisions of paragraph (d)(2) of this section, the qualifying DRGs must meet the following criteria for both of the 2 most recent years for which data are available:

(i) The DRG must have a geometric mean length of stay of at least 3 days.

(ii) The DRG must have at least 14,000 cases identified as postacute care transfer cases.

(iii) The DRG must have at least 10 percent of the postacute care transfers occurring before the geometric mean length of stay for the DRG.

(iv) If the DRG is one of a paired DRG based on the presence or absence of a comorbidity or complication, one of the DRGs meets the criteria specified under paragraphs (d)(1)(i) through (d)(1)(iii) of this section.

(v) To initially qualify, the DRG must meet the criteria specified in paragraphs (d)(1)(i) through (d)(1)(iv) of this section and must have a decline in the geometric mean length of stay for the DRG during the most recent 5 years of at least 7 percent. Once a DRG initially qualifies, the DRG is subject to the criteria specified in paragraphs (d)(1)(i) through (d)(1)(iv) of this section for each subsequent fiscal year.

(2) For purposes of paragraph (c), a discharge is also considered to be a transfer if it meets the following conditions:

(i) The discharge is assigned to a DRG that contains only cases that were assigned to a DRG that qualified under this paragraph within the previous 2 years; and

(ii) The latter DRG was split or otherwise modified within the previous 2 fiscal years.

(3) For fiscal years beginning with FY 2006, for purposes of paragraph (c) of this section—

(i) The qualifying DRGs must meet the following criteria using data from the March 2005 update of the FY 2004 MedPAR file and Version 23.0 of the DRG Definitions Manual (FY 2006):

(A) The DRG has at least 2,050 total postacute care transfer cases;

(B) At least 5.5 percent of the cases in the DRG are discharged to postacute care prior to the geometric mean length of stay for the DRG;

(C) The DRG must have a geometric mean length of stay greater than 3 days;

(D) The DRG is paired with a DRG based on the presence or absence of a comorbidity or complication or major cardiovascular condition that, it meets the criteria specified in paragraphs (d)(3)(i)(A) and (d)(3)(ii)(B) of this section.

(ii) If a DRG did not exist in Version 23.0 of the DRG Definitions Manual or a DRG included in Version 23.0 of the DRG Definitions Manual is revised, the DRG will be a qualifying DRG if it meets the following criteria based on the version of the DRG Definitions Manual in use when the new or revised DRG first becomes effective, using the most recent complete year of MedPAR data:

(A) The total number of discharges to postacute care in the DRG must equal or exceed the 55th percentile for all DRGs;

(B) The proportion of short-stay discharges to postacute care to total discharges in the DRG exceeds the 55th percentile for all DRGs;

(C) The DRG is paired with a DRG based on the presence or absence of a comorbidity or a complication or major cardiovascular condition that

meets the criteria specified under paragraphs (d)(3)(ii)(A) and (d)(3)(ii)(B) of this section; and

(D) In the case of MS-DRGs that share the same base MS-DRG, if one MS-DRG meets the criteria specified under paragraph (d)(3)(ii)(B) of this section, every MS-DRG that shares the same base MS-DRG is a qualifying DRG.

(e) *Payment for discharges.* The hospital discharging an inpatient (under paragraph (a) of this section) is paid in full, in accordance with § 412.2(b).

(f) *Payment for transfers*—(1) *General rule.* Except as provided in paragraph (f)(2) or (f)(3) of this section, a hospital that transfers an inpatient under the circumstances described in paragraph (b) or (c) of this section, is paid a graduated per diem rate for each day of the patient's stay in that hospital, not to exceed the amount that would have been paid under subparts D and M of this part if the patient had been discharged to another setting. The per diem rate is determined by dividing the appropriate prospective payment rate (as determined under subparts D and M of this part) by the geometric mean length of stay for the specific DRG to which the case is assigned. Payment is graduated by paying twice the per diem amount for the first day of the stay, and the per diem amount for each subsequent day, up to the full DRG payment.

(2) *Special rule for DRGs 209, 210, and 211 for fiscal years prior to FY 2006.* For fiscal years prior to FY 2006, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section and the transfer is assigned to DRGs 209, 210, or 211 is paid as follows:

(i) 50 percent of the appropriate prospective payment rate (as determined under subparts D and M of this part) for the first day of the stay; and

(ii) 50 percent of the amount calculated under paragraph (f)(1) of this section for each day of the stay, up to the full DRG payment.

(3) *Transfer assigned to DRG for newborns that die or are transferred to another hospital.* If a transfer is classified into CMS DRG 385 (Neonates, Died or Transferred) prior to October 1, 2007, or into MS-DRG 789 (Neonates, Died or Transferred to Another Acute Care Facility) on or after October 1, 2007, the transferring hospital is paid in accordance with § 412.2(b).

(4) *Outliers.* Effective with discharges occurring on or after October 1, 1984, a transferring hospital may qualify for an additional payment for extraordinarily high-cost cases that meet the criteria for cost outliers as described in subpart F of this part.

(5) *Special rule for DRGs meeting specific criteria.* For discharges occurring on or after October 1, 2005, and prior to October 1, 2007, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section is paid using the provisions of paragraphs (f)(2)(i) and (f)(2)(ii) of this section if the transfer case is assigned to one of the DRGs meeting the following criteria:

(i) The DRG meets the criteria specified in paragraph (d)(3)(i) or (d)(3)(ii) of this section.

(ii) The average charges of the 1-day discharge cases in the DRG must be at least 50 percent of the average charges for all cases in the DRG; and

(iii) The geometric mean length of stay for the DRG is greater than 4 days; and

(iv) If a DRG is paired with a DRG based on the presence or absence of a comorbidity or complication or a major cardiovascular complication that meets the criteria specified in paragraphs (f)(5)(i) through (f)(5)(iii) of this section, that DRG will also be paid under the provisions of paragraphs (f)(2)(i) and (f)(2)(ii) of this section.

(6) *Special rule for DRGs meeting specific criteria.* For discharges occurring on or after October 1, 2007, a hospital that transfers an inpatient under the circumstances described in paragraph (c) of this section is paid using the provisions of paragraphs (f)(2)(i) and (f)(2)(ii) of this section if the transfer case is assigned to one of the DRGs meeting the following criteria:

(i) The DRG meets the criteria specified in paragraph (d)(3)(i) or (d)(3)(ii) of this section;

(ii) The average charges of the 1-day discharge cases in the DRG must be at least 50 percent of the average charges for all cases in the DRG; and

(iii) The geometric mean length of stay for the DRG is greater than 4 days.

(iv) If a DRG is part of an MS-DRG group that meets the criteria specified in paragraphs (f)(6)(i) through (f)(6)(iii) of this section, that DRG will also be paid under the provisions of paragraphs (f)(2)(i) and (f)(2)(ii) of this section.

[63 FR 41003, July 31, 1998, as amended at 65 FR 47106, Aug. 1, 2000; 67 FR 50111, Aug. 1, 2002; 68 FR 45469, Aug. 1, 2003; 69 FR 49240, Aug. 11, 2004; 70 FR 47484, Aug. 12, 2005; 72 FR 47410, Aug. 22, 2007; 75 FR 50413, Aug. 16, 2010; 83 FR 41700, Aug. 17, 2018]

§ 412.6 Cost reporting periods subject to the prospective payment systems.

(a) *Initial cost reporting period for each prospective payment system.* (1) Each subject hospital is paid under the prospective payment system for operating costs for inpatient hospital services effective with the hospital's first cost reporting period beginning on or after October 1, 1983 and for inpatient capital-related costs effective with the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) The hospital is paid the applicable prospective payment rate for inpatient operating costs and capital-related costs for each discharge occurring on or after the first day of its first cost reporting period subject to the applicable prospective payment system.

(3) If a discharged beneficiary was admitted to the hospital before the first day of the hospital's first cost reporting period subject to the prospective payment system for inpatient operating costs, the reasonable costs of services furnished before that day are paid under the cost reimbursement provisions of part 413 of this chapter. For such discharges, the amount otherwise payable under the applicable prospective payment rate is reduced by the amount paid on a reasonable cost basis for inpatient hospital services furnished to that beneficiary during the hospital stay. If the amount paid under reasonable cost exceeds the inpatient operating prospective payment amount, the reduction is limited to the inpatient operating prospective payment amount.

(b) *Changes in cost reporting periods.* CMS recognizes a change in a hospital's cost reporting period made after November 30, 1982 only if the change has been requested in writing by the hospital and approved by the intermediary in accordance with § 413.24(f)(3) of this chapter.

[57 FR 39819, Sept. 1, 1992]

§ 412.8 Publication of schedules for determining prospective payment rates.

(a) *Initial prospective payment rates—*(1) *For inpatient operating costs.* Initial prospective payment rates for inpatient operating costs (for the period October 1, 1983 through September 30, 1984) were determined in accordance with documents published in the FEDERAL REGISTER on September 1, 1983 (48 FR 39838), and January 3, 1984 (49 FR 324).

(2) *For inpatient capital-related costs.* Initial prospective payment rates for inpatient capital-related costs (for the period October 1, 1991 through September 30, 1992) were determined in accordance with the final rule published in the FEDERAL REGISTER on August 30, 1991 (56 FR 43196).

(b) *Annual publication of schedule for determining prospective payment rates.* (1) CMS proposes changes in the methods, amounts, and factors used to determine inpatient prospective payment rates in a FEDERAL REGISTER document published for public comment not later than the April 1 before the beginning of the Federal fiscal year in which the proposed changes would apply.

(2) Except as provided in paragraph (c) of this section, CMS publishes a FEDERAL REGISTER document setting forth final methods, amounts, and factors for determining inpatient prospective payment rates not later than the August 1 before the Federal fiscal year in which the rates would apply.

(c) *Publication schedule for FY 2007.* For FY 2007, not later than August 1, 2006, CMS publishes a FEDERAL REGISTER document setting forth a description of the methodology and data used in computing the inpatient prospective payment rates for that year.

[57 FR 39820, Sept. 1, 1992, as amended at 62 FR 46025, Aug. 29, 1997; 71 FR 48136, Aug. 18, 2006]

§ 412.10 Changes in the DRG classification system.

(a) *General rule.* CMS issues changes in the DRG classification system in a FEDERAL REGISTER notice at least annually. Except as specified in paragraphs (c) and (d) of this section, the DRG changes are effective prospectively with discharges occurring on or after the same date the payment rates are effective.

(b) *Basis for changes in the DRG classification system.* All changes in the DRG classification system are made using the principles established for the DRG system. This means that cases are classified so each DRG is—

(1) Clinically coherent; and

(2) Embraces an acceptable range of resource consumption.

(c) *Interim coverage changes*—(1) *Criteria.* CMS makes interim changes to the DRG classification system during the Federal fiscal year to incorporate items and services newly covered under Medicare.

(2) *Implementation and effective date.* CMS issues interim coverage changes through its administrative issuance system and makes the change effective as soon as is administratively feasible.

(3) *Publication for comment.* CMS publishes any change made under paragraph (c)(1) of this section in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(d) *Interim changes to correct omissions and inequities*—(1) *Criteria.* CMS makes interim changes to the DRG classification system to correct a serious omission or inequity in the system only if failure to make the changes would have—

(i) A potentially substantial adverse impact on the health and safety of beneficiaries; or

(ii) A significant and unwarranted fiscal impact on hospitals or the Medicare program.

(2) *Publication and effective date.* CMS publishes these changes in the FEDERAL REGISTER in a final notice with comment period with a prospective effective date. The change is also published for public information in the next annual notice of changes to the DRG classification system published in accordance with paragraph (a) of this section.

(e) *Review by ProPAC.* Changes published annually in accordance with paragraph (a) of this section are subject to review and comment by ProPAC upon publication. Interim changes to the DRG classification system that are made in accordance with paragraphs (c) and (d) of this section are subject to review by ProPAC before implementation.

[50 FR 35688, Sept. 3, 1985, as amended at 51 FR 31496, Sept. 3, 1986; 57 FR 39820, Sept. 1, 1992]

Subpart B—Hospital Services Subject to and Excluded From the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.20 Hospital services subject to the prospective payment systems.

(a) Except for services described in paragraphs (b), (c), (d), and (e) of this section, all covered hospital inpatient services furnished to beneficiaries during the subject cost reporting periods are paid under the prospective payment system as specified in § 412.1(a)(1).

(b) Effective for cost reporting periods beginning on or after January 1, 2005, covered inpatient hospital services furnished to Medicare beneficiaries by an inpatient psychiatric facility that meets the conditions of § 412.404 are paid under the prospective payment system described in subpart N of this part.

(c)(1) Effective for cost reporting periods beginning on or after January 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a rehabilitation hospital or rehabilitation unit that meet the conditions of § 412.604 are paid under the prospective payment system described in subpart P of this part.

(2) CMS will not pay for services under subpart P of this part if the services are paid for by a health maintenance organization (HMO) or competitive medical plan (CMP) that elects not

to have CMS make payments to an inpatient rehabilitation facility for services, which are inpatient hospital services, furnished to the HMO's or CMP's Medicare enrollees, as provided under part 417 of this chapter.

(d) Effective for cost reporting periods beginning on or after October 1, 2002, covered inpatient hospital services furnished to Medicare beneficiaries by a long-term care hospital that meets the conditions for payment of §§ 412.505 through 412.511 are paid under the prospective payment system described in subpart O of this part.

(e) Inpatient hospital services will not be paid under the prospective payment systems specified in § 412.1(a)(1) under any of the following circumstances:

(1) The services are furnished by a hospital (or hospital unit) explicitly excluded from the prospective payment systems under §§ 412.23, 412.25, 412.27, and 412.29.

(2) The services are emergency services furnished by a nonparticipating hospital in accordance with § 424.103 of this chapter.

(3) The services are paid for by an HMO or competitive medical plan (CMP) that elects not to have CMS make payments directly to a hospital for inpatient hospital services furnished to the HMO's or CMP's Medicare enrollees, as provided in §§ 417.240(d) and 417.586 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 6648, Mar. 2, 1988; 57 FR 39820, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 66 FR 41386, Aug. 7, 2001; 67 FR 56048, Aug. 30, 2002; 68 FR 45698, Aug. 1, 2003; 69 FR 66976, Nov. 15, 2004]

§ 412.22 Excluded hospitals and hospital units: General rules.

(a) *Criteria.* Subject to the criteria set forth in paragraph (e) of this section, a hospital is excluded from the prospective payment systems specified in § 412.1(a)(1) of this part if it meets the criteria for one or more of the excluded classifications described in § 412.23. For purposes of this subpart, the term ''hospital'' includes a critical access hospital (CAH).

(b) *Cost reimbursement.* Except for those hospitals specified in paragraph (c) of this section, and § 412.20(b), (c), and (d), all excluded hospitals (and excluded hospital units, as described in § 412.23 through § 412.29) are reimbursed under the cost reimbursement rules set forth in part 413 of this chapter, and are subject to the ceiling on the rate of hospital cost increases as specified in § 413.40 of this chapter.

(c) *Special payment provisions.* The following classifications of hospitals are paid under special provisions and therefore are not generally subject to the cost reimbursement or prospective payment rules of this chapter.

(1) Veterans Administration hospitals.

(2) Hospitals reimbursed under State cost control systems approved under part 403 of this chapter.

(3) Hospitals reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)).

(4) Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

(d) *Changes in hospitals' status.* For purposes of exclusion from the prospective payment systems under this subpart, the status of each currently participating hospital (excluded or not excluded) is determined at the beginning of each cost reporting period and is effective for the entire cost reporting period. Any changes in the status of the hospital are made only at the start of a cost reporting period.

(e) *Hospitals-within-hospitals.* A hospital-within-a-hospital is a hospital that occupies space in a building also used by another hospital, or in one or more separate buildings located on the same campus as buildings used by another hospital. Prior to October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-a-hospital must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1). On or after October 1, 2017, except as provided in paragraphs (e)(1)(vi) and (f) of this section, a hospital-within-hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1) that occupies space in a building also used by a hospital which is not excluded from the prospective payment

systems specified in § 412.1(a)(1), or in one or more separate buildings located on the same campus as buildings used by a hospital not excluded from the prospective payment systems specified in § 412.1(a)(1) must meet the following criteria in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

(1) Except as specified in paragraph (f) of this section, for cost reporting periods beginning on or after October 1, 1997—

(i) *Separate governing body.* The hospital has a governing body that is separate from the governing body of the hospital occupying space in the same building or on the same campus. The hospital's governing body is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals.

(ii) *Separate chief medical officer.* The hospital has a single chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of the hospital. The chief medical officer of the hospital is not employed by or under contract with either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(iii) *Separate medical staff.* The hospital has a medical staff that is separate from the medical staff of the hospital occupying space in the same building or on the same campus. The hospital's medical staff is directly accountable to the governing body for the quality of medical care provided in the hospital, and adopts and enforces by-laws governing medical staff activities, including criteria and procedures for recommending to the governing body the privileges to be granted to individual practitioners.

(iv) *Chief executive officer.* The hospital has a single chief executive officer through whom all administration authority flows, and who exercises control and surveillance over all administrative activities of the hospital. The chief executive officer is not employed by, or under contract with, either the hospital occupying space in the same building or on the same campus or any third entity that controls both hospitals.

(v) *Performance of basic hospital functions.* Prior to October 1, 2017, the hospital meets one of the following criteria:

(A) The hospital performs the basic functions specified in §§ 482.21 through 482.27, 482.30, 482.42, 482.43, and 482.45 of this chapter through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals. Food and dietetic services and housekeeping, maintenance, and other services necessary to maintain a clean and safe physical environment could be obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals.

(B) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of patients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for a period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtains under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c). For purposes of this paragraph (e)(1)(v)(B), however, the costs of preadmission services are those specified under § 413.40(c)(2) rather than those specified under § 412.2(c)(5).

(C) For the same period of at least 6 months used to determine compliance with the criterion regarding the age of inpatients in § 412.23(d)(2) or the length-of-stay criterion in § 412.23(e)(2), or for hospitals other than children's or long-term care hospitals, for the period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital has an inpatient population of whom at least 75 percent were referred to the

hospital from a source other than another hospital occupying space in the same building or on the same campus.

(vi) Effective October 1, 2008, if a State hospital that is occupying space in the same building or on the same campus as another State hospital cannot meet the criterion under paragraph (e)(1)(i) of this section solely because its governing body is under the control of the State hospital with which it shares a building or a campus, or is under the control of a third entity that also controls the State hospital with which it shares a building or a campus, the State hospital can nevertheless qualify for an exclusion if it meets the other applicable criteria in this section and—

(A) Both State hospitals occupy space in the same building or on the same campus and have been continuously owned and operated by the State since October 1, 1995;

(B) Is required by State law to be subject to the governing authority of the State hospital with which it shares space or the governing authority of a third entity that controls both hospitals; and

(C) Was excluded from the inpatient prospective payment system before October 1, 1995, and continues to be excluded from the inpatient prospective payment system through September 30, 2008.

(2) Effective for long-term care hospitals-within-hospitals for cost reporting periods beginning on or after October 1, 2004, the hospital must meet the governance and control requirements at paragraphs (e)(1)(i) through (e)(1)(iv) of this section.

(3) *Notification of co-located status.* A long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (e)(1) or (e)(2) of this section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number those hospital(s) with which it is co-located.

(f) *Application for certain hospitals.* Except as provided in paragraph (f)(3) of this section, if a hospital was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital, the criteria in paragraph (e) of this section do not apply to the hospital as long as the hospital—

(1) Continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 1995; or

(2) In the case of a hospital that changes the terms and conditions under which it operates after September 30, 1995, but before October 1, 2003, continues to operate under the same terms and conditions, including the number of beds, unless the hospital is a children's hospital as defined at § 412.23(d), and square footage considered to be part of the hospital for purposes of Medicare participation and payment in effect on September 30, 2003.

(3) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (f)(1) or (f)(2) of this section, any hospital that was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital may increase or decrease the square footage or decrease the number of beds considered to be part of the hospital at any time without affecting the provisions of paragraph (f)(1) or (f)(2) of this section.

(i) If a hospital to which the provisions of paragraph (f)(1) of this section applies decreases its number of beds below the number of beds considered to be part of the hospital on September 30, 1995, it may subsequently increase the number of beds at any time as long as the resulting total number of beds considered to be part of the hospital

does not exceed the number of beds at the hospital on September 30, 1995.

(ii) If a hospital to which the provisions of paragraph (f)(2) of this section applies decreases its number of beds below the number of beds considered to be part of the hospital on September 30, 2003, it may subsequently increase the number of beds at any time as long as the resulting total number of beds considered to be part of the hospital does not exceed the number of beds at the hospital on September 30, 2003.

(g) *Definition of control.* For purposes of this section, control exists if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(h) *Satellite facilities.* (1) For purposes of paragraphs (h)(2) through (h)(5) of this section, a satellite facility is a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (h)(3), (h)(4), (h)(5), (h)(7) and (h)(8) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a hospital (other than a children's hospital) that was excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the hospital's number of State-licensed and Medicare-certified beds, including those at the satellite facilities, does not exceed the hospital's number of State-licensed and Medicare-certified beds on the last day of the hospital's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For psychiatric hospitals, the requirements under § 412.23(a);

(B) For rehabilitation hospitals, the requirements under § 412.23(b)(2);

(C) For the children's hospitals, the requirements under § 412.23(d)(2); or

(D) For long-term care hospitals, the requirements under §§ 412.23(e)(1) through (e)(3)(i).

(iii) The satellite facility meets all of the following requirements:

(A) Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(*1*) Except as provided in paragraph (h)(2)(iii)(A)(*2*) of this section, effective for cost reporting periods beginning on or after October 1, 2009, the governing body of the hospital of which the satellite facility is a part is not under the control of any third entity that controls both the hospital of which the satellite facility is a part and the hospital with which the satellite facility is co-located.

(*2*) If a hospital and its satellite facility were excluded from the inpatient prospective payment system under the provisions of this section for the most recent cost reporting period beginning prior to October 1, 2009, the hospital does not have to meet the requirements of paragraph (h)(2)(iii)(A)(*1*) of this section, with respect to that satellite facility, in order to retain its IPPS-excluded status.

(*3*) A hospital described in paragraph (h)(2)(iii)(A)(*2*) of this section that establishes an additional satellite facility in a cost reporting period beginning on or after October 1, 2009, must meet the criteria in this section, including the provisions of paragraph (h)(2)(iii)(A)(*1*) of this section with respect to the additional satellite facility, in order to be excluded from the inpatient prospective payment system.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital of which it is a part.

(E) It is treated as a separate cost center of the hospital of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(*4*) On or after October 1, 2018, a satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that provides inpatient services in a building also used by another hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is excluded from the prospective payment systems specified in § 412.1(a)(1), is not required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the inpatient prospective payment system. A satellite facility that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) which is located in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), is required to meet the criteria specified in paragraphs (h)(2)(iii)(A)(*1*) through (*3*) of this section in order to be excluded from the prospective payment systems specified in § 412.1(a)(1).

(3) Except as provided in paragraphs (h)(4) and (h)(5) of this section, the provisions of paragraph (h)(2) of this section do not apply to—

(i) Any hospital structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the hospital continues operating under the same terms and conditions, including the number of beds and square footage considered, for the purposes of Medicare participation and payment, to be part of the hospital, in effect on September 30, 1999; or

(ii) Any hospital excluded from the prospective payment systems under § 412.23(e)(2)(ii).

(4) For cost reporting periods beginning before October 1, 2006, in applying the provisions of paragraph (h)(3) of this section, any hospital structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility if these changes are made necessary by relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (h)(3) of this section—

(i) Any hospital structured as a satellite facility on September 30, 1999, may increase or decrease the square footage or decrease the number of beds considered to be part of the satellite facility at any time without affecting the provisions of paragraph (h)(3) of this section; and

(ii) If the satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, it may subsequently increase the number of beds at any time as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) *Notification of co-located status.* A satellite of a long-term care hospital that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital and that meets the criteria of paragraphs (h)(1) through (h)(5) of this

section must notify its fiscal intermediary and CMS in writing of its co-location and identify by name, address, and Medicare provider number, those hospital(s) with which it is co-located.

(7) The provisions of paragraph (h)(2)(i) of this section do not apply to any long-term care hospital that is subject to the long-term care hospital prospective payment system under Subpart O of this subpart, effective for cost reporting periods occurring on or after October 1, 2002, and that elects to be paid based on 100 percent of the Federal prospective payment rate as specified in § 412.533(c), beginning with the first cost reporting period following that election, or when the LTCH is fully transitioned to 100 percent of the Federal prospective rate, or to a new long-term care hospital, as defined in § 412.23(e)(4).

(8) The provisions of paragraph (h)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(i)(1) *Requirements for extended neoplastic disease care hospitals.* For cost reporting periods beginning on or after January 1, 2015, an extended neoplastic disease care hospital is a hospital that was first excluded from the prospective payment system under this section in 1986 which has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(2) *Payment to extended neoplastic disease care hospitals.* Payment for inpatient operating costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(3). Payment for capital costs for hospitals classified under paragraph (i)(1) of this section is made as set forth in § 412.526(c)(4).

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.22, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.23 Excluded hospitals: Classifications.

Hospitals that meet the requirements for the classifications set forth in this section are not reimbursed under the prospective payment systems specified in § 412.1(a)(1):

(a) *Psychiatric hospitals.* A psychiatric hospital must—

(1) Meet the following requirements to be excluded from the prospective payment system as specified in § 412.1(a)(1) and to be paid under the prospective payment system as specified in § 412.1(a)(2) and in subpart N of this part;

(2) Be primarily engaged in providing, by or under the supervision of a psychiatrist, psychiatric services for the diagnosis and treatment of mentally ill persons; and

(3) Meet the conditions of participation for hospitals and special conditions of participation for psychiatric hospitals set forth in part 482 of this chapter.

(b) *Rehabilitation hospitals.* A rehabilitation hospital or unit must meet the requirements specified in § 412.29 of this subpart to be excluded from the prospective payment systems specified in § 412.1(a)(1) of this subpart and to be paid under the prospective payment system specified in § 412.1(a)(3) of this subpart and in subpart P of this part.

(c) [Reserved]

(d) *Children's hospitals.* A children's hospital must—

(1) Have a provider agreement under part 489 of this chapter to participate as a hospital; and

(2) Be engaged in furnishing services to inpatients who are predominantly individuals under the age of 18.

(e) *Long-term care hospitals.* A long-term care hospital must meet the requirements of paragraph (e)(1) and (e)(2) of this section and, when applicable, the additional requirement of § 412.22(e), to be excluded from the prospective payment system specified in § 412.1(a)(1) and to be paid under the prospective payment system specified

in § 412.1(a)(4) and in Subpart O of this part.

(1) *Provider agreements.* The hospital must have a provider agreement under Part 489 of this chapter to participate as a hospital; and

(2) *Average length of stay.* (i) The hospital must have an average Medicare inpatient length of stay of greater than 25 days (which includes all covered and noncovered days of stay of Medicare patients) as calculated under paragraph (e)(3) of this section; or

(ii) For cost reporting periods beginning on or after August 5, 1997 and on or before December 31, 2014, a hospital that was first excluded from the prospective payment system under this section in 1986 meets the length-of-stay criterion if it has an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days and demonstrates that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in fiscal year 1997 have a principal diagnosis that reflects a finding of neoplastic disease as defined in paragraph (f)(1)(iv) of this section.

(3) *Calculation of average length of stay.* (i) Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section and paragraphs (e)(4)(iv) and (v) of this section as applicable, the average Medicare inpatient length of stay specified under paragraph (e)(2)(i) of this section is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting period. Subject to the provisions of paragraphs (e)(3)(ii) through (vii) of this section, the average inpatient length of stay specified under paragraph (e)(2)(ii) of this section is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

(ii) Effective for cost reporting periods beginning on or after July 1, 2004, in calculating the hospital's average length of stay, if the days of a stay of an inpatient involves days of care furnished during two or more separate consecutive cost reporting periods, that is, an admission during one cost reporting period and a discharge during a future consecutive cost reporting period, the total number of days of the stay are considered to have occurred in the cost reporting period during which the inpatient was discharged. However, if after application of this provision, a hospital fails to meet the average length of stay specified under paragraphs (e)(2)(i) and (ii) of this section, Medicare will determine the hospital's average inpatient length of stay for cost reporting periods beginning on or after July 1, 2004, but before July 1, 2005, by dividing the applicable total days for Medicare inpatients under paragraph (e)(2)(i) of this section or the total days for all inpatients under paragraph (e)(2)(ii) of this section, during the cost reporting period when they occur, by the number of discharges occurring during the same cost reporting period.

(iii) If a change in a hospital's average length of stay specified under paragraph (e)(2)(i) or (e)(2)(ii) of this section would result in the hospital not maintaining an average Medicare inpatient length of stay of greater than 25 days, the calculation is made by the same method for the period of at least 5 consecutive months of the immediately preceding 6-month period.

(iv) [Reserved]

(v) For periods beginning on or after October 1, 2011, a hospital that is excluded from the inpatient prospective payment system as a long-term care hospital that plans to undergo a change of ownership (as described in § 489.18 of this chapter) must notify its fiscal intermediary or MAC within 30 days of the effective date of such change of ownership, as specified in § 424.516(e) of this subchapter. The hospital will continue to be excluded from the inpatient prospective payment system as a long-term care hospital for the cost reporting period following the change of ownership only if, for the period of at least 5 months of the 6 months immediately preceding the change of ownership, the hospital meets the required average length of

stay (calculated in accordance with paragraph (e)(3)(i) of this section).

(vi) For cost reporting periods beginning on or after October 1, 2015, the Medicare inpatient days and discharges that are paid at the site neutral payment rate specified at §412.522(c)(1) or paid under a Medicare Advantage plan (Medicare Part C) will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

(vii) For cost reporting periods beginning on or after October 1, 2019, the Medicare inpatient days and discharges that are associated with patients discharged from a unit of the hospital will not be included in the calculation of the Medicare inpatient average length of stay specified under paragraph (e)(2)(i) of this section.

(4) For the purpose of calculating the average length of stay for hospitals seeking to become long-term care hospitals, with the exception of paragraphs (e)(3)(iii) and (v) of this section, the provisions of paragraph (e)(3) of this section apply.

(i) *Definition.* For the purpose of payment under the long-term care hospital prospective payment system under subpart O of this part, a new long-term care hospital is a provider of inpatient hospital services that meets the qualifying criteria in paragraphs (e)(1) and (e)(2) of this section; meets the applicable requirements of paragraphs (e)(4)(ii) through (v) of this section; and, under present or previous ownership (or both), its first cost reporting period as a LTCH begins on or after October 1, 2002.

(ii) *Satellite facilities and remote locations of hospitals seeking to become new long-term care hospitals.* Except as specified in paragraph (e)(4)(iii) of this section, a satellite facility (as defined in §412.22(h)) or a remote location of a hospital (as defined in §413.65(a)(2) of this chapter) that voluntarily reorganizes as a separate Medicare participating hospital, with or without a concurrent change in ownership, and that seeks to qualify as a new long-term care hospital for Medicare payment purposes must demonstrate through documentation that it meets the average length of stay requirement as specified under paragraphs (e)(2)(i) or (e)(2)(ii) of this section based on discharges that occur on or after the effective date of its participation under Medicare as a separate hospital.

(iii) *Provider-based facility or organization identified as a satellite facility and remote location of a hospital prior to July 1, 2003.* Satellite facilities and remote locations of hospitals that became subject to the provider-based status rules under §413.65 as of July 1, 2003, that become separately participating hospitals, and that seek to qualify as long-term care hospitals for Medicare payment purposes may submit to the fiscal intermediary discharge data gathered during the period of at least 5 consecutive months of the immediate 6 months preceding the facility's separation from the main hospital for calculation of the average length of stay specified under paragraph (e)(2)(i) or paragraph (e)(2)(ii) of this section.

(iv) *Qualifying period for hospitals seeking to become long-term care hospitals.* A hospital may be classified as a long-term care hospital after a 6-month qualifying period, provided that the average length of stay during the period of at least 5 consecutive months of that 6-month qualifying period, calculated under paragraph (e)(2) of this section, is greater than 25 days. The 6-month qualifying period for a hospital is the 6 months immediately preceding the date of long-term care hospital classification.

(v) *Special rule for hospitals seeking to become long-term care hospitals that experience a change in ownership.* If a hospital seeks exclusion from the inpatient prospective payment system as a long-term care hospital and a change of ownership (as described in §489.18 of this chapter) occurs within the period of at least 5 consecutive months of the 6-month period preceding its petition for long-term care hospital status, the hospital may be excluded from the inpatient prospective payment system as a long-term care hospital for the next cost reporting period if, for the period of at least 5 consecutive months of the 6 months immediately preceding the start of the cost reporting period for which the hospital is seeking exclusion

from the inpatient prospective payment system as a long-term care hospital (including time before the change of ownership), the hospital has met the required average length of stay, has continuously operated as a hospital, and has continuously participated as a hospital in Medicare.

(5) *Freestanding long-term care hospital.* For purposes of this paragraph, a freestanding long-term care hospital means a hospital that meets the requirements of paragraph (e)(1) and (2) of this section and all of the following:

(i) Does not occupy space in a building also used by another hospital.

(ii) Does not occupy space in one or more separate or entire buildings located on the same campus as buildings used by another hospital.

(iii) Is not part of a hospital that provides inpatient services in a building also used by another hospital.

(6) *Moratorium on the establishment of new long-term care hospitals and long-term care hospital satellite facilities*—(i) *General rule.* Except as specified in paragraphs (e)(6)(ii) and (e)(6)(iii) of this section for the period beginning December 29, 2007 and ending December 28, 2012, and the period beginning April 1, 2014 and ending September 30, 2017, a moratorium applies to the establishment and classification of a long-term care hospital as described in paragraphs (e) and (e)(1) through (e)(5) of this section or a long-term care hospital satellite facility as described in § 412.22(h).

(ii) *Exception.* The moratorium specified in paragraph (e)(6)(i) of this section is not applicable to the establishment and classification of a long-term care hospital that meets the requirements of paragraphs (e) introductory text and (e)(1) through (e)(5) of this section, or a long-term care hospital satellite facility that meets the requirements of § 412.22(h), if the long-term care hospital or long-term care satellite facility meets one or more of the following criteria on or before December 27, 2007, or prior to April 1, 2014, as applicable:

(A) Began its qualifying period for payment in accordance with paragraph (e) of this section.

(B)(*1*) Has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease or demolition for a long-term care hospital; and

(*2*)(*i*) Has expended prior to December 29, 2007, at least 10 percent (or, if less, $2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(*1*) of his section; or

(*ii*) Has expended, before April 1, 2014, at least 10 percent (or, if less, $2.5 million) of the estimated cost of the project specified in paragraph (e)(6)(ii)(B)(*1*) of this section.

(C) Had obtained an approved certificate of need from the State, when required by State law.

(7) *Moratorium on increasing the number of beds in existing long-term care hospitals and existing long-term care hospital satellite facilities.* (i) For purposes of this paragraph, an existing long-term care hospital or long-term care hospital satellite facility means a long-term care hospital that meets the requirements of paragraph(e) of this section or a long-term care hospital satellite facility that meets the requirements of § 412.22(h) that received payment under the provisions of subpart O of this part prior to the dates noted in the following moratorium clauses.

(ii) December 29, 2007, through December 28, 2007—

(A) Except as specified in paragraph (e)(7)(ii)(B) and (C) of this section, the number of Medicare-certified beds in an existing long-term care hospital or an existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section must not be increased beyond the number of Medicare-certified beds on December 29, 2007.

(B) Except as specified in paragraph (e)(7)(ii)(C) of this section, the moratorium specified in paragraph (e)(7)(ii)(A) of this section is not applicable to—

(*1*) An existing long-term care hospital or existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section that meets both of the following requirements:

(*i*) Is located in a State where there is only one other long-term care hospital that meets the criteria specified in § 412.23(e) of this subpart.

(*ii*) Requests an increase in the number of Medicare-certified beds after the

closure or decrease in the number of Medicare-certified beds of another long-term care hospital in the State; or

(*2*) An existing long-term care hospital or existing long-term care hospital satellite facility as defined in paragraph (e)(7)(i) of this section that obtained a certificate of need for an increase in beds and that meets both of the following requirements:

(*i*) Is in a State for which such certificate of need is required, and

(*ii*) Such certificate was issued on or after April 1, 2005, and before December 29, 2007.

(C) The exceptions specified in paragraph (e)(7)(ii)(B) of this section do not affect the limitation on increasing beds under §412.22(f) and §412.22(h)(3) of subpart.

(iii) April 1, 2014 through September 30, 2017—The number of Medicare-certified beds in an existing long-term care hospital or an existing long-term care hospital satellite facility must not be increased beyond the number of Medicare-certified beds prior to April 1, 2014, unless one of the exceptions specified in paragraph (e)(6)(ii) of this section is met.

(8) *Application of LTCH moratorium on the increase in beds at section 114(d)(1)(B) of Public Law 110–173 to LTCHs and LTCH satellite facilities established or classified as such under section 114(d)(2) of Public Law 110–173.* Effective for the period beginning October 1, 2011, and ending December 28, 2012, for long-term care hospitals and long-term care hospital satellite facilities established under paragraph (e)(6)(ii) of this section for the period beginning December 29, 2007, and ending September 30, 2011, the moratorium under paragraph (e)(7) of this section applies and the number of Medicare-certified beds must not be increased beyond the number of beds that were certified by Medicare at the long-term care hospital or the long-term care hospital satellite facility as of October 1, 2011.

(f) *Cancer hospitals*—(1) *General rule.* Except as provided in paragraph (f)(2) of this section, if a hospital meets the following criteria, it is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after October 1, 1989. A hospital classified after December 19, 1989, is excluded beginning with its first cost reporting period beginning after the date of its classification.

(i) It was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983.

(ii) It is classified on or before December 31, 1990, or, if on December 19, 1989, the hospital was located in a State operating a demonstration project under section 1814(b) of the Act, the classification is made on or before December 31, 1991.

(iii) It demonstrates that the entire facility is organized primarily for treatment of and research on cancer (that is, the facility is not a subunit of an acute general hospital or university-based medical center).

(iv) It shows that at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease. (The principal diagnosis for this purpose is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital. For the purposes of meeting this definition, only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V58.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect neoplastic disease.)

(2) *Alternative.* A hospital that applied for and was denied, on or before December 31, 1990, classification as a cancer hospital under the criteria set forth in paragraph (f)(1) of this section is classified as a cancer hospital and is excluded from the prospective payment systems beginning with its first cost reporting period beginning on or after January 1, 1991, if it meets the criterion set forth in paragraph (f)(1)(i) of this section and the hospital is—

(i) Licensed for fewer than 50 acute care beds as of August 5, 1997;

(ii) Is located in a State that as of December 19, 1989, was not operating a demonstration project under section 1814(b) of the Act; and

(iii) Demonstrates that, for the 4-year period ending on December 31, 1996, at least 50 percent of its total discharges have a principal diagnosis that reflects a finding of neoplastic disease

as defined in paragraph (f)(1)(iv) of this section.

(3) *PCHQR Program.* All hospitals classified as cancer hospitals under this paragraph must comply with the requirements of the PPS-Exempt Cancer Hospital Quality Reporting Program, as described in § 412.24.

(g) *Hospitals outside the 50 States, the District of Columbia, or Puerto Rico.* A hospital is excluded from the prospective payment systems if it is not located in one of the fifty States, the District of Columbia, or Puerto Rico.

(h) *Hospitals reimbursed under special arrangements.* A hospital must be excluded from prospective payment for inpatient hospital services if it is reimbursed under special arrangement as provided in § 412.22(c).

(i) *Changes in classification of hospitals.* For purposes of exclusions from the prospective payment system, the classification of a hospital is effective for the hospital's entire cost reporting period. Any changes in the classification of a hospital are made only at the start of a cost reporting period.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.23, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

(a) *Applicability.* The PCHQR Program applies to hospitals that are classified as cancer hospitals (PCHs) under the criteria described in § 412.23(f)(1) or (2).

(b) *Participation in the PCHQR Program.* In order to participate in the PCHQR Program, a PCH must do both of the following:

(1) Register with QualityNet (*http://qualitynet.cms.gov*) prior to reporting, including designating a QualityNet security official who completes all steps of the PCHQR Program registration process as described on the QualityNet website.

(2) Enroll in CDC's National Healthcare Safety Network (*https://www.cdc.gov/nhsn/enrollment/index.html*).

(c) *Submission of PCHQR Program data.* Except as provided in paragraph (e) of this section, PCHs that participate in the PCHQR Program must submit to CMS data on quality measures specified under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. PCHs that participate in the PCHQR Program must also submit an annual online Data Accuracy and Completeness Acknowledgement via the Hospital Quality Reporting (HQR) system that attests to the accuracy and completeness of these data by the deadline specified by CMS on the QualityNet website (*http://qualitynet.cms.gov*).

(d) *Quality measure updates, retention, and removal*—(1) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the PCHQR Program. CMS announces technical measure specification updates through the QualityNet website (*http://qualitynet.cms.gov*) and listserv announcements.

(2) *Measure retention.* All quality measures specified under section 1866(k)(3) for the PCHQR Program measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a quality measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* The collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (d)(3)(i) of this section if the continued collection of data on the quality measure would align with a stated CMS or HHS policy objective, including, but not limited to, an objective to increase the number of quality measures that a PCH can report electronically, or an objective to collect data on the measure in one or more other CMS quality reporting programs.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for PCHs to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the PCHQR measure set. CMS will, upon removal of the measure—

(A) Provide notice to PCHs and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if PCHs continued to submit data on the measure; and

(B) Provide notice of the removal in the FEDERAL REGISTER.

(e) *Extraordinary circumstances exceptions (ECEs).* (1) CMS may grant an ECE to a PCH that has requested an extension or exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the PCH.

(2) CMS may grant an ECE to one or more PCHs that has not requested an exception if CMS determines that—

(i) An extraordinary circumstance has affected an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems has directly affected the ability of the PCH to submit data in accordance with paragraph (c) of this section.

(3) A PCH participating in the PCHQR Program that wishes to request an ECE must submit an ECE request to CMS via the QualityNet website (*https://qualitynet.cms.gov/pch/pchqr/resource*) within 90 days of the date that the extraordinary circumstances occurred, along with the following information:

(i) The PCH's CCN, name, reason for requesting an extension or exception, and evidence of the impact of extraordinary circumstances, including but not limited to photographs and media articles;

(ii) The date when the PCH will again be able to submit PCHQR Program data and a justification for that proposed date;

(iii) The following contact information for the PCH's CEO and any other designated personnel:

(A) Name.

(B) Email address.

(C) Telephone number.

(D) Physical mailing address (not a post office box); and

(iv) The signature of the PCH's CEO or designee on the ECE request.

(f) *Public reporting of PCHQR Program data.* CMS makes data submitted by PCHs under the PCHQR Program available to the public on the Provider Data Catalog website (*https://data.cms.gov/provider-data/*). Prior to making any such data submitted by a PCH available to the public, CMS gives the PCH an opportunity to review the data via the Hospital Quality Reporting (HQR) system (*https://hqr.cms.gov/hqrng/login*) and announces the timeline for review on the QualityNet website (*http://qualitynet.cms.gov*) and applicable listservs.

[86 FR 45518, Aug. 13, 2021, as amended at 87 FR 49403, Aug. 10, 2022]

§ 412.25 Excluded hospital units: Common requirements.

(a) *Basis for exclusion.* In order to be excluded from the prospective payment systems as specified in § 412.1(a)(1) and be paid under the inpatient psychiatric facility prospective payment system as specified in § 412.1(a)(2) or the inpatient rehabilitation facility prospective payment system as specified in § 412.1(a)(3), a psychiatric or rehabilitation unit must meet the following requirements.

(1) Be part of an institution that—

(i) Has in effect an agreement under part 489 of this chapter to participate as a hospital;

(ii) Prior to October 1, 2019, is not excluded in its entirety from the prospective payment systems; and

(iii) Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are paid under the applicable payment system under which the hospital is paid, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the hospital must have enough beds that are paid under the applicable payment system under which the hospital is paid to permit the provision of adequate cost information, as required by §413.24(c) of this chapter.

(2) Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.

(3) Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(4) Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.

(5) Meet applicable State licensure laws.

(6) Have utilization review standards applicable for the type of care offered in the unit.

(7) Have beds physically separate from (that is, not commingled with) the hospital's other beds.

(8) Be serviced by the same fiscal intermediary as the hospital.

(9) Be treated as a separate cost center for cost finding and apportionment purposes.

(10) Use an accounting system that properly allocates costs.

(11) Maintain adequate statistical data to support the basis of allocation.

(12) Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.

(13) As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric or rehabilitation care regardless of whether there are any inpatients in the unit on that date.

(b) *Changes in the size of excluded units.* Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit. A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting period. Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(c) The status of a hospital unit may be changed from not excluded to excluded or excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the hospital unit. A change in the status of a hospital unit from not excluded to excluded or excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

(d) *Number of excluded units.* Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in

§ 412.1(a)(1). A hospital excluded from the prospective payment systems as specified in § 412.1(a)(1) may not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital.

(e) *Satellite facilities.* (1) For purposes of paragraphs (e)(2) through (e)(5) of this section, a satellite facility is a part of a hospital unit that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

(2) Except as provided in paragraphs (e)(3) and (e)(6) of this section, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:

(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of State-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997.

(ii) The satellite facility independently complies with—

(A) For a rehabilitation unit, the requirements under § 412.29 of this subpart; or

(B) For a psychiatric unit, the requirements under § 412.27(a).

(iii) The satellite facility meets all of the following requirements:

(A) Except as provided in paragraph (e)(2)(iv) of this section, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located.

(B) It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.

(C) It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.

(D) It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.

(E) It is treated as a separate cost center of the hospital unit of which it is a part.

(F) For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

(G) It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.

(iv) Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of paragraph (e)(2)(iii)(A) of this section do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in § 412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in § 412.1(a)(1).

(3) Except as specified in paragraphs (e)(4) and (e)(5) of this section, the provisions of paragraph (e)(2) of this section do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999.

(4) In applying the provisions of paragraph (e)(3) of this section, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the

number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—

(i) To permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility; or

(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

(5) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (e)(3) of this section—

(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of this section, without affecting the provisions of paragraph (e)(3) of this section; and

(ii) If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of this section, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999.

(6) The provisions of paragraph (e)(2)(i) of this section do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of this part, effective for cost reporting periods beginning on or after October 1, 2003.

(f) *Changes in classification of hospital units.* For purposes of exclusions from the prospective payment system under this section, the classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the classification of a hospital unit is made only at the start of a cost reporting period.

(g) *CAH units not meeting applicable requirements.* If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of § 485.647 with respect to a cost reporting period, no payment may be made to the CAH for services furnished in that unit for that period. Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of § 485.647.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.25, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.27 Excluded psychiatric units: Additional requirements.

In order to be excluded from the prospective payment system as specified in § 412.1(a)(1), and paid under the prospective payment system as specified in § 412.1(a)(2), a psychiatric unit must meet the following requirements:

(a) Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the International Classification of Diseases, Tenth Revision, Clinical Modification.

(b) Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, and therapeutic activities.

(c) Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements:

(1) *Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.

(i) The identification data must include the inpatient's legal status.

(ii) A provisional or admitting diagnosis must be made on every inpatient

at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(iii) The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.

(iv) The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

(v) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(2) *Psychiatric evaluation.* Each inpatient must receive a psychiatric evaluation that must—

(i) Be completed within 60 hours of admission;

(ii) Include a medical history;

(iii) Contain a record of mental status;

(iv) Note the onset of illness and the circumstances leading to admission;

(v) Describe attitudes and behavior;

(vi) Estimate intellectual functioning, memory functioning, and orientation; and

(vii) Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.

(3) *Treatment plan.* (i) Each inpatient must have an individual comprehensive treatment plan that must be based on an inventory of the inpatient's strengths and disabilities. The written plan must include a substantiated diagnosis; short-term and long-term goals; the specific treatment modalities utilized; the responsibilities of each member of the treatment team; and adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out; and

(ii) The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.

(4) *Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

(5) *Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

(d) Meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures and engage in discharge planning, as follows:

(1) *Personnel.* The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—

(i) Evaluate inpatients;

(ii) Formulate written, individualized, comprehensive treatment plans;

(iii) Provide active treatment measures; and

(iv) Engage in discharge planning.

(2) *Director of inpatient psychiatric services: Medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(i) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(ii) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(3) *Nursing services.* The unit must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.

(i) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(ii) The staffing pattern must ensure the availability of a registered nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.

(4) *Psychological services.* The unit must provide or have available psychological services to meet the needs of the inpatients. The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.

(5) *Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures. Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.

(6) *Therapeutic activities.* The unit must provide a therapeutic activities program.

(i) The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(ii) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39820, Sept. 1, 1992; 59 FR 45397, 45400, Sept. 1, 1994; 69 FR 66976, Nov. 15, 2004; 71 FR 27086, May 9, 2006; 83 FR 38619, Aug. 6, 2018]

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

To be excluded from the prospective payment systems described in § 412.1(a)(1) and to be paid under the prospective payment system specified in § 412.1(a)(3), an inpatient rehabilitation hospital or an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements:

(a) Have (or be part of a hospital that has) a provider agreement under part 489 of this chapter to participate as a hospital.

(b) Except in the case of a ''new'' IRF or ''new'' IRF beds, as defined in paragraph (c) of this section, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:

(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of this section. A patient with a comorbidity, as defined at § 412.602 of this part, may be included in the inpatient

population that counts toward the required applicable percentage if—

(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of this section;

(ii) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of this section; and

(iii) The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of this part and that cannot be appropriately performed in another care setting covered under this title.

(2) List of conditions.

(i) Stroke.

(ii) Spinal cord injury.

(iii) Congenital deformity.

(iv) Amputation.

(v) Major multiple trauma.

(vi) Fracture of femur (hip fracture).

(vii) Brain injury.

(viii) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease.

(ix) Burns.

(x) Active, polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xi) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xii) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation. (A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(xiii) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(A) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(B) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(C) The patient is age 85 or older at the time of admission to the IRF.

(c) In the case of new IRFs (as defined in paragraph (c)(1) of this section) or new IRF beds (as defined in paragraph (c)(2)of this section), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of this section. This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost

reporting period during which the new beds are added to the IRF.

(1) *New IRFs.* An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part for at least 5 calendar years. A new IRF will be considered new from the point that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.

(2) *New IRF beds.* Any IRF beds that are added to an existing IRF must meet all applicable State Certificate of Need and State licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit and the addition of new IRF beds to that IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of this section from the time that they are added to the IRF.

(3) *Change of ownership or leasing.* An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in § 489.18 of this chapter, retains its excluded status and will continue to be paid under the prospective payment system specified in § 412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in § 412.1(a)(1).

(4) *Mergers.* If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in § 412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF.

(d) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient hospital program. This procedure must ensure that the preadmission screening for each Medicare Part A fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.

(e) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622, during the Public Health Emergency, as defined in § 400.200 of this chapter, have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits

per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process except that during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). Beginning with the second week, as defined in § 412.622, of admission to the IRF, a non-physician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.

(f) Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.

(g) Have a director of rehabilitation who—

(1) Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week;

(2) Is a doctor of medicine or osteopathy;

(3) Is licensed under State law to practice medicine or surgery; and

(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services.

(h) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.

(i) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge, as defined in § 412.622 of this chapter, during the Public Health Emergency, as defined in § 400.200 of this chapter, use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the appropriateness of treatment.

(j) *Retroactive adjustments.* If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in § 412.1(a)(1) and paid under the prospective payment system specified in § 412.1(a)(3) for a cost reporting period under paragraph (c) of this section, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of this section, we adjust payments to the IRF retroactively in accordance with the provisions in § 412.130.

[76 FR 47891, Aug. 5, 2011, as amended at 78 FR 47934, Aug. 6, 2013; 85 FR 19287, Apr. 6, 2020; 85 FR 27621, May 8, 2020; 85 FR 48462, Aug. 10, 2020]

§ 412.30 [Reserved]

Subpart C—Conditions for Payment Under the Prospective Payment Systems for Inpatient Operating Costs and Inpatient Capital-Related Costs

§ 412.40 General requirements.

(a) A hospital must meet the conditions of this subpart to receive payment under the prospective payment systems for inpatient hospital services furnished to Medicare beneficiaries.

(b) If a hospital fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may, as appropriate—

(1) Withhold Medicare payment (in full or in part) to the hospital until the hospital provides adequate assurances of compliance; or

(2) Terminate the hospital's provider agreement.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39821, Sept. 1, 1992]

§ 412.42 Limitations on charges to beneficiaries.

(a) *Prohibited charges.* A hospital may not charge a beneficiary for any services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment systems.

(b) *Permitted charges—Stay covered.* A hospital receiving payment under the prospective payment systems for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the following:

(1) The applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter.

(2) Noncovered items and services, furnished at any time during a covered stay, unless they are excluded from coverage only on the basis of the following:

(i) The exclusion of custodial care under § 411.15(g) of this chapter (see paragraph (c) of this section for when charges may be made for custodial care).

(ii) The exclusion of medically unnecessary items and services under § 411.15(k) of this chapter (see paragraphs (c) and (d) of this section for when charges may be made for medically unnecessary items and services).

(iii) The exclusion under § 411.15(m) of this chapter of nonphysician services furnished to hospital inpatients by other than the hospital or a provider or supplier under arrangements made by the hospital.

(iv) The exclusion of items and services furnished when the patient is not entitled to Medicare Part A benefits under subpart A of part 406 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished when the patient is not entitled to benefits).

(v) The exclusion of items and services furnished after Medicare Part A benefits are exhausted under § 409.61 of this chapter (see paragraph (e) of this section for when charges may be made for items and services furnished after benefits are exhausted).

(c) *Custodial care and medically unnecessary inpatient hospital care.* A hospital may charge a beneficiary for services excluded from coverage on the basis of § 411.15(g) of this chapter (custodial care) or § 411.15(k) of this chapter (medically unnecessary services) and furnished by the hospital after all of the following conditions have been met:

(1) The hospital (acting directly or through its utilization review committee) determines that the beneficiary no longer requires inpatient hospital care. (The phrase ''inpatient hospital care'' includes cases where a beneficiary needs a SNF level of care, but, under Medicare criteria, a SNF-level bed is not available. This also means that a hospital may find that a patient awaiting SNF placement no longer requires inpatient hospital care because either a SNF-level bed has become available or the patient no longer requires SNF-level care.)

(2) The attending physician agrees with the hospital's determination in writing (for example, by issuing a written discharge order). If the hospital believes that the beneficiary does not require inpatient hospital care but is unable to obtain the agreement of the physician, it may request an immediate review of the case by the QIO as described in § 405.1208 of this chapter. Concurrence by the QIO in the hospital's determination will serve in lieu of the physician's agreement.

(3) The hospital (acting directly or through its utilization review committee) notifies the beneficiary (or his or her representative) of his or her discharge rights in writing consistent with § 405.1205 and notifies the beneficiary, in accordance with § 405.1206 of this chapter (if applicable) that in the hospital's opinion, and with the attending physician's concurrence or that of the QIO, the beneficiary no longer requires inpatient hospital care.

(4) If the beneficiary remains in the hospital after the appropriate notification, and the hospital, the physician who concurred in the hospital determination on which the notice was based, or QIO subsequently finds that the beneficiary requires an acute level of inpatient hospital care, the hospital may not charge the beneficiary for continued care until the hospital once again determines that the beneficiary no longer requires inpatient care, secures concurrence, and notifies the beneficiary, as required in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(d) *Medically unnecessary diagnostic and therapeutic services.* A hospital may charge a beneficiary for diagnostic procedures and studies, and therapeutic procedures and courses of treatment (for example, experimental procedures) that are excluded from coverage under § 411.15(k) of this chapter (medically unnecessary items and services), even though the beneficiary requires continued inpatient hospital care, if those services are furnished after the beneficiary (or the person acting on his or her behalf) has acknowledged in writing that the hospital (acting directly or through its utilization review committee and with the concurrence of the intermediary) has informed him or her as follows:

(1) In the hospital's opinion, which has been agreed to by the intermediary, the services to be furnished are not considered reasonable and necessary under Medicare.

(2) Customary charges will be made if he or she receives the services.

(3) If the beneficiary receives the services, a formal determination on the validity of the hospital's finding is made by the intermediary and, to the extent that the decision requires the exercise of medical judgment, the QIO.

(4) The determination is appealable by the hospital, the attending physician, or the beneficiary under the appeals procedure that applies to determinations affecting Medicare Part A payment.

(5) The charges for the services will be invalid and, to the extent collected, will be refunded by the hospital if the services are found to be covered by Medicare.

(e) *Services furnished on days when the individual is not entitled to Medicare Part A benefits or has exhausted the available benefits.* The hospital may charge the beneficiary its customary charges for noncovered items and services furnished on outlier days (as described in Subpart F of this part) for which payment is denied because the beneficiary is not entitled to Medicare Part A or his or her Medicare Part A benefits are exhausted. (1) If payment is considered for outlier days, the entire stay is reviewed and days up to the number of days in excess of the outlier threshold may be denied on the basis of nonentitlement to Part A or exhaustion of benefits. (2) In applying this rule, the latest days will be denied first.

(f) *Differential for private room or other luxury services.* The hospital may charge the beneficiary the customary charge differential for a private room or other luxury service that is more expensive than is medically required and is furnished for the personal comfort of the beneficiary at his or her request (or the request of the person acting on his or her behalf).

(g) *Review.* (1) The QIO or intermediary may review any cases in which the hospital advises the beneficiary (or the person acting on his or her behalf) of the noncoverage of the services in accordance with paragraph (c)(3) or (d) of this section.

(2) The hospital must identify such cases to the QIO or intermediary in accordance with CMS instructions.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, Sept. 3, 1985; 54 FR 41747, Oct. 11, 1989; 57 FR 39821, Sept. 1, 1992; 71 FR 48137, Aug. 18, 2006; 71 FR 68722, Nov. 27, 2006; 85 FR 72909, Nov. 16, 2020]

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier

provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

[50 FR 15326, Apr. 17, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 50 FR 41886, Oct. 16, 1985]

§ 412.46 Medical review requirements.

(a) *Physician acknowledgement.* (1) *Basis.* Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

(2) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

> Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(3) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(b) *Physician's order and certification regarding medical necessity.* No presumptive weight shall be assigned to the physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of the chapter in determining the medical necessity of inpatient hospital services under section 1862(a)(1) of the Act. A physician's order or certification will be evaluated in the context of the evidence in the medical record.

[78 FR 50965, Aug. 19, 2013]

§ 412.48 Denial of payment as a result of admissions and quality review.

(a) If CMS determines, on the basis of information supplied by a QIO that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission of an individual entitled to benefits under Part A, unnecessary multiple admissions of an individual, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, CMS may as appropriate—

(1) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided with respect to such an unnecessary admission or subsequent readmission of an individual; or

(2) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(b) When payment with respect to admission of an individual patient is denied by a QIO under paragraph (a)(1) of this section, and liability is not waived in accordance with §§ 411.400 through 411.402 of this chapter, notice and appeals are provided under procedures established by CMS to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(c) A determination under paragraph (a) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment systems, is referred to the Department's Office of Inspector General, for handling in accordance with § 1001.301 of this title.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35688, 35689, Sept. 3, 1985; 51 FR 34787, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992; 71 FR 48137, Aug. 18, 2006]

§ 412.50 Furnishing of inpatient hospital services directly or under arrangements.

(a) The applicable payments made under the prospective payment systems, as described in subparts H and M of this part, are payment in full for all inpatient hospital services, as defined in § 409.10 of this chapter. Inpatient hospital services do not include the following types of services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse mid-wife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(b) CMS does not pay any provider or supplier other than the hospital for services furnished to a beneficiary who is an inpatient, except for the services described in paragraphs (a)(1) through (a)(6) of this section.

(c) The hospital must furnish all necessary covered services to the beneficiary either directly or under arrangements (as defined in § 409.3 of this chapter).

[50 FR 12741, Mar. 29, 1985, as amended at 53 FR 38527, Sept. 30, 1988; 57 FR 39821, Sept. 1, 1992; 60 FR 63188, Dec. 8, 1995; 65 FR 18537, Apr. 7, 2000]

§ 412.52 Reporting and recordkeeping requirements.

All hospitals participating in the prospective payment systems must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 57 FR 39821, Sept. 1, 1992]

Subpart D—Basic Methodology for Determining Prospective Payment Federal Rates for Inpatient Operating Costs

§ 412.60 DRG classification and weighting factors.

(a) *Diagnosis-related groups.* CMS establishes a classification of inpatient hospital discharges by Diagnosis-Related Groups (DRGs).

(b) *DRG weighting factors.* CMS assigns, for each DRG, an appropriate weighting factor that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, subject to a maximum ten percent reduction to the weighting factor for a DRG as compared to the weighting factor for the same DRG for the prior fiscal year.

(c) *Assignment of discharges to DRGs.* CMS establishes a methodology for classifying specific hospital discharges within DRGs which ensures that each hospital discharge is appropriately assigned to a single DRG based on essential data abstracted from the inpatient bill for that discharge.

(1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and discharge status.

(2) Each discharge is assigned to only one DRG (related, except as provided in paragraph (c)(3) of this section, to the patient's principal diagnosis) regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill is returned to the hospital for validation and reverification. CMS's DRG classification system provides a DRG, and an appropriate weighting factor, for the group of cases for which the unrelated diagnosis and procedure are confirmed.

(d) *Review of DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of

a discharge to a DRG to request a review of that assignment. The hospital may submit additional information as a part of its request.

(2) The intermediary reviews the hospital's request and any additional information and decides whether a change in the DRG assignment is appropriate. If the intermediary decides that a higher-weighted DRG should be assigned, the case will be reviewed by the appropriate QIO as specified in § 466.71(c)(2) of this chapter.

(3) Following the 60-day period described in paragraph (d)(1) of this section, the hospital may not submit additional information with respect to the DRG assignment or otherwise revise its claim.

(e) *Revision of DRG classification and weighting factors.* Beginning with discharges in fiscal year 1988, CMS adjusts the classifications and weighting factors established under paragraphs (a) and (b) of this section at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources.

[50 FR 12741, Mar. 29, 1985, as amended at 52 FR 33057, Sept. 1, 1987; 57 FR 39821, Sept. 1, 1992; 59 FR 45397, Sept. 1, 1994; 87 FR 49403, Aug. 10, 2022]

§ 412.62 Federal rates for inpatient operating costs for fiscal year 1984.

(a) *General rule.* CMS determines national adjusted DRG prospective payment rates for operating costs, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a hospital in the United States subject to the prospective payment system under subpart B of this part, and determines regional adjusted DRG prospective payment rates for inpatient operating costs for such discharges in each region, for which payment may be made under Medicare Part A. Such rates are determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described in paragraphs (b) through (k) of this section.

(b) *Determining allowable individual hospital inpatient operating costs.* CMS determines the Medicare allowable operating costs per discharge of inpatient hospital services for each hospital in the data base for the most recent cost reporting period for which data are available.

(c) *Updating for fiscal year 1984.* CMS updates each amount determined under paragraph (b) of this section for fiscal year 1984 by—

(1) Updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under paragraph (b) of this section and fiscal year 1983; and

(2) Projecting for fiscal year 1984 by the applicable percentage increase in the hospital market basket for fiscal year 1984.

(d) *Standardizing amounts.* CMS standardizes the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for area variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Adjusting for the effects of a higher cost of living for hospitals located in Alaska and Hawaii.

(e) *Computing urban and rural averages.* CMS computes an average of the standardized amounts determined under paragraph (d) of this section for urban and rural hospitals in the United States and for urban and rural hospitals in each region.

(f) *Geographic classifications.* (1) For purposes of paragraph (e) of this section, the following definitions apply:

(i) The term *region* means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

(ii) The term *urban area* means—

(A) A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget; or

(B) The following New England counties, which are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note)): Litchfield County, Connecticut; York

County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(iii) The term *rural area* means any area outside an urban area.

(iv) The phrase *hospital reclassified as rural* means a hospital located in a county that was part of an MSA or NECMA, as defined by the Executive Office of Management and Budget, but is not part of an MSA or NECMA as a result of an Executive Office of Management and Budget redesignation occurring after April 20, 1983.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) If a hospital would receive a lower Federal rate because most of the hospitals are located in a census division with a lower Federal rate than the rate applicable to the census division in which the hospital is located, the payment rate will not be reduced for the hospital's cost reporting period beginning before October 1, 1984.

(iii) If an equal number of hospitals within the MSA or NECMA are located in each census division, such hospitals are deemed to be in the census division with the higher Federal rate.

(g) *Adjusting the average standardized amounts.* CMS adjusts each of the average standardized amounts determined under paragraphs (c), (d), and (e) of this section by factors representing CMS's estimates of the following:

(1) The amount of payment that would have been made under Medicare Part B for nonphysician services to hospital inpatients during the first cost reporting period subject to prospective payment were it not for the fact that such services must be furnished either directly by hospitals or under arrangements in order for any Medicare payment to be made after September 30, 1983 (the effective date of § 405.310(m) of this chapter).

(2) The amount of FICA taxes that would be incurred during the first cost reporting period subject to the prospective payment system, by hospitals that had not incurred such taxes for any or all of their employees during the base period described in paragraph (c) of this section.

(h) *Reducing for value of outlier payments.* CMS reduces each of the adjusted average standardized amounts determined under paragraphs (c) through (g) of this section by a proportion equal to the proportion (estimated by CMS) of the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under subpart F of this part.

(i) *Maintaining budget neutrality.* (1) CMS adjusts each of the reduced standardized amounts determined under paragraphs (c) through (h) of this section as required for fiscal year 1984 so that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for Federal fiscal year 1984) is not greater or less than 25 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the Social Security Act as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control quality improvement organization, as allowed under section 1866(a)(1)(F) of the Act.

(j) *Computing Federal rates for inpatient operating costs for urban and rural hospitals in the United States and in each region.* For each discharge classified within a DRG, CMS establishes a national prospective payment rate for inpatient operating costs and a regional prospective payment rate for inpatient operating costs for each region, as follows:

(1) For hospitals located in an urban area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in an urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in the United States or in that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraphs (c) through (i) of this section) for hospitals located in a rural area in the United States or that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(k) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Federal rates computed under paragraph (j) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 53 FR 38527, Sept. 30, 1988; 57 FR 39821, Sept. 1, 1992; 58 FR 46337, Sept. 1, 1993]

§ 412.63 Federal rates for inpatient operating costs for Federal fiscal years 1984 through 2004.

(a) *General rule.* (1) CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal years 1985 through 2004 involving inpatient hospital service of a hospital in the United States, subject to the PPS, and determines a regional adjusted PPS rate for operating costs for such discharges in each region for which payment may be made under Medicare Part A.

(2) Each such rate is determined for hospitals located in urban or rural areas within the United States and within each such region, respectively, as described under paragraphs (b) through (u) of this section.

(b) *Geographic classifications.* Effective for fiscal years 1985 through 2004, the following rules apply.

(1) For purposes of this section, the definitions set forth in § 412.62(f) apply, except that, effective January 1, 2000, a hospital reclassified as rural may mean a reclassification that results from a geographic redesignation as set forth in § 412.62(f)(1)(iv) or a reclassification that results from an urban hospital applying for reclassification as rural as set forth in § 412.103.

(2) For hospitals within an MSA or NECMA that crosses census division boundaries, the following provisions apply:

(i) The MSA or NECMA is deemed to belong to the census division in which most of the hospitals within the MSA or NECMA are located.

(ii) A hospital that met the conditions specified in § 412.62(f)(2)(ii) and therefore did not receive a lower Federal rate that would have applied for cost reporting periods beginning before October 1, 1984, receives the lower Federal rate applicable to all hospitals in the MSA or NECMA in which it is located effective with the hospital's cost reporting period that begins on or after October 1, 1984.

(iii) The higher Federal rate is payable to all hospitals in the MSA or NECMA if an equal number of hospitals within the MSA or NECMA are located in each census division.

(3) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs or NECMAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs or NECMAs. These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from CMS, East High Rise Building, room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(4) For purposes of this section, any change in an MSA or NECMA designation is recognized on the October 1 following the effective date of the change.

(5) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurs.

(c) *Updating previous standardized amounts.* (1) For discharges occurring in fiscal year 1985 through fiscal year 2003, CMS computes average standardized amounts for hospitals in urban areas and rural areas within the United States, and in urban areas and rural areas within each region. For discharges occurring in fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

(2) Each of those amounts is equal to the respective adjusted average standardized amount computed for fiscal year 1984 under § 412.62(g)—

(i) Increased for fiscal year 1985 by the applicable percentage increase in the hospital market basket;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements;

(iii) Reduced by a proportion equal to the proportion (estimated by CMS) of the total amount of prospective payments that are additional payment amounts attributable to outlier cases under subpart F of this part; and

(iv) Adjusted for budget neutrality under paragraph (h) of this section.

(3) For fiscal year 1986 and thereafter. CMS computes, for urban and rural hospitals in the United States and for urban and rural hospitals in each region, average standardized amount equal to the respective adjusted average standardized amounts computed for the previous fiscal year—

(i) Increased by the applicable percentage increase determined under paragraphs (d) through (g) of this section;

(ii) Adjusted by the estimated amount of Medicare payment for nonphysician services furnished to hospital inpatients that would have been paid under Part B were it not for the fact that such services must be furnished either directly by hospitals or under arrangements; and

(iii) For discharges occurring on or after October 1, 1985 and before October 1, 1986, reduced by a proportion (estimated by CMS) of the amount of payments based on the total amount of prospective payments that are additional payment amounts attributable to outlier cases under subpart F of this part, and for discharges occurring on or after October 1, 1986, reduced by a proportion (estimated by CMS) of the amount of payments that, based on the total amount of prospective payments for urban hospitals and the total amount of prospective payments for rural hospitals, are additional payments attributable to outlier cases in such hospitals under subpart F of this part.

(4) For fiscal years 1987 through 1990 CMS standardizes the average standardized amounts by excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(5) For fiscal years 1987 through 2004, CMS standardizes the average standardized amounts by excluding an estimate of indirect medical education payments.

(6) For fiscal years 1988 through 2003, CMS computes average standardized amounts for hospitals located in large urban areas, other urban areas, and rural areas. The term *large urban area* means an MSA with a population of more than 1,000,000 or an NECMA, with a population of more than 970,000 based on the most recent available population data published by the Census Bureau. For fiscal year 2004, CMS computes an average standardized amount for hospitals located in all areas.

(d) *Applicable percentage change for fiscal year 1986.* (1) The applicable percentage change for fiscal year 1986 is—

(i) For discharges occurring on or after October 1, 1985 and before May 1. 1986, zero percent; and

(ii) For discharges occurring on or after May 1, 1986, one-half of one percent.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1986, the applicable percentage increase for fiscal year 1986 is deemed to have been one-half of one percent.

(e) *Applicable percentage change for fiscal year 1987.* The applicable percentage change for fiscal year 1987 is 1.15 percent.

(f) *Applicable percentage change for fiscal year 1988.* (1) The applicable percentage change for fiscal year 1988 is—

(i) For discharges occurring on or after October 1, 1987 and before November 21, 1987, zero percent;

(ii) For discharges occurring on or after November 21, 1987 and before April 1, 1988, 2.7 percent; and

(iii) For discharges occurring on or after April 1, 1988 and before October 1, 1988—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1988 (for Federal fiscal year 1989), the applicable percentage change for fiscal year 1988 is deemed to have been—

(i) 3.0 percent for hospitals located in rural areas;

(ii) 1.5 percent for hospitals located in large urban areas; and

(iii) 1.0 percent for hospitals located in other urban areas.

(g) *Applicable percentage change for fiscal year 1989.* The applicable percentage change for fiscal year 1989 is the percentage increase in the market basket index (as defined in §413.40(a)(3) of this chapter)—

(1) Minus 1.5 percentage points for hospitals located in rural areas;

(2) Minus 2.0 percentage points for hospitals in large urban areas; and

(3) Minus 2.5 percentage points for hospitals in other urban areas.

(h) *Applicable percentage change for fiscal year 1990.* (1) The applicable percentage change for fiscal year 1990 is—

(i) For discharges occurring on or after October 1, 1989 and before January 1, 1990, 5.5 percent; and

(ii) For discharges occurring on or after January 1, 1990 and before October 1, 1990—

(A) 9.72 percent for hospitals located in rural areas;

(B) 5.62 percent for hospitals located in large urban areas; and

(C) 4.97 percent for hospitals located in other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1990, the applicable percentage change for fiscal year 1990 is deemed to have been the percentage change provided for in paragraph (h)(1)(ii) of this section.

(i) *Applicable percentage change for fiscal year 1991.* (1) The applicable percentage change for fiscal year 1991 is—

(i) For discharges occurring on or after October 1, 1990 and before October 21, 1990, 5.2 percent;

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, 0.0 percent; and

(iii) For discharges occurring on or after January 1, 1991 and before October 1, 1991—

(A) 4.5 percent for hospitals located in rural areas; and

(B) 3.2 percent for hospitals located in large urban areas and other urban areas.

(2) For purposes of determining the standardized amounts for discharges occurring on or after October 1, 1991, the applicable percentage change for fiscal year 1991 is deemed to have been the percentage change provided for in paragraph (i)(1)(iii) of this section.

(j) *Applicable percentage change for fiscal year 1992.* The applicable percentage change for fiscal year 1992 is the percentage increase in the market basket index for prospective payment hospitals (as defined in §413.40(a)(3) of this chapter)—

(1) Minus 0.6 percentage points for hospitals located in rural areas.

(2) Minus 1.6 percentage points for hospitals located in large urban areas and other urban areas.

(k) *Applicable percentage change for fiscal year 1993.* The applicable percentage change for fiscal year 1993 is the

percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a)(3) of this chapter)—

(1) Minus 0.55 percentage points for hospitals located in rural areas.

(2) Minus 1.55 percentage points for hospitals located in large urban areas and other urban areas.

(l) *Applicable percentage change for fiscal year 1994.* The applicable percentage change for fiscal year 1994 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter)—

(1) Minus 1.0 percentage point for hospitals located in rural areas.

(2) Minus 2.5 percentage points for hospitals located in large urban areas and other urban areas.

(m) *Applicable percentage change for fiscal year 1995.* The applicable percentage change for fiscal year 1995 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter)—

(1) Plus, for hospitals located in rural areas, the percentage increase necessary so that the average standardized amounts computed under paragraph (c) through (i) of this section are equal to the average standardized amounts for hospitals located in an urban area other than a large urban area.

(2) Minus 2.5 percentage points for hospitals located in large urban areas and other urban areas.

(n) *Applicable percentage change for fiscal year 1996.* The applicable percentage change for fiscal year 1996 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 2.0 percentage points for all areas.

(o) *Applicable percentage change for fiscal year 1997.* The applicable percentage change for fiscal year 1997 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 0.5 percentage point for all areas.

(p) *Applicable percentage change for fiscal year 1998.* The applicable percentage change for fiscal year 1998 is 0 percent for hospitals in all areas.

(q) *Applicable percentage change for fiscal year 1999.* The applicable percentage change for fiscal year 1999 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) minus 1.9 percentage points for hospitals in all areas.

(r) *Applicable percentage change for fiscal year 2000.* The applicable percentage change for fiscal year 2000 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 1.8 percentage points for hospitals in all areas.

(s) *Applicable percentage change for fiscal year 2001.* The applicable percentage change for discharges occurring in fiscal year 2001 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas as follows:

(1) For discharges occurring on October 1, 2000 or before April 1, 2001 the percentage increase in the market basket index for prospective payment hospitals (as defined in § 41340(a) of this subchapter) for sole community hospitals and the increase in the market basket index minus 1.1 percentage points for other hospitals in all areas; and

(2) For discharges occurring on April 1, 2001 or before October 1, 2001 the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for sole community hospitals and the increase in the market basket index plus 1.1 percentage points for other hospitals in all areas.

(t) *Applicable percentage change for fiscal years 2002 and 2003.* The applicable percentage change for fiscal years 2002 and 2003 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) minus 0.55 percentage points for hospitals in all areas.

(u) *Applicable percentage change for fiscal year 2004.* The applicable percentage change for fiscal year 2004 is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this subchapter) for hospitals in all areas.

(v) *Maintaining budget neutrality for fiscal year 1985.* (1) For fiscal year 1985, CMS will adjust each of the reduced standardized amounts determined under paragraph (c) of this section as required for fiscal year 1985 to ensure that the estimated amount of aggregate payments made, excluding the hospital-specific portion (that is, the total of the Federal portion of transition payments, plus any adjustments and special treatment of certain classes of hospitals for fiscal year 1985) is not greater or less than 50 percent of the payment amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985 under the law as in effect on April 19, 1983.

(2) The aggregate payments considered under this paragraph exclude payments for per case review by a utilization and quality control quality improvement organization, as allowed under section 1866(a)(1)(F) of the Act.

(w) *Computing Federal rates for inpatient operating costs for hospitals located in large urban and other areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a national prospective payment rate and a regional prospective payment rate for inpatient operating costs, for each region, as follows:

(1) For hospitals located in a large urban area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban area in the United States or in that region; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in an other area in the United States or that region respectively, the rate equals the product of—

(i) The adjusted average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in an other area in the United States or that region; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(x) *Adjusting for different area wage levels.* (1) CMS adjusts the proportion (as estimated by CMS from time to time) of Federal rates for inpatient operating costs computed under paragraph (j) of this section that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The wage index is updated annually.

(2)(i) CMS makes a midyear correction to the wage index for an area only if a hospital can show that—

(A) The intermediary or CMS made an error in tabulating its data; and

(B) The hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

(ii) A midyear correction to the wage index is effective prospectively from the date the change is made to the wage index.

(3) If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.63, see the List of CFR Sections Affected, which appears in the finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

(a) *General rule.* CMS determines a national adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge in Federal fiscal year 2005 and subsequent fiscal years involving inpatient hospital services of a hospital in the United States subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.* (1) For purposes of this section, the following definitions apply:

(i) The term *region* means one of the 9 metropolitan divisions comprising the 50 States and the District of Columbia, established by the Executive Office of Management and Budget for statistical and reporting purposes.

(ii) The term *urban area* means—

(A) A Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by the Executive Office of Management and Budget; or

(B) For discharges occurring on or after October 1, 1983, and before October 1, 2007, the following New England counties are deemed to be parts of urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note); Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(C) The term *rural area* means any area outside an urban area.

(2) For hospitals within an MSA that crosses census division boundaries, the MSA is deemed to belong to the census division in which most of the hospitals within the MSA are located.

(3)(i) For discharges occurring on or after October 1, 2004, a hospital that is located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. Qualifying counties are determined based upon OMB standards, using the most recent OMB standards for delineating statistical areas adopted by CMS.

(ii) For discharges occurring on or after October 1, 2007, hospitals in the following New England counties, if not already located in an urban area, are deemed to be located in urban areas under section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21, 42 U.S.C. 1395ww (note): Litchfield County, Connecticut; York County, Maine; Sagadahoc County, Maine; Merrimack County, New Hampshire; and Newport County, Rhode Island.

(4) For purposes of this section, any change in an MSA designation is recognized on October 1 following the effective date of the change. Such a change in MSA designation may occur as a result of redesignation of an MSA by the Executive Office of Management and Budget.

(5) For hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate is based on the geographic location of the hospital facility at which the discharge occurred.

(c) *Computing the standardized amount.* CMS computes an average standardized amount that is applicable to all hospitals located in all areas, updated by the applicable percentage increase specified in paragraph (d) of this section. CMS standardizes the average standardized amount by excluding an estimate of indirect medical education payments.

(d) *Applicable percentage change for fiscal year 2005 and for subsequent fiscal years.* (1) The applicable percentage change for updating the standardized amount for all hospitals in all areas is—

(i) For fiscal year 2005 through fiscal year 2009, the percentage increase in the market basket index (as defined in §413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section.

(ii) For fiscal year 2010, for discharges—

(A) On or after October 1, 2009 and before April 1, 2010, the percentage increase in the market basket index (as defined in §413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section; and

(B) On or after April 1, 2010 and before October 1, 2010, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less 0.25 percentage point.

(iii) For fiscal year 2011, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this subchapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less 0.25 percentage point.

(iv) For fiscal years 2012 and 2013, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.1 percentage point.

(v) For fiscal year 2014, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraph (d)(2) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.3 percentage point.

(vi) For fiscal years 2015 and 2016, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.2 percentage point.

(vii) For fiscal years 2017, 2018, and 2019, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

(viii) For fiscal year 2020 and subsequent fiscal years, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS).

(2)(i) In the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that does not submit quality data on a quarterly basis to CMS, in the form and manner specified by CMS, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal years 2005 and 2006, by 0.4 percentage points; and

(B) For fiscal year 2007 through 2014, by 2 percentage points.

(C) For fiscal year 2015 and subsequent fiscal years, by one-fourth.

(ii) Any reduction pursuant to this paragraph (d)(2) will apply only to the fiscal year involved and will not be taken into account in computing the applicable percentage change for a subsequent fiscal year.

(3)(i) Beginning fiscal year 2015, in the case of a ''subsection (d) hospital,'' as defined under section 1886(d)(1)(B) of the Act, that is not a meaningful electronic health record (EHR) user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2015, by 33⅓ percent;

(B) For fiscal year 2016, by 66⅔ percent; and

(C) For fiscal year 2017 and subsequent fiscal years, by 100 percent.

(ii) Beginning fiscal year 2022, in the case of a ''subsection (d) Puerto Rico hospital,'' as defined under section 1886(d)(9)(A) of the Act, that is not a meaningful EHR user as defined in part 495 of this chapter for the applicable EHR reporting period and does not receive an exception, three-fourths of the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals is reduced—

(A) For fiscal year 2022, by 33⅓ percent;

(B) For fiscal year 2023, by 66⅔ percent; and

(C) For fiscal year 2024 and subsequent fiscal years, by 100 percent.

(4) *Exception*—(i) *General rules.* The Secretary may, on a case-by-case basis, exempt an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user would result in a significant hardship for the eligible hospital.

(ii) To be considered for an exception, a hospital must submit an application, in the manner specified by CMS, demonstrating that it meets one or more than one of the criteria specified in this paragraph (d)(4) of this section. These types of exceptions are subject to annual renewal, but in no case may a hospital be granted this type of exception for more than 5 years. (See § 495.4 for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.)

(A) During any 90-day period from the beginning of the fiscal year that is 2 years before the payment adjustment year to July 1 of the year before the payment adjustment year, or a later date specified by CMS, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring internet connectivity, and faced insurmountable barriers to obtaining such internet connectivity. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(B)(*1*) During the fiscal year that is 2 fiscal years before the payment adjustment year, the hospital that has previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(*2*) During the fiscal year preceding the payment adjustment year, the hospital that has not previously demonstrated meaningful use faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user. Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS.

(C) The hospital is new in the payment adjustment year, and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare covered patient. For purposes of this exception, the following hospitals are not considered new hospitals:

(*1*) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A hospital that closes and subsequently reopens.

(*3*) A hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital inpatient prospective payment systems.

(iii) *Exception for decertified EHR technology.* Beginning with the fiscal year 2019 payment adjustment year, the Secretary shall exempt an eligible hospital that is not a qualifying eligible hospital from the application of the reduction under paragraph (d)(3) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the eligible hospital has been decertified under ONC's Health IT Certification Program. To be considered for an exception, an eligible hospital must submit an application, in the manner specified by CMS, demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year, and that the eligible hospital made a good faith effort to obtain another certified EHR technology for that EHR reporting period.

(See § 495.4 of this chapter for definitions of payment adjustment year, EHR reporting period, and meaningful EHR user.) Applications requesting this exception must be submitted by July 1 of the year before the applicable payment adjustment year, or a later date specified by CMS. This exception is subject to annual renewal, but in no case may an eligible hospital be granted an exception under paragraph (d)(4) of this section for more than 5 years.

(5) A State in which hospitals are paid for services under section 1814(b)(3) of the Act must—

(i) Adjust the payments to each eligible hospital in the State that is not a meaningful EHR user in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each eligible hospital in the State in a manner comparable to the reduction under paragraph (d)(3) of this section; and

(ii) Provide to the Secretary, by January 1, 2013, a report on the method that it proposes to employ in order to make the requisite payment adjustment described in paragraph (d)(5)(i) of this section.

(e) *Maintaining budget neutrality.* (1) CMS makes an adjustment to the standardized amount to ensure that—

(i) Changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to hospitals are not affected; and

(ii) Except as provided in paragraphs (e)(4) and (h)(4)(vii) of this section, the annual updates and adjustments to the wage index under paragraph (h) of this section are made in a manner that ensures that aggregate payments are not affected; and

(2) CMS also makes an adjustment to the rates to ensure that aggregate payments after implementation of reclassifications under subpart L of this part are equal to the aggregate prospective payments that would have been made in the absence of these provisions.

(3) To the extent CMS determines that changes to the DRG classification and recalibrations of the DRG relative weights for a previous year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in coding or classification of discharges that do not reflect real changes in case mix, CMS may adjust the standardized amount for subsequent fiscal years so as to eliminate the effect of such coding and classification changes.

(4) CMS makes an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the Balanced Budget Act of 1997 (Pub. L. 105–33) and, for discharges on or after October 1, 2004, and before October 1, 2018, the imputed floor under paragraph (h)(4) of this section are equal to the aggregate prospective payments that would have been made in the absence of such provisions as follows:

(i) Beginning October 1, 2008, such adjustment is transitioned from a nationwide to a statewide adjustment as follows:

(A) From October 1, 2008 through September 30, 2009, the wage index is a blend of 20 percent of a wage index with a statewide adjustment and 80 percent of a wage index with a nationwide adjustment.

(B) From October 1, 2009 through September 30, 2010, the wage index is a blend of 50 percent of a wage index with a statewide adjustment and 50 percent of a wage index with a nationwide adjustment.

(ii) Beginning October 1, 2010, such adjustment is a full nationwide adjustment.

(5) CMS makes an adjustment to the standardized amount to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are made in a manner so that aggregate payments to hospitals are not affected.

(f) *Adjustment for outlier payments.* CMS reduces the adjusted average standardized amount determined under paragraph (c) through (e) of this section by a proportion equal to the proportion (estimated by CMS) to the total amount of payments based on DRG prospective payment rates that are additional payments for outlier cases under subpart F of this part.

(g) *Computing Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a national prospective payment rate for inpatient operating costs based on the standardized amount for the fiscal year and the weighting factor determined under § 412.60(b) for that DRG.

(h) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Federal rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the national average level of hospital wages and wage-related costs. The adjustment described in this paragraph (h) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Federal rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual regulation updating the system of payment for inpatient hospital operating costs.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (h)(2) of this section.

(4) For discharges on or after October 1, 2004 and before October 1, 2018, and for discharges on or after October 1, 2021, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

(i) CMS computes the ratio of the lowest-to-highest wage index for each all-urban State;

(ii) CMS computes the average of the ratios of the lowest-to-highest wage indexes of all the all-urban States;

(iii) For each all-urban State, CMS determines the higher of the State's own lowest-to-highest rate (as determined under paragraph (h)(4)(i) of this section) or the average lowest-to-highest rate (as determined under paragraph (h)(4)(ii) of this section);

(iv) For each State, CMS multiplies the rate determined under paragraph (h)(4)(iii) of this section by the highest wage index value in the State;

(v) The product determined under paragraph (h)(4)(iv) of this section is the minimum wage index value for the State, except as provided under paragraph (h)(4)(vi) of this section;

(vi) For discharges on or after October 1, 2012 and before October 1, 2018, and for discharges on or after October 1, 2021, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

(A) CMS estimates a percentage representing the average percentage increase in wage index for hospitals receiving the rural floor due to such floor.

(B) For each all-urban State, CMS makes a onetime determination of the lowest hospital wage index in the State (including all adjustments to the hospital's wage index, except for the rural floor, the rural floor budget neutrality, and the outmigration adjustment) and increases this wage index by the percentage determined under paragraph (h)(4)(vi)(A) of this section, the result of which establishes the alternative minimum wage index value for the State.

(vii) For discharges on or after October 1, 2021, the minimum wage index computed under this paragraph must not be applied in a budget neutral manner.

(5)(i) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2004 and before October 1, 2018, an all-urban State is a State with no rural areas, as defined in this

section, or a State in which there are no hospitals classified as rural. For purposes of this definition, a State with rural areas and with hospitals reclassified as rural under § 412.103 is not an all-urban State.

(ii) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2021, an all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural under section 1886 of the Act. For purposes of this definition, a hospital is classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

(6) If a new rural hospital that is subject to the hospital inpatient prospective payment system opens in a State that has an imputed rural floor and has rural areas, CMS uses the imputed floor as the hospital's wage index until the hospital's first cost report as an inpatient prospective payment system provider is contemporaneous with the cost reporting period being used to develop a given fiscal year's wage index.

(7) Beginning with fiscal year 2023, if CMS determines that a hospital's wage index value for a fiscal year would decrease by more than 5 percent as compared to the hospital's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(i) *Adjusting the wage index to account for commuting patterns of hospital workers*—(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying counties to recognize the commuting patterns of hospital employees. A qualifying county is a county that meets all of the following criteria:

(i) Hospital employees in the county commute to work in an MSA (or MSAs) with a wage index (or wage indices) higher than the wage index of the MSA or rural statewide area in which the county is located.

(ii) At least 10 percent of the county's hospital employees commute to an MSA (or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the county equals or exceeds the 3-year average hourly wage of all hospitals in the MSA or rural statewide area in which the county is located.

(2) *Amount of adjustment.* A hospital located in a county that meets the criteria under paragraphs (i)(1)(i) through (i)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the postreclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the postreclassified wage index of the MSA or rural statewide area in which the qualifying county is located, weighted by the overall percentage of the hospital employees residing in the qualifying county who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.* (i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each county.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying counties and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying county.

(iii) Any wage index adjustment made under this paragraph (i) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the Federal Register.

(iv) A hospital in a qualifying county that receives a wage index adjustment under this paragraph (i) is not eligible for reclassification under subpart L of this part or section 1886(d)(8) of the Act.

(j) *Wage index assignment for rural referral centers for FY 2005.* (1) CMS makes an exception to the wage index assignment of a rural referral center for FY 2005 if the rural referral center meets the following conditions:

(i) The rural referral center was reclassified for FY 2004 by the MGCRB to another MSA, but, upon applying to the MGCRB for FY 2005, was found to be ineligible for reclassification because its average hourly wage was less than 84 percent (but greater than 82 percent) of the average hourly wage of the hospitals geographically located in the MSA to which the rural referral center applied for reclassification for FY 2005.

(ii) The hospital may not qualify for any geographic reclassification under subpart L of this part, effective for discharges occurring on or after October 1, 2004.

(2) CMS will assign a rural referral center that meets the conditions of paragraph (j)(1) of this section the wage index value of the MSA to which it was reclassified by the MGCRB in FY 2004. The wage index assignment is applicable for discharges occurring during the 3-year period beginning October 1, 2004 and ending September 30, 2007.

(k) *Midyear corrections to the wage index.* (1) CMS makes a midyear correction to the wage index for an area only if a hospital can show that—

(i) The intermediary or CMS made an error in tabulating its data; and

(ii) The hospital could not have known about the error, or did not have the opportunity to correct the error, before the beginning of the Federal fiscal year.

(2)(i) Except as provided in paragraph (k)(2)(ii) of this section, a midyear correction to the wage index is effective prospectively from the date the change is made to the wage index.

(ii) Effective October 1, 2005, a change to the wage index may be made retroactively to the beginning of the Federal fiscal year, if, for the fiscal year in question, CMS determines all of the following—

(A) The fiscal intermediary or CMS made an error in tabulating data used for the wage index calculation;

(B) The hospital knew about the error in its wage data and requested the fiscal intermediary and CMS to correct the error both within the established schedule for requesting corrections to the wage data (which is at least before the beginning of the fiscal year for the applicable update to the hospital inpatient prospective payment system) and using the established process; and

(C) CMS agreed before October 1 that the fiscal intermediary or CMS made an error in tabulating the hospital's wage data and the wage index should be corrected.

(l) *Judicial decision.* If a judicial decision reverses a CMS denial of a hospital's wage data revision request, CMS pays the hospital by applying a revised wage index that reflects the revised wage data as if CMS's decision had been favorable rather than unfavorable.

(m) *Adjusting the wage index to account for the Frontier State floor*—(1) *General criteria.* For discharges occurring on or after October 1, 2010, CMS adjusts the hospital wage index for hospitals located in qualifying States to recognize the wage index floor established for frontier States. A qualifying frontier State meets both of the following criteria:

(i) At least 50 percent of counties located within the State have a reported 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 wage index adjustment.* A hospital located in a qualifying State will receive a wage index value not less than 1.00.

(3) *Process for determining and posting wage index adjustments.* (i) CMS uses 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 include a listing of qualifying frontier States and denote the hospitals receiving a wage index increase attributable to this provision in its annual updates to the hospital inpatient prospective payment system published in the FEDERAL REGISTER.

[69 FR 49242, Aug. 11, 2004]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.64, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at *www.govinfo.gov*.

Subpart E—Determination of Transition Period Payment Rates for the Prospective Payment System for Inpatient Operating Costs

§ 412.70 General description.

For discharges occurring on or after April 1, 1988, and before October 1, 1996, payments to a hospital are based on the greater of the national average standardized amount or the sum of 85 percent of the national average standardized amount and 15 percent of the average standardized amount for the region in which the hospital is located.

[57 FR 39822, Sept. 1, 1992, as amended at 58 FR 46338, Sept. 1, 1993]

§ 412.71 Determination of base-year inpatient operating costs.

(a) *Base-year costs.* (1) For each hospital, the intermediary will estimate the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1982 and before September 30, 1983.

(2) If the hospital's last cost reporting period ending before September 30, 1983 is for less than 12 months, the base period will be the hospital's most recent 12-month or longer cost reporting period ending before such short reporting period, with an appropriate adjustment for inflation. (The rules applicable to new hospitals are set forth in § 412.74.)

(b) *Modifications to base-year costs.* Prior to determining the hospital-specific rate, the intermediary will adjust the hospital's estimated base-year inpatient operating costs, as necessary, to include malpractice insurance costs in accordance with § 413.53(a)(1)(i) of this chapter, and exclude the following:

(1) Medical education costs as described in § 413.85 of this chapter.

(2) Capital-related costs as described in § 413.130 of this chapter.

(3) Kidney acquisition costs incurred by hospitals with approved kidney transplant programs as described in § 412.100. Kidney acquisition costs in the base year are determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants covered by Medicare Part A during the base period.

(4) Higher costs that were incurred for purposes of increasing base-year costs.

(5) One-time nonrecurring higher costs or revenue offsets that have the effect of distorting base-year costs as an appropriate basis for computing the hospital-specific rate.

(6) Higher costs that result from changes in hospital accounting principles initiated in the base year.

(7) The costs of qualified nonphysician anesthetists' services, as described in § 412.113(c).

(c) *Hospital's request for adjustment of base-year inpatient operating costs.* (1) Before the date it becomes subject to the prospective payment system for inpatient operating costs, a hospital may request the intermediary to further adjust its estimated base-period costs to take into account the following:

(i) Services paid for under Medicare Part B during the hospital's base year that will be paid for under prospective payments. The base-year costs may be increased to include estimated payments for certain services previously billed as physicians' services before the effective date of § 415.102(a) of this chapter, and estimated payments for nonphysicians' services that were not furnished either directly or under arrangements before October 1, 1983 (the effective date of § 405.310(m) of this chapter), but may not include the costs of anesthetists' services for which a physician employer continues to bill under § 405.553(b)(4) of this chapter.

(ii) The payment of FICA taxes during cost reporting periods subject to the prospective payment system, if the hospital had not paid such taxes for all its employees during its base period and will be required to participate effective January 1, 1984.

(2) If a hospital requests that its base-period costs be adjusted under paragraph (c)(1) of this section, it must timely provide the intermediary with sufficient documentation to justify the

adjustment, and adequate data to compute the adjusted costs. The intermediary decides whether to use part or all of the data on the basis of audit, survey and other information available.

(d) *Intermediary's determination.* The intermediary uses the best data available at the time in estimating each hospital's base-year costs and the modifications to those costs authorized by paragraphs (b) and (c) of this section. The intermediary's estimate of base-year costs and modifications thereto is final and may not be changed after the first day of the first cost reporting period beginning on or after October 1, 1983, except as provided in § 412.72.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 52 FR 33057, Sept. 1, 1987; 57 FR 33897, July 31, 1992; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 60 FR 63188, Dec. 8, 1995; 86 FR 73510, Dec. 27, 2021]

§ 412.72 Modification of base-year costs.

(a) *Bases for modification of base-year costs.* Base-year costs as determined under § 412.71(d) may be modified under the following circumstances:

(1) *Inadvertent omissions.* (i) A hospital that becomes subject to the prospective payment system beginning on or after October 1, 1983 and before November 16, 1983 has until November 15, 1983 to request its intermediary to re-estimate its base-period costs to take into account inadvertent omissions in its previous submissions to the intermediary related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(ii) The intermediary may also initiate changes to the estimation—

(A) For any reason before the date the hospital becomes subject to prospective payment; and

(B) Before November 16, 1983, for corrections to take into account inadvertent omissions in the hospital's previous submissions related to changes made by the prospective payment legislation for purposes of estimating the base-period costs.

(iii) Such omissions pertain to adjustments to exclude capital-related costs and the direct medical education costs of approved educational activities and to adjustments specified in § 412.71(c).

(iv) The intermediary must notify the provider of any change to the hospital-specific amount as a result of the provider's request within 30 days of receipt of the additional data.

(v) Any change to base-period costs made under this paragraph (a)(1) will be made effective retroactively, beginning with the first day of the affected hospital's fiscal year.

(2) *Correction of mathematical errors of calculations.* (i) The hospital must report mathematical errors of calculations to the intermediary within 90 days of the intermediary's notification to the hospital of the hospital's payments rates.

(ii) The intermediary may also identify such errors and initiate their correction during this period.

(iii) The intermediary will either make an appropriate adjustment or notify the hospital that no adjustment is warranted within 30 days of receipt of the hospital's report of an error.

(iv) Corrections of errors of calculation will be effective with the first day of the hospital's first cost reporting period subject to the prospective payment system.

(3) *Recognition of additional costs.* (i) The intermediary may adjust base-period costs to take into account additional costs recognized as allowable costs for the hospital's base year as the result of any of the following:

(A) A reopening and revision of the hospital's base-year notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(B) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(C) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(D) An administrative or judicial review decision under § 405.1831, § 405.1871, or § 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-year notice of amount of program reimbursement.

(ii) The intermediary will recalculate the hospital's base-year costs, incorporating the additional costs recognized as allowable for the hospital's base year. Adjustments to base-year costs to take into account these additional costs—

(A) Will be effective with the first day of the hospital's first cost reporting period beginning on or after the date of the revision, order or finding, or review decision; and

(B) Will not be used to recalculate the hospital-specific portion as determined for fiscal years beginning before the date of the revision, order or finding, or review decision.

(4) *Successful appeal.* The intermediary may modify base-year costs to take into account a successful appeal relating to modifications to base-year costs that were made under § 412.71(b). If a hospital successfully contests a modification to base-year costs—

(i) The intermediary will recalculate the hospital's base-year costs to reflect the modification determined appropriate as a result of the appeal; and

(ii) Such adjustments will be effective retroactively to the time of the intermediary's initial estimation of base-year costs.

(5) *Unlawfully claimed costs.* The intermediary may modify base-year costs to exclude costs that were unlawfully claimed as determined as a result of criminal conviction, imposition of a civil judgment under the False Claims Act (31 U.S.C. 3729–3731), or a proceeding for exclusion from the Medicare program. In addition to adjusting base-year costs, CMS will recover both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates. The amount to be recovered will be computed on the basis of the final resolution of the amount of the inappropriate base-year costs.

(b) *Right to administrative and judicial review.* (1) An intermediary's estimation of a hospital's base-year costs, and modifications, made for purposes of determining the hospital-specific rate, are subject to administrative and judicial review. Review will be available to a hospital upon receipt of its notice of amount of program reimbursement following the close of its cost reporting period, but only with respect to whether the intermediary followed the provisions of §§ 412.71 and 412.72. (Sections 405.1803 and 405.1807 of this chapter set forth the rules for intermediary determinations and notice of amount of program reimbursement and the effect of those determinations.)

(2) In any administrative or judicial review of whether the intermediary used the best data available at the time, as required by § 412.71(d), an intermediary's estimation will be revised on the basis of this review only if the estimation was unreasonable and clearly erroneous in light of the data available at the time the estimation was made.

(3) Specifically excluded from administrative or judicial review are any issues based on data, information, or arguments not presented to the intermediary at the time of the estimation.

§ 412.73 Determination of the hospital-specific rate based on a Federal fiscal year 1982 base period.

(a) *Costs on a per discharge basis.* The intermediary will determine the hospital's estimated adjusted base-year operating cost per discharge by dividing the total adjusted operating costs by the number of discharges in the base period.

(b) *Case-mix adjustment.* The intermediary will divide the adjusted base-year costs by the hospital's 1981 case-mix index. If the hospital's case-mix index is statistically unreliable (as determined by CMS), the hospital's base-year costs will be divided by the lower of the following:

(1) The hospital's estimated case-mix index.

(2) The average case-mix index for the appropriate classifications of all

hospitals subject to cost limits established under § 413.30 of this chapter for cost reporting periods beginning on or after October 1, 1982 and before October 1, 1983.

(c) *Updating base-year costs*—(1) *For Federal fiscal year 1984.* The case-mix adjusted base-year cost per discharge will be updated by the applicable updating factor, that is, the rate-of-increase percentage determined under § 413.40(c)(3) of this chapter, as adjusted for budget neutrality.

(2) *For Federal fiscal year 1985.* The amount determined under paragraph (c)(1) of this section will be updated by the applicable updating factor, as adjusted for budget neutrality.

(3) *For Federal fiscal year 1986.* (i) The amount determined under paragraph (c)(2) of this section is updated by—

(A) Zero percent for the first seven months of the hospital's cost reporting period; and

(B) One-half of one percent for the remaining five months of the hospital's cost reporting period.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1987 (that is, on or after October 1, 1986 and before October 1, 1987), the update factor for the previous cost reporting period is deemed to have been one-half of one percent.

(4) *For Federal fiscal year 1987.* The amount determined under paragraph (c)(3)(ii) of this section is updated by 1.15 percent.

(5) *For Federal fiscal year 1988.* (i) For purposes of determining the prospective payment rates for sole community hospitals under § 412.92(d) for cost reporting periods beginning in Federal fiscal year 1988 (that is, on or after October 1, 1987 and before October 1, 1988), the base-year cost per discharge is updated as follows:

(A) For the first 51 days of the hospital's cost reporting period, by zero percent.

(B) For the next 132 days of the hospital's cost reporting period, by 2.7 percent.

(C) For the remainder of the hospital's cost reporting period, by—

(*1*) 3.0 percent for hospitals located in rural areas;

(*2*) 1.5 percent for hospitals located in large urban areas; and

(*3*) 1.0 percent for hospitals located in other urban areas.

(ii) For purposes of determining the updated base-year costs for cost reporting periods beginning in Federal fiscal year 1989 (that is, beginning on or after October 1, 1988 and before October 1, 1989), the update factor for the cost reporting period beginning during federal Fiscal year 1988 is deemed to have been—

(A) 3.0 percent for hospitals located in rural areas;

(B) 1.5 percent for hospitals located in large urban areas; and

(C) 1.0 percent for hospitals located in other urban areas.

(6) *For Federal fiscal year 1989.* For cost reporting periods beginning in Federal fiscal year 1989, the update factor is determined using the methodology set forth in § 412.63(g).

(7) *For Federal fiscal year 1990.* (i) Except as described in paragraph (c)(7)(ii) of this section, for cost reporting periods beginning in Federal fiscal year 1990, the base-period cost per discharge is updated as follows:

(A) For cost reporting periods beginning on or after October 1, 1989 and before January 1, 1990, by 5.5 percent for discharges occurring before January 1, 1990 and by the factors set forth in paragraph (c)(7)(i)(B) of this section for discharges occurring on or after January 1, 1990.

(B) For cost reporting periods beginning on or after January 1, 1990 and before October 1, 1990, by—

(*1*) 9.72 percent for hospitals located in rural areas;

(*2*) 5.62 percent for hospitals located in large urban areas; and

(*3*) 4.97 percent for hospitals located in other urban areas.

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, the base-period cost per discharge, updated as set forth in paragraph (c)(7)(i) of this section, is reduced by 5.5 percent.

(iii) For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1991 (that is, beginning on or after October 1, 1990 and before October 1, 1991), the update factor for the

cost reporting period beginning during Federal fiscal year 1990 is deemed to have been the percentage change provided for in paragraph (c)(7)(i)(B) of this section.

(8) *For Federal fiscal year 1991.* (i) Except as described in paragraph (c)(8)(ii) of this section, for cost reporting periods beginning in Federal fiscal year 1991, the base-period cost per discharge is updated by 5.2 percent.

(ii) For discharges occurring on or after October 21, 1990 and before January 1, 1991, the base-period cost per discharge is updated by 0.0 percent.

(iii) For purposes of determining the updated base period costs for cost reporting periods beginning in Federal fiscal year 1992, the update factor for the cost reporting period beginning during Federal fiscal year 1991 is deemed to have been the percentage change provided for in paragraph (c)(8)(i) of this section.

(9) *For Federal fiscal years 1992 and 1993.* For Federal fiscal years 1992 and 1993, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(10) *For Federal fiscal year 1994.* For Federal fiscal year 1994, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of the chapter) minus 2.3 percentage points. For purposes of determining the hospital-specific rate for Federal fiscal year 1994 and subsequent years, this update factor is adjusted to take into account the portion of the 12-month cost reporting period beginning during Federal fiscal year 1993 that occurs in Federal fiscal year 1994.

(11) *For Federal fiscal year 1995.* For Federal fiscal year 1995, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 2.2 percentage points.

(12) *For Federal fiscal years 1996 through 2000.* For Federal fiscal years 1996 through 2000, the update factor is the applicable percentage change for other prospective payment hospitals in each respective year as set forth in §§ 412.63(n) through (r).

(13) *For Federal fiscal year 2001.* For Federal fiscal year 2001, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(14) *For Federal fiscal year 2002.* For Federal fiscal year 2002, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter) minus 1.1 percentage points.

(15) *For Federal fiscal year 2003 through Federal fiscal year 2009.* For Federal fiscal year 2003 through Federal fiscal year 2009, the update factor is the percentage increase in the market basket index for prospective payment hospitals (as defined in § 413.40(a) of this chapter).

(16) *For Federal fiscal year 2010 and subsequent years.* For Federal fiscal year 2010 and subsequent years, the update factor is the percentage increase specified in § 412.64(d).

(d) *Budget neutrality*—(1) *Federal fiscal year 1984.* For cost reporting periods beginning on or after October 1, 1983 and before October 1, 1984, CMS adjusts the target rate percentage used under paragraph (c)(1) of this section. This adjustment is based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payments based on the hospital-specific portion of the transition payment rates is neither greater nor less than 75 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1984 under the law in effect before April 20, 1983.

(2) *Federal fiscal year 1985.* For cost reporting periods beginning on or after October 1, 1984 and before October 1, 1985, CMS adjusts the target rate percentage used under paragraph (c)(2) of this section. This adjustment is based on a factor actuarially estimated to ensure that the estimated amount of aggregate Medicare payment based on the hospital-specific portion of the transition payment rates is neither greater nor less than 50 percent of the amounts that would have been payable for the inpatient operating costs for those same hospitals for fiscal year 1985

under the Social Security Act as in effect on April 19, 1983.

(e) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 16787, May 6, 1986; 51 FR 34793, Sept. 30, 1986; 51 FR 42234, Nov. 24, 1986; 52 FR 33057, Sept. 1, 1987; 53 FR 38528, Sept. 30, 1988; 55 FR 15173, Apr. 20, 1990; 56 FR 573, Jan. 7, 1991; 57 FR 39822, Sept. 1, 1992; 58 FR 46338, Sept. 1, 1993; 59 FR 1658, Jan. 12, 1994; 59 FR 32383, June 23, 1994; 65 FR 47106, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005; 75 FR 50413, Aug. 16, 2010]

§ 412.75 Determination of the hospital-specific rate for inpatient operating costs based on a Federal fiscal year 1987 base period.

(a) *Base-period costs*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, for each hospital, the intermediary determines the hospital's Medicare part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(2) *Exceptions.* (i) If the hospital's last cost reporting period ending before September 30, 1988 is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

(ii) If the hospital does not have a cost reporting period ending on or after September 30, 1987 and before September 30, 1988 and does have a cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, that cost reporting period is the base period unless the cost reporting period is for less than 12 months. In that case, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short cost reporting period.

(b) *Costs on a per discharge basis.* The intermediary determines the hospital's average base-period operating cost per discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(c) *Case-mix adjustment.* The intermediary divides the average base-period cost per discharge by the hospital's case-mix index for the base period.

(d) *Updating base-period costs.* For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1988, the update factor is determined using the methodology set forth in §§ 412.73(c)(15) and 412.73(c)(16).

(e) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Notice of hospital-specific rate.* The intermediary furnishes the hospital a notice of its hospital-specific rate, which contains a statment of the hospital's Medicare part A allowable inpatient operating costs, number of Medicare discharges, and case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 1987 base period.

(g) *Right to administrative and judicial review.* An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to a hospital upon receipt of the notice of the hospital-specific rate. This notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(h) *Modification of hospital-specific rate.* (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or

judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the hospital's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the hospital's base-period notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under §§ 405.1831, 405.1871, or 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (h)(1) and (2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(i) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[55 FR 15173, Apr. 20, 1990, as amended at 55 FR 36069, Sept. 4, 1990; 55 FR 39775, Sept. 2, 1990; 56 FR 573, Jan. 7, 1991; 55 FR 46887, Nov. 7, 1990; 57 FR 39822, Sept. 1, 1992; 58 FR 46338, Sept. 1, 1993; 65 FR 47106, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005; 75 FR 50414, Aug. 16, 2010]

§ 412.76 Recovery of excess transition period payment amounts resulting from unlawful claims.

If a hospital's base-year costs, as estimated for purposes of determining the hospital-specific portion, are determined, by criminal conviction or imposition of a civil money penalty or assessment, to include costs that were unlawfully claimed, the hospital's base-period costs are adjusted to remove the effect of the excess costs, and CMS recovers both the excess costs reimbursed for the base period and the additional amounts paid due to the inappropriate increase of the hospital-specific portion of the hospital's transition payment rates.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39822, Sept. 1, 1992. Redesignated at 65 FR 47106, Aug. 1, 2000, and further redesignated at 73 FR 48754, Aug. 19, 2008]

§ 412.77 Determination of the hospital-specific rate for inpatient operating costs for sole community hospitals based on a Federal fiscal year 1996 base period.

(a) *Applicability.* (1) This section applies to a hospital that has been designated as a sole community hospital, as described in § 412.92. If the 1996 hospital-specific rate exceeds the rate that would otherwise apply, that is, either the Federal rate under § 412.64 (or under § 412.63 for periods prior to FY 2005) or the hospital-specific rates for either FY 1982 under § 412.73 or FY 1987 under § 412.75, this 1996 rate will be used in the payment formula set forth in § 412.92(d)(1).

(2) This section applies only to cost reporting periods beginning on or after October 1, 2000.

(3) The formula for determining the hospital-specific costs for hospitals described under paragraph (a)(1) of this section is set forth in paragraph (f) of this section.

(b) *Based costs for hospitals subject to fiscal year 1996 rebasing*—(1) *General rule.*

Except as provided in paragraph (b)(2) of this section, for each hospital eligible under paragraph (a) of this section, the intermediary determines the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 1996 and before September 30, 1997, and computes the hospital-specific rate for purposes of determining prospective payment rates for inpatient operating costs as determined under § 412.92(d).

(2) *Exceptions.* (i) If the hospital's last cost reporting period ending before September 30, 1997 is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

(ii) If the hospital does not have a cost reporting period ending on or after September 30, 1996 and before September 30, 1997, and does have a cost reporting period beginning on or after October 1, 1995 and before October 1, 1996, that cost reporting period is the base period unless the cost reporting period is for less than 12 months. If that cost reporting period is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short cost reporting period. If a hospital has no cost reporting period beginning in fiscal year 1996, the hospital will not have a hospital-specific rate based on fiscal year 1996.

(c) *Costs on a per discharge basis.* The intermediary determines the hospital's average base-period operating cost per discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(d) *Case-mix adjustment.* The intermediary divides the average base-period cost per discharge by the hospital's case-mix index for the base period.

(e) *Updating base-period costs.* For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 1996, the update factor is determined using the methodology set forth in § 412.73(c)(12) through (c)(16).

(f) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(g) *Notice of hospital-specific rates.* The intermediary furnishes a hospital eligible for rebasing a notice of the hospital-specific rate as computed in accordance with this section. The notice will contain a statement of the hospital's Medicare Part A allowable inpatient operating costs, the number of Medicare discharges, and the case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 1996 base period.

(h) *Right to administrative and judicial review.* An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to a hospital upon receipt of the notice of the hospital-specific rate. This notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter.

(i) *Modification of hospital-specific rate.* (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the hospital's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for the recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the hospital's base-period notice of amount of program reimbursement under

§§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under § 405.1831, § 405.1871, or § 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (i)(1) and (i)(2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(j) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[65 FR 47106, Aug. 1, 2000, as amended at 66 FR 32192, June 13, 2001; 70 FR 47485, Aug. 12, 2005; 75 FR 50414, Aug. 16, 2010]

§ 412.78 Determination of the hospital-specific rate for inpatient operating costs for sole community hospitals based on a Federal fiscal year 2006 base period.

(a) *Applicability.* (1) This section applies to a hospital that has been designated as a sole community hospital, as described in § 412.92. If the 2006 hospital-specific rate exceeds the rate that would otherwise apply, that is, either the Federal rate under § 412.64 or the hospital-specific rates for either FY 1982 under § 412.73, FY 1987 under § 412.75 or FY 1996 under § 412.77, this 2006 rate will be used in the payment formula set forth in § 412.92(d)(1).

(2) This section applies only to cost reporting periods beginning on or after January 1, 2009.

(3) The formula for determining the hospital-specific costs for hospitals described under paragraph (a)(1) of this section is set forth in paragraph (f) of this section.

(b) *Based costs for hospitals subject to fiscal year 2006 rebasing*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, for each hospital eligible under paragraph (a) of this section, the intermediary determines the hospital's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period ending on or after September 30, 2006, and before September 30, 2007, and computes the hospital-specific rate for purposes of determining prospective payment rates for inpatient operating costs as determined under § 412.92(d).

(2) *Exceptions.* (i) If the hospital's last cost reporting period ending before September 30, 2007 is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

(ii) If the hospital does not have a cost reporting period ending on or after September 30, 2006 and before September 30, 2007, and does have a cost reporting period beginning on or after October 1, 2005 and before October 1, 2006, that cost reporting period is the base period unless the cost reporting period is for less than 12 months. If that cost reporting period is for less than 12 months, the base period is the hospital's most recent 12-month or longer cost reporting period ending before the short cost reporting period. If a hospital has no cost reporting period beginning in fiscal year 2006, the hospital will not have a hospital-specific rate based on fiscal year 2006.

(c) *Costs on a per discharge basis.* The intermediary determines the hospital's average base-period operating cost per

discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as defined in § 412.4(b) is considered to be a discharge.

(d) *Case-mix adjustment.* The intermediary divides the average base-period cost per discharge by the hospital's case-mix index for the base period.

(e) *Updating base-period costs.* For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 2006, the update factor is determined using the methodology set forth in§§ 412.73(c)(15) and 412.73(c)(16).

(f) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(g) *Notice of hospital-specific rates.* The intermediary furnishes a hospital eligible for rebasing a notice of the hospital-specific rate as computed in accordance with this section. The notice will contain a statement of the hospital's Medicare Part A allowable inpatient operating costs, the number of Medicare discharges, and the case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 2006 base period.

(h) *Right to administrative and judicial review.* An intermediary's determination under this section of the hospital-specific rate for a hospital is subject to administrative and judicial review in accordance with § 412.77(h).

(i) *Modification of hospital-specific rate.* The intermediary recalculates the hospital-specific rate determined under this section in the manner set forth in § 412.77(i).

(j) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate determined under this section in the manner set forth in § 412.77(j).

[73 FR 48754, Aug. 19, 2008, as amended at 75 FR 50414, Aug. 16, 2010]

§ 412.79 Determination of the hospital-specific rate for inpatient operating costs for Medicare-dependent, small rural hospitals based on a Federal fiscal year 2002 base period.

(a) *Base-period costs*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, for each MDH, the intermediary determines the MDH's Medicare Part A allowable inpatient operating costs, as described in § 412.2(c), for the 12-month or longer cost reporting period beginning on or after October 1, 2001, and before October 1, 2002.

(2) *Exceptions.* (i) If the MDH's last cost reporting period beginning before October 1, 2002, is for less than 12 months, the base period is the MDH's most recent 12-month or longer cost reporting period beginning before that short cost reporting period.

(ii) If the MDH does not have a cost reporting period beginning on or after October 1, 2001, and before October 1, 2002, and does have a cost reporting period beginning on or after October 1, 2000, and before October 1, 2001, that cost reporting period is the base period unless the cost reporting is for less than 12 months. In that case, the base period is the MDH's most recent 12-month or longer cost reporting period beginning before that short cost reporting period.

(b) *Costs on a per discharge basis.* The intermediary determines the MDH's average base-period operating cost per discharge by dividing the total operating costs by the number of discharges in the base period. For purposes of this section, a transfer as described in § 412.4(b) is considered to be a discharge.

(c) *Case-mix adjustment.* The intermediary divides the average base-period cost per discharge by the MDH's case-mix index for the base period.

(d) *Updating base period costs.* For purposes of determining the updated base-period costs for cost reporting periods beginning in Federal fiscal year 2002, the update factor is determined using the methodology set forth in § 412.73(c)(14) through (c)(16).

(e) *DRG adjustment.* The applicable hospital-specific cost per discharge is multiplied by the appropriate DRG

weighting factor to determine the hospital-specific base payment amount (target amount) for a particular covered discharge.

(f) *Notice of hospital-specific rate.* The intermediary furnishes the MDH a notice of its hospital-specific rate which contains a statement of the hospital's Medicare Part A allowable inpatient operating costs, number of Medicare discharges, and case-mix index adjustment factor used to determine the hospital's cost per discharge for the Federal fiscal year 2002 base period.

(g) *Right to administrative and judicial review.* An intermediary's determination of the hospital-specific rate for a hospital is subject to administrative and judicial review. Review is available to an MDH upon receipt of the notice of the hospital-specific rate. The notice is treated as a final intermediary determination of the amount of program reimbursement for purposes of subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(h) *Modification of hospital-specific rate.* (1) The intermediary recalculates the hospital-specific rate to reflect the following:

(i) Any modifications that are determined as a result of administrative or judicial review of the hospital-specific rate determinations; or

(ii) Any additional costs that are recognized as allowable costs for the MDH's base period as a result of administrative or judicial review of the base-period notice of amount of program reimbursement.

(2) With respect to either the hospital-specific rate determination or the amount of program reimbursement determination, the actions taken on administrative or judicial review that provide a basis for recalculations of the hospital-specific rate include the following:

(i) A reopening and revision of the MDH's base-period notice of amount of program reimbursement under §§ 405.1885 through 405.1889 of this chapter.

(ii) A prehearing order or finding issued during the provider payment appeals process by the appropriate reviewing authority under § 405.1821 or § 405.1853 of this chapter that resolved a matter at issue in the MDH's base-period notice of amount of program reimbursement.

(iii) An affirmation, modification, or reversal of a Provider Reimbursement Review Board decision by the Administrator of CMS under § 405.1875 of this chapter that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(iv) An administrative or judicial review decision under § 405.1831, § 405.1871, or § 405.1877 of this chapter that is final and no longer subject to review under applicable law or regulations by a higher reviewing authority, and that resolved a matter at issue in the hospital's base-period notice of amount of program reimbursement.

(v) A final, nonappealable court judgment relating to the base-period costs.

(3) The adjustments to the hospital-specific rate made under paragraphs (h)(1) and (2) of this section are effective retroactively to the time of the intermediary's initial determination of the rate.

(i) *Maintaining budget neutrality.* CMS makes an adjustment to the hospital-specific rate to ensure that changes to the DRG classifications and recalibrations of the DRG relative weights are made in a manner so that aggregate payments to section 1886(d) hospitals are not affected.

[71 FR 48137, Aug. 18, 2006, as amended at 75 FR 50414, Aug. 16, 2010]

Subpart F—Payments for Outlier Cases, Special Treatment Payment for New Technology, and Payment Adjustment for Certain Replaced Devices

PAYMENT FOR OUTLIER CASES

§ 412.80 Outlier cases: General provisions.

(a) *Basic rule*—(1) *Discharges occurring on or after October 1, 1994 and before October 1, 1997.* For discharges occurring on or after October 1, 1994, and before October 1, 1997, except as provided in paragraph (b) of this section concerning transferring hospitals, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital

services furnished to a Medicare beneficiary if either of the following conditions is met:

(i) The beneficiary's length-of-stay (including days at the SNF level of care if a SNF bed is not available in the area) exceeds the mean length-of-stay for the applicable DRG by the lesser of the following:

(A) A fixed number of days, as specified by CMS; or

(B) A fixed number of standard deviations, as specified by CMS.

(ii) The beneficiary's length-of-stay does not exceed criteria established under paragraph (a)(1)(i) of this section, but the hospital's charges for covered services furnished to the beneficiary, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(2) *Discharges occurring on or after October 1, 1997 and before October 1, 2001.* For discharges occurring on or after October 1, 1997 and before October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios, as described in § 412.84(h), exceed the DRG payment for the case, payments for indirect costs of graduate medical education (§ 412.105), and payments for serving disproportionate share of low-income patients (§ 412.106), plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(3) *Discharges occurring on or after October 1, 2001.* For discharges occurring on or after October 1, 2001, except as provided in paragraph (b) of this section concerning transfers, CMS provides for additional payment, beyond standard DRG payments and beyond additional payments for new medical services or technology specified in §§ 412.87 and 412.88, to a hospital for covered inpatient hospital services furnished to a Medicare beneficiary if the hospital's charges for covered services, adjusted to operating costs and capital costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case (plus payments for indirect costs of graduate medical education (§ 412.105), payments for serving a disproportionate share of low-income patients (§ 412.106), and additional payments for new medical services or technologies) plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS.

(b) *Outlier cases in transferring hospitals.* CMS provides cost outlier payments to a transferring hospital for cases paid in accordance with § 412.4(f), if the hospital's charges for covered services furnished to the beneficiary, adjusted to costs by applying cost-to-charge ratios as described in § 412.84(h), exceed the DRG payment for the case plus a fixed dollar amount (adjusted for geographic variation in costs) as specified by CMS, divided by the geometric mean length of stay for the DRG, and multiplied by an applicable factor determined as follows:

(1) For transfer cases paid in accordance with § 412.4(f)(1), the applicable factor is equal to the length of stay plus 1 day.

(2) For transfer cases paid in accordance with § 412.4(f)(2), the applicable factor is equal to 0.5 plus the product of the length of stay plus 1 day multiplied by 0.5.

(c) *Publication and revision of outlier criteria.* CMS will issue threshold criteria for determining outlier payment in the annual notice of the prospective payment rates published in accordance with § 412.8(b).

[62 FR 46028, Aug. 29, 1997, as amended at 63 FR 41003, July 31, 1998; 66 FR 46924, Sept. 7, 2001; 67 FR 50111, Aug. 1, 2002]

§ 412.82 Payment for extended length-of-stay cases (day outliers).

(a) For discharges occurring before October 1, 1997, if the hospital stay reflected by a discharge includes covered days of care beyond the applicable threshold criterion, the intermediary will make an additional payment, on a per diem basis, to the discharging hospital for those days. A special request or submission by the hospital is not necessary to initiate this payment.

However, a hospital may request payment for day outliers before the medical review required in paragraph (b) of this section.

(b) The QIO must review and approve to the extent required by CMS—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

(c) Except as provided in § 412.83, the per diem payment made under paragraph (a) of this section is derived by taking a percentage of the average per diem payment for the applicable DRG, as calculated by dividing the Federal prospective payment rate for inpatient operating costs and inpatient capital-related costs determined under subpart D of this part, by the arithmetic mean length of stay for that DRG. CMS issues the applicable percentage of the average per diem payment in the annual publication of the prospective payment rates in accordance with § 412.8(b).

(d) Any days in a covered stay identified as noncovered reduce the number of days reimbursed at the day outlier rate but not to exceed the number of days that occur after the day outlier threshold.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 15326, Apr. 17, 1985; 50 FR 35689, Sept. 3, 1985; 53 FR 38529, Sept. 30, 1988; 57 FR 39822, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997; 85 FR 59020, Sept. 18, 2020]

§ 412.84 Payment for extraordinarily high-cost cases (cost outliers).

(a) A hospital may request its intermediary to make an additional payment for inpatient hospital services that meet the criteria established in accordance with § 412.80(a).

(b) The hospital must request additional payment—

(1) With initial submission of the bill; or

(2) Within 60 days of receipt of the intermediary's initial determination.

(c) Except as specified in paragraph (e) of this section, an additional payment for a cost outlier case is made prior to medical review.

(d) As described in paragraph (f) of this section, the QIO reviews a sample of cost outlier cases after payment. The charges for any services identified as noncovered through this review are denied and any outlier payment made for these services are recovered, as appropriate, after a determination as to the provider's liability has been made.

(e) If the QIO finds a pattern of inappropriate utilization by a hospital, all cost outlier cases from that hospital are subject to medical review, and this review may be conducted prior to payment until the QIO determines that appropriate corrective actions have been taken.

(f) The QIO reviews the cost outlier cases, using the medical records and itemized charges, to verify the following:

(1) The admission was medically necessary and appropriate.

(2) Services were medically necessary and delivered in the most appropriate setting.

(3) Services were ordered by the physician, actually furnished, and not duplicatively billed.

(4) The diagnostic and procedural codings are correct.

(g) The intermediary bases the operating and capital costs of the discharge on the billed charges for covered inpatient services adjusted by the cost to charge ratios applicable to operating and capital costs, respectively, as described in paragraph (h) of this section.

(h) For discharges occurring before October 1, 2003, the operating and capital cost-to-charge ratios used to adjust covered charges are computed annually by the intermediary for each hospital based on the latest available settled cost report for that hospital and charge data for the same time period as that covered by the cost report. For discharges occurring before August 8, 2003, statewide cost-to-charge ratios are used in those instances in which a hospital's operating or capital cost-to-charge ratios fall outside reasonable parameters. CMS sets forth the reasonable parameters and the statewide cost-to-charge ratios in each year's annual notice of prospective payment rates published in the FEDERAL REGISTER in accordance with § 412.8(b).

(i)(1) For discharges occurring on or after August 8, 2003, CMS may specify an alternative to the ratios otherwise applicable under paragraphs (h) or (i)(2) of this section. A hospital may also request that its fiscal intermediary 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 Regional Office.

(2) For discharges occurring on or after October 1, 2003, the operating and capital cost-to-charge ratios applied at the time a claim is processed are 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.

(3) For discharges occurring on or after August 8, 2003, the fiscal intermediary may use a statewide average cost-to-charge ratio if it is unable to determine an accurate operating or capital cost-to-charge ratio for a hospital in one of the following circumstances:

(i) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, 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.)

(ii) Hospitals whose operating or capital 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 § 412.8(b).

(iii) Other hospitals for whom the fiscal intermediary obtains accurate data with which to calculate either an operating or capital cost-to-charge ratio (or both) are not available.

(4) For discharges occurring on or after August 8, 2003, any reconciliation of outlier payments will be based on operating and capital cost-to-charge ratios 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 discharge is settled.

(j) If any of the services are determined to be noncovered, the charges for these services will be deducted from the requested amount of reimbursement but not to exceed the amount claimed above the cost outlier threshold.

(k) Except as provided in paragraph (l) of this section, the additional amount is derived by first taking 80 percent of the difference between the hospital's adjusted operating cost for the discharge (as determined under paragraph (g) of this section) and the operating threshold criteria established under § 412.80(a)(1)(ii); 80 percent is also taken of the difference between the hospital's adjusted capital cost for the discharge (as determined under paragraph (g) of this section) and the capital threshold criteria established under § 412.80(a)(1)(ii). The resulting capital amount is then multiplied by the applicable Federal portion of the payment as determined in § 412.340(a) or § 412.344(a).

(l) For discharges occurring on or after April 1, 1988, the additional payment amount for the DRGs related to burn cases, which are identified in the most recent annual notice of prospective payment rates published in accordance with § 412.8(b), is computed under the provisions of paragraph (k) of this section except that the payment is made using 90 percent of the difference between the hospital's adjusted cost for the discharge and the threshold criteria.

(m) Effective for discharges occurring on or after August 8, 2003, at the time of any reconciliation under paragraph (i)(4) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment will be based upon a widely available index to be established in advance by the Secretary, and will be applied from the midpoint of the cost reporting period to the date of reconciliation.

[50 FR 12741, Mar. 29, 1985, as amended at 50 FR 35689, Sept. 3, 1985; 51 FR 31496, Sept. 3, 1986; 53 FR 38529, Sept. 30, 1988; 54 FR 36494, Sept. 1, 1989; 55 FR 15174, Apr. 20, 1990; 56 FR 43448, Aug. 30, 1991; 57 FR 39823, Sept. 1, 1992; 59 FR 45398, Sept. 1, 1994; 62 FR 46028, Aug. 29, 1997; 68 FR 34515, June 9, 2003; 71 FR 48138, Aug. 18, 2006]

PAYMENT ADJUSTMENT FOR CERTAIN CLINICAL TRIAL CASES AND EXPANDED ACCESS USE IMMUNOTHERAPY

§ 412.85 Payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

(a) *General rule.* For discharges occurring on or after October 1, 2020, the amount of payment for a discharge described in paragraph (b) of this section is adjusted as described in paragraph (c) of this section.

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS–DRG 018 involving expanded access use of immunotherapy, or that are part of an applicable clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge.

(c) *Adjustment.* The DRG weighting factor determined under §412.60(b) is adjusted by a factor that reflects the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy, or are part of an applicable clinical trial, to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of an applicable clinical trial.

[85 FR 59020, Sept. 18, 2020]

§ 412.83 Payment for extraordinarily high-cost day outliers.

For discharges occurring before October 1, 1997, if a discharge that qualifies for an additional payment under the provisions of §412.82 has charges adjusted to costs that exceed the cost outlier threshold criteria for an extraordinarily high-cost case as set forth in §412.80(a)(1)(ii), the additional payment made for the discharge is the greater of—

(a) The applicable per diem payment computed under §412.82 (c) or (d); or

(b) The payment that would be made under §412.84 (i) or (j) if the case had not met the day outlier criteria threshold set forth in §412.80(a)(1)(i).

[53 FR 38529, Sept. 30, 1988, as amended at 62 FR 46028, Aug. 29, 1997. Redesignated at 85 FR 59020, Sept. 18, 2020]

412.86 [Reserved]

ADDITIONAL SPECIAL PAYMENT FOR CERTAIN NEW TECHNOLOGY

§ 412.87 Additional payment for new medical services and technologies: General provisions.

(a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.

(b) *Eligibility criteria.* For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in §412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:

(1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(i) The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(ii) A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:

(A) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

(B) The new medical service or technology offers the ability to diagnose a

medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.

(C) The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the outcomes described in paragraphs (b)(1)(ii)(C(*1*) through (*7*) of this section.

(*1*) A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication.

(*2*) A decreased rate of at least one subsequent diagnostic or therapeutic intervention.

(*3*) A decreased number of future hospitalizations or physician visits.

(*4*) A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time

(*5*) An improvement in one or more activities of daily living

(*6*) An improved quality of life

(*7*) A demonstrated greater medication adherence or compliance.

(D) The totality of the information otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

(iii) Evidence from published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Information source may include the following:

(A) Clinical trials;

(B) Peer reviewed journal articles;

(C) Study results;

(D) Meta-analyses;

(E) Consensus statements;

(F) White papers;

(G) Patient surveys;

(H) Case studies;

(I) Reports;

(J) Systematic literature reviews;

(K) Letters from major healthcare associations;

(L) Editorials and letters to the editor; and,

(M) Public comments.

(N) Other appropriate information sources may be considered.

(iv) The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

(v) The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

(2) A medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new service or technology (depending on when a new code is assigned and data on the new service or technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service or technology will no longer be considered ''new'' under the criterion of this section.

(3) The DRG prospective payment rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate, based on application of a threshold amount to estimated charges incurred with respect to such discharges. To determine whether the payment would be adequate, CMS will determine whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75

percent of one standard deviation beyond the geometric mean standardized charge for all cases in the DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant DRGs if the new medical service or technology occurs in many different DRGs). Standardized charges reflect the actual charges of a case adjusted by the prospective payment system payment factors applicable to an individual hospital, such as the wage index, the indirect medical education adjustment factor, and the disproportionate share adjustment factor.

(c) *Eligibility criteria for alternative pathway for certain transformative new devices.* For discharges occurring on or after October 1, 2020, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical devices, if the following conditions are met:

(1) A new medical device is part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

(2) A medical device that meets the condition in paragraph (c)(1) of this section will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

(3) The new medical device meets the conditions described in paragraph (b)(3) of this section.

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* (1)(i) A new medical product is designated by FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation; or

(ii) For discharges occurring on or after October 1, 2021, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.

(2) A medical product that meets the condition in paragraph (d)(1) of this section will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Social Security Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

(3) The new medical product meets the conditions described in paragraph (b)(3) of this section.

(e) *FDA status requirement.* CMS only considers, for add-on payments for a particular fiscal year, an application for which one of the following conditions are met at the time of new technology add-on payment application submission:

(1) The new medical service or technology is FDA market authorized for the indication that is the subject of the new technology add-on payment application.

(2) The new medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing of the request is provided to CMS.

(f) *Announcement of determinations and deadline for consideration of new medical service or technology applications, and conditional approval for certain antimicrobial products.* (1) CMS will consider whether a new medical service or technology meets the eligibility criteria specified in paragraph (b), (c), or

(d) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the IPPS. CMS will only consider any particular new medical service or technology for add-on payments under paragraph (b), (c), or (d) of this section.

(2) Except as provided for in paragraph (f)(3) of this section, CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by May 1 prior to the particular fiscal year.

(3) A technology for which an application is submitted under an alternative pathway for certain antimicrobial products under paragraph (d) of this section that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments may be conditionally approved for the new technology add-on payment for that fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

[66 FR 46924, Sept. 7, 2001, as amended at 68 FR 45469, Aug. 1, 2003; 69 FR 49243, Aug. 11, 2004; 73 FR 48755, Aug. 19, 2008; 74 FR 43997, Aug. 27, 2009; 82 FR 38511, Aug. 14, 2017; 84 FR 42611, Aug. 16, 2019; 85 FR 59020, Sept. 18, 2020; 88 FR 59331, Aug. 28, 2023]

§ 412.88 Additional payment for new medical service or technology.

(a) For discharges involving new medical services or technologies that meet the criteria specified in § 412.87, Medicare payment will be:

(1) One of the following:

(i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);

(ii) The payment determined under § 412.4(f) for transfer cases;

(iii) The payment determined under § 412.92(d) for sole community hospitals; or

(iv) The payment determined under § 412.108(c) for Medicare-dependent hospitals; plus

(2)(i) *For discharges occurring before October 1, 2019.* If the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(A) 50 percent of the costs of the new medical service or technology; or

(B) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

(ii) *For discharges occurring on or after October 1, 2019.* (A) Except as provided under paragraph (a)(2)(ii)(B) of this section, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(*1*) 65 percent of the costs of the new medical service or technology; or

(*2*) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

(B) For a medical product designated by FDA as a Qualified Infectious Disease Product or, for discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(*1*) 75 percent of the costs of the new medical service or technology; or

(*2*) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

(C) For a medical product that is a gene therapy that is indicated and used specifically for the treatment of sickle cell disease and approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule, for discharges occurring on or after October 1, 2024, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

(*1*) 75 percent of the costs of the new medical service or technology; or

(*2*) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

(b)(1) *For discharges occurring before October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus—

(i) 65 percent of the estimated costs of the new medical service or technology;

(ii) For a medical product designated by FDA as a Qualified Infectious Disease Product, 75 percent of the estimated costs of the new medical service or technology; or

(iii) For discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, 75 percent of the estimated costs of the new medical service or technology.

(iv) For discharges occurring on or after October 1, 2024, for a medical product that is a gene therapy that is indicated and used specifically for the treatment of sickle cell disease and approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule, 75 percent of the estimated costs of the new medical service or technology.

[66 FR 46924, Sept. 7, 2001, as amended at 67 FR 50111, Aug. 1, 2002; 69 FR 49244, Aug. 11, 2004; 72 FR 47411, Aug. 22, 2007; 84 FR 42612, Aug. 16, 2019; 85 FR 59021, Sept. 18, 2020; 89 FR 69910, Aug. 28, 2024]

PAYMENT ADJUSTMENT FOR CERTAIN REPLACED DEVICES

§ 412.89 Payment adjustment for certain replaced devices.

(a) *General rule.* For discharges occurring on or after October 1, 2007, the amount of payment for a discharge described in paragraph (b) of this section is reduced when—

(1) A device is replaced without cost to the hospital;

(2) The provider received full credit for the cost of a device; or

(3) The provider receives a credit equal to 50 percent or more of the cost of the device.

(b) *Discharges subject to payment adjustment.* (1) Payment is reduced in accordance with paragraph (a) of this section only if the implantation of the device determines the DRG assignment.

(2) CMS lists the DRGs that qualify under paragraph (b)(1) of this section in the annual final rule for the hospital inpatient prospective payment system.

(c) *Amount of reduction.* (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DRG payment.

[72 FR 47411, Aug. 22, 2007]

Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

§ 412.90 General rules.

(a) *Sole community hospitals.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hosptials, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under § 412.92(a), its prospective payment rates for inpatient operating costs are determined under § 412.92(d).

(b) *Referral center.* CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in § 412.96.

(c) [Reserved]

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney

transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

(e) *Hospitals located in areas that are reclassified from urban to rural.* (1) CMS adjusts the rural Federal payment amounts for inpatient operating costs for hospitals located in geographic areas that are reclassified from urban to rural as defined in subpart D of this part. This adjustment is set forth in § 412.102.

(2) CMS establishes a procedure by which certain individual hospitals located in urban areas may apply for reclassification as rural. The criteria for reclassification are set forth in § 412.103.

(f) *Hospitals that have a high percentage of ESRD beneficiary discharges.* CMS makes an additional payment to a hospital if ten percent or more of its total Medicare discharges in a cost reporting period beginning on or after October 1, 1984 are ESRD beneficiary discharges. In determining ESRD discharges, discharges in DRG Nos. 302, 316, and 317 are excluded. The criteria for this additional payment are set forth in § 412.104.

(g) *Hosptials that incur indirect costs for graduate medical education programs.* CMS makes an additional payment for inpatient operating costs to a hospital for indirect medical education costs attributable to an approved graduate medical education program. The criteria for this additional payment are set forth in § 412.105.

(h) *Hospitals that serve a disproportionate share of low-income patients.* For discharges occurring on or after May 1, 1986, CMS makes an additional payment for inpatient operating costs to hospitals that serve a disproportionate share of low-income patients. The criteria for this additional payment are set forth in § 412.106.

(i) *Hospitals that receive an additional update for FYs 1998 and 1999.* For FYs 1998 and 1999, CMS makes an upward adjustment to the standardized amounts for certain hospitals that do not receive indirect medical education or disproportionate share payments and are not Medicare- dependent, small rural hospitals. The criteria for identifying these hospitals are set forth in § 412.107.

(j) *Medicare-dependent, small rural hospitals.* For cost reporting periods beginning on or after April 1, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before January 1, 2025, CMS adjusts the prospective payment rates for inpatient operating costs determined under subparts D and E of this part if a hospital is classified as a Medicare-dependent, small rural hospital.

(k) *Essential access community hospitals (EACHs).* If a hospital was designated as an EACH by CMS as described in § 412.109(a) and is located in a rural area as defined in § 412.109(b), CMS determines the prospective payment rate for that hospital, as it does for sole community hospitals, under § 412.92(d).

[57 FR 39823, Sept. 1, 1992, as amended at 58 FR 30669, May 26, 1993; 62 FR 46028, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999; 65 FR 47047, Aug. 1, 2000; 70 FR 47485, Aug. 12, 2005; 71 FR 48138, Aug. 18, 2006; 82 FR 38511, Aug. 14, 2017; 83 FR 41701, Aug. 17, 2018; 86 FR 73511, Dec. 27, 2021; 88 FR 59331, Aug. 28, 2023; 89 FR 69910, Aug. 28, 2024]

§ 412.92 Special treatment: Sole community hospitals.

(a) *Criteria for classification as a sole community hospital.* CMS classifies a hospital as a sole community hospital if it is located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

(i) No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;

(ii) The hospital has fewer than 50 beds and the MAC certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due

to the unavailability of necessary specialty services at the community hospital; or

(iii) Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

(4) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (a)(1)(i) and (ii) of this section are met. For the mileage and rural location criteria in paragraph (a) of this section and the mileage, accessibility, and travel time criteria specified in paragraphs (a)(1) through (3) of this section, the hospital must demonstrate that the main campus and its remote location(s) each independently satisfy those requirements.

(b) *Classification procedures*—(1) *Request for classification as sole community hospital.* (i) The hospital must make its request to its MAC.

(ii) If a hospital is seeking sole community hospital classification under paragraph (a)(1)(i) or (a)(1)(ii) of this section, the hospital must include the following information with its request:

(A) The hospital must provide patient origin data (for example, the number of patients from each zip code from which the hospital draws inpatients) for all inpatient discharges to document the boundaries of its service area.

(B) The hospital must provide patient origin data from all other hospitals located within a 35 mile radius of it or, if larger, within its service area, to document that no more than 25 percent of either all of the population or the Medicare beneficiaries residing in the hospital's service area and hospitalized for inpatient care were admitted to other like hospitals for care.

(iii)(A) If the hospital is unable to obtain the information required under paragraph (b)(1)(ii)(A) of this section concerning the residences of Medicare beneficiaries who were inpatients in other hospitals located within a 35 mile radius of the hospital or, if larger, within the hospital's service area, the hospital may request that CMS provide this information.

(B) If a hospital obtains the information as requested under paragraph (b)(1)(iii)(A) of this section, that information is used by both the MAC and CMS in making the determination of the residences of Medicare beneficiaries under paragraphs (b)(1)(iii) and (b)(1)(iv) of this section, regardless of any other information concerning the residences of Medicare beneficiaries submitted by the hospital.

(iv) The MAC reviews the request and send the request, with its recommendation, to CMS.

(v) CMS reviews the request and the MAC's recommendation and forwards its approval or disapproval to the MAC.

(2) *Effective dates of classification.*(i) For applications received on or before September 30, 2018, sole community hospital status is effective 30 days after the date of CMS' written notification of approval, except as provided in paragraph (b)(2)(v) of this section. For applications received on or after October 1, 2018, sole community hospital status is effective as of the date the MAC receives the complete application, except as provided in paragraphs (b)(2)(v) and (vi) of this section.

(ii) When a court order or a determination by the Provider Reimbursement Review Board (PRRB) reverses a CMS denial of sole community hospital status and no further appeal is made, the sole community hospital status is effective as follows:

(A) If the hospital's application was submitted prior to October 1, 1983, its

status as a sole community hospital is effective at the start of the cost reporting period for which it sought exemption from the cost limits.

(B) If the hospital's application for sole community hospital status was received on or after October 1, 1983 and on or before September 30, 2018, the effective date is 30 days after the date of CMS' original written notification of denial.

(C) If the hospital's application for sole community hospital status was received on or after October 1, 2018, the effective date is as provided in paragraph (b)(2)(i) of this section.

(iii) When a hospital is granted retroactive approval of sole community hospital status by a court order or a PRRB decision and the hospital wishes its sole community hospital status terminated before the date of the court order or PRRB determination, it must submit written notice to the CMS regional office within 90 days of the court order or PRRB decision. A written request received after the 90-day period is effective no later than 30 days after the request is submitted.

(iv) For applications received on or before September 30, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification. For applications received on or after October 1, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after the effective date as provided in paragraph (b)(2)(i) of this section.

(v) If a hospital that is classified as an MDH under § 412.108 applies for classification as a sole community hospital because its status under the MDH program expires with the expiration of the MDH program, and that hospital's sole community hospital status is approved, the effective date of approval of sole community hospital status is the day following the expiration date of the MDH program if the hospital—

(A) Applies for classification as a sole community hospital prior to 30 days before the expiration of the MDH program; and

(B) Requests that sole community hospital status be effective with the expiration of the MDH program.

(vi) For applications received on or after October 1, 2023, where eligibility for sole community hospital classification is dependent on the hospital's merger with another hospital, sole community hospital status is effective as of the effective date of the approved merger if, and only if, the date that the Medicare administrative contractor (MAC) receives the complete application is within 90 days of CMS' written notification to the hospital of the approval of the merger.

(3) *Duration of classification.* (i) An approved classification as a sole community hospital remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. An approved sole community hospital must notify the MAC if any change that is specified in paragraph (b)(3)(ii) of this section occurs. If CMS determines that a sole community hospital failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date that the hospital no longer met the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(ii) A sole community hospital must report the following to the MAC within 30 days of the event:

(A) The opening of a new hospital in its service area.

(B) The opening of a new road between itself and a like provider within 35 miles.

(C) An increase in the number of beds to more than 50 if the hospital qualifies as a sole community hospital under paragraph (a)(1)(ii) of this section.

(D) Its geographic classification changes.

(E) Any changes to the driving conditions that result in a decrease in the amount of travel time between itself and a like provider if the hospital qualifies as a sole community hospital under paragraph (a)(3) of this section.

(iii) A sole community hospital must report to the MAC if it becomes aware of any change that would affect its

classification as a sole community hospital beyond the events listed in paragraph (b)(3)(ii) of this section within 30 days of the event. If CMS determines that a sole community hospital has failed to comply with this requirement, CMS will cancel the hospital's classification as a sole community hospital effective with the date the hospital became aware of the event that resulted in the sole community hospital no longer meeting the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(iv) A sole community hospital must report to the MAC any factor or information that could have affected its initial classification as a sole community hospital.

(A) If CMS determines that a sole community hospital has failed to comply with the requirement of paragraph ((b)(3)(iv) of this section, CMS may cancel the hospital's classification as a sole community hospital effective with the date the hospital failed to meet the criteria for such classification, consistent with the provisions of § 405.1885 of this chapter.

(B) Effective on or after October 1, 2012, if a hospital reports to CMS any factor or information that could have affected its initial determination and CMS determines that the hospital should not have qualified for sole community hospital status, CMS will cancel the sole community hospital status effective 30 days from the date of the determination.

(4) *Cancellation of classification.* (i) A hospital may at any time request cancellation of its classification as a sole community hospital, and be paid at rates determined under subparts D and E of this part, as appropriate.

(ii) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(iii) If a hospital requests that its sole community hospital classification be cancelled, it may not be reclassified as a sole community hospital unless it meets the following conditions:

(A) At least one full year has passed since the effective date of its cancellation.

(B) The hospital meets the qualifying criteria set forth in paragraph (a) of this section in effect at the time it reapplies.

(5) *Automatic classification as a sole community hospital.* A hospital that has been granted an exemption from the hospital cost limits before October 1, 1983, or whose request for the exemption was received by the appropriate intermediary before October 1, 1983, and was subsequently approved, is automatically classified as a sole community hospital unless that classification has been cancelled under paragraph (b)(3) of this section, or there is a change in the circumstances under which the classification was approved.

(c) *Terminology.* As used in this section—

(1) The term *miles* means the shortest distance in miles measured over improved roads. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road includes the paved surface up to the front entrance of the hospital.

(2) The term *like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

(3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital. If the most recent cost reporting period ending before the hospital applies for classification as a sole community hospital is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

(d) *Determining prospective payment rates for inpatient operating costs for sole*

community hospitals—(1) *General rule.* For cost reporting periods beginning on or after April 1, 1990, a sole community hospital is paid based on whichever of the following amounts yields the greatest aggregate payment for the cost reporting period:

(i) The Federal payment rate applicable to the hospitals as determined under subpart D of this part.

(ii) The hospital-specific rate as determined under § 412.73.

(iii) The hospital-specific rate as determined under § 412.75.

(iv) For cost reporting periods beginning on or after October 1, 2000, the hospital-specific rate as determined under § 412.77 (calculated under the transition schedule set forth in paragraph (d)(2) of this section).

(v) For cost reporting periods beginning on or after January 1, 2009, the hospital-specific rate as determined under § 412.78.

(2) *Transition of FY 1996 hospital-specific rate.* The MAC calculates the hospital-specific rate determined on the basis of the fiscal year 1996 base period rate as follows:

(i) For Federal fiscal year 2001, the hospital-specific rate is the sum of 75 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 25 percent of the hospital-specific rate as determined under § 412.77.

(ii) For Federal fiscal year 2002, the hospital-specific rate is the sum of 50 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 50 percent of the hospital-specific rate as determined under § 412.77.

(iii) For Federal fiscal year 2003, the hospital-specific rate is the sum of 25 percent of the greater of the amounts specified in paragraph (d)(1)(i), (d)(1)(ii), or (d)(1)(iii) of this section, plus 75 percent of the hospital-specific rate as determined under § 412.77.

(iv) For Federal fiscal year 2004 and any subsequent fiscal years, the hospital-specific rate is 100 percent of the hospital-specific rate specified in paragraph (d)(1)(iv) of this section.

(3) *Adjustment to payments.* A sole community hospital may receive an adjustment to its payments to take into account a significant decrease in the number of discharges, as described in paragraph (e) of this section.

(e) *Additional payments to sole community hospitals experiencing a significant volume decrease.* (1) For cost reporting periods beginning on or after October 1, 1983, the MAC provides for a payment adjustment for a sole community hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (e)(2) of this section a more than five percent decrease in its total discharges of inpatients as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the MAC must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a sole community hospital must submit its request no later than 180 days after the date on the MAC's Notice of Amount of Program Reimbursement—

(i) Submit to the MAC documentation demonstrating the size of the decrease in discharges, and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) Effective for cost reporting periods beginning before October 1, 2017, the MAC determines a lump sum adjustment amount not to exceed the difference between the hospital's Medicare inpatient operating costs and the hospital's total DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105). Effective for cost reporting periods beginning on or after October 1, 2017, the MAC determines a

lump sum adjustment amount equal to the difference between the hospital's fixed Medicare inpatient operating costs and the hospital's total MS–DRG revenue based on MS–DRG-adjusted prospective payment rates for inpatient operating costs (including outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made for inpatient operating costs for hospitals that serve a disproportionate share of low-income patients as determined under § 412.106 and for indirect medical education costs as determined under § 412.105) multiplied by the ratio of the hospital's fixed inpatient operating costs to its total inpatient operating costs.

(i) In determining the adjustment amount, the MAC considers—

(A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) The MAC makes its determination within 180 days from the date it receives the hospital's request and all other necessary information.

(iii) The MAC determination is subject to review under subpart R of part 405 of this chapter.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.92, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.96 Special treatment: Referral centers.

(a) *Criteria for classification as a referral center: Basic rule.* CMS classifies a hospital as a referral center only if the hospital is a Medicare participating acute care hospital and meets the applicable criteria of paragraph (b) or (c) of this section.

(b) *Criteria for cost reporting periods beginning on or after October 1, 1983.* The hospital meets either of the following criteria:

(1) The hospital is located in a rural area (as defined in subpart D of this part) and has the following number of beds, as determined under the provisions of § 412.105(b) available for use:

(i) Effective for discharges occurring before April 1, 1988, the hospital has 500 or more beds.

(ii) Effective for discharges occurring on or after April 1, 1988, the hospital has 275 or more beds during its most recently completed cost reporting period unless the hospital submits written documentation with its application that its bed count has changed since the close of its most recently completed cost reporting period for one or more of the following reasons:

(A) Merger of two or more hospitals.

(B) Reopening of acute care beds previously closed for renovation.

(C) Transfer to the prospective payment system of acute care beds previously classified as part of an excluded unit.

(D) Expansion of acute care beds available for use and permanently maintained for lodging inpatients, excluding beds in corridors and other temporary beds.

(2) The hospital shows that—(i) At least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the staff of the hospital; and

(ii) At least 60 percent of the hospital's Medicare patients live more than 25 miles from the hospital, and at least 60 percent of all the services that the hospital furnishes to Medicare beneficiaries are furnished to beneficiaries who live more than 25 miles from the hospital.

(c) *Alternative criteria.* For cost reporting periods beginning on or after October 1, 1985, a hospital that does not meet the criteria of paragraph (b) of this section is classified as a referral center if it is located in a rural area (as defined in subpart D of this part) and meets the criteria specified in paragraphs (c)(1) and (c)(2) of this section and at least one of the three criteria specified in paragraphs (c)(3), (c)(4), and (c)(5) of this section.

(1) *Case-mix index.* CMS sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under §412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (h) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by CMS from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to CMS. The hospital's case-mix index for discharges (not including discharges from units excluded from the prospective payment system under subpart B of this part) during the same Federal fiscal year used to compute the case mix index values under paragraph (h) of this section must be at least equal to—

(i) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the national or regional case-mix index value; or

(ii) For hospitals applying for rural referral center status for cost—reporting periods beginning on or after October 1, 1986, the national case-mix index value as established by CMS or the median case-mix index value for urban hospitals located in each region. In calculating the median case-mix index for each region, CMS excludes the case-mix indexes of hospitals receiving indirect medical education payments as provided in §412.105.

(2) *Number of discharges.* (i) CMS sets forth the national and regional number of discharges in each year's annual notice of prospective payment rates published under §412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (i) of this section. Except as provided in paragraph (c)(2)(ii) of this section for an osteopathic hospital, for the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section, its number of discharges (not including discharges from units excluded from the prospective payments system under subpart B of this part or from newborn units) is at least equal to—

(A) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1985 and before October 1, 1986, the number of discharges under either the national or regional criterion; or

(B) For hospitals applying for rural referral center status for cost reporting periods beginning on or after October 1, 1986, 5,000 discharges or, if less, the median number of discharges for urban hospitals located in each region.

(ii) For cost reporting periods beginning on or after January 1, 1986, an osteopathic hospital, recognized by the American Osteopathic Healthcare Association (or any successor organization), that is located in a rural area must have at least 3,000 discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section to meet the number of discharges criterion. A hospital applying for rural referral center status under the number of discharges criterion in this paragraph must demonstrate its status as an osteopathic hospital.

(iii) If the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section is for less than 12 months or longer than 12 months, the hospital's number of discharges for that cost reporting period will be annualized to estimate the total number of discharges for a 12-month cost reporting period.

(3) *Medical staff.* More than 50 percent of the hospital's active medical staff are specialists who meet one of the following conditions:

(i) Are certified as specialists by one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(ii) Have completed the current training requirements for admission to the certification examination of one of the Member Boards of the American Board of Medical Specialties or the Advisory Board of Osteopathic Specialists.

(iii) Have successfully completed a residency program in a medical specialty accredited by the Accreditation Council of Graduate Medical Education or the American Osteopathic Association.

(4) *Source of inpatients.* At least 60 percent of all its discharges are for inpatients who reside more than 25 miles from the hospital.

(5) *Volume of referrals.* At least 40 percent of all inpatients treated at the hospital are referred from other hospitals or from physicians not on the hospital's staff.

(d) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at § 413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location(s) are required to demonstrate that the criteria specified in paragraphs (b)(1) and (2) and (c)(1) through (5) of this section are met. For the rural location criteria specified in paragraphs (b)(1) and (c) of this section and the mileage criteria specified in paragraphs (b)(2)(ii) and (c)(4) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy those requirements.

(e) *Payment to rural referral centers.* Effective for discharges occurring on or after April 1, 1988, and before October 1, 1994, a hospital that is located in a rural area and meets the criteria of paragraphs (b)(1), (b)(2) or (c) of this section is paid prospective payments for inpatient operating costs per discharge based on the applicable other urban payment rates as determined in accordance with § 412.63, as adjusted by the hospital's area wage index.

(f) [Reserved]

(g) *Hospital cancellation of referral center status.* (1) A hospital may at any time request cancellation of its status as a referral center and be paid prospective payments per discharge based on the applicable rural rate, as determined in accordance with subpart D of this part.

(2) The cancellation becomes effective no later than 30 days after the date the hospital submits its request.

(3) If a hospital requests that its referral center status be canceled, it may not be reclassified as a referral center unless it meets the qualifying criteria set forth in paragraph (a) of this section in effect at the time it reapplies.

(4) A hospital that submits a written request on or after October 1, 2007, to cancel its reclassification under § 412.103(g) is deemed to have cancelled its status as a rural referral center effective on the same date the cancellation under § 412.103(g) takes effect. The provision of this paragraph (g)(4) applies to hospitals that qualify as rural referral centers under § 412.96 based on rural status acquired under § 412.103.

(h) *Methodology for calculating case-mix index criteria.* CMS calculates the national and regional case-mix index value criteria as described in paragraphs (h)(1) through (h)(4) of this section.

(1) *Updating process.* CMS updates the national and regional case-mix index standards using the best available data from hospitals subject to the prospective payment system for the Federal fiscal year.

(2) *Source of data.* In making the calculations described in paragraph (h)(1) of this section, CMS uses all inpatient hospital bills received for discharges subject to prospective payment during the Federal fiscal year being monitored.

(3) *Effective date.* CMS sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are used to determine if a hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

(i) *Methodology for calculating number of discharges criteria.* For purposes of determining compliance with the national or regional number of discharges criterion under paragraph (c)(2) of this section, CMS calculates the criteria as follows:

(1) *Updating process.* CMS updates the national and regional number of discharges using the best available data

for levels of admissions or discharges or both.

(2) *Source of data.* In making the calculations described in paragraph (i)(1) of this section, CMS uses the best available hospital admissions or discharge data.

(3) *Annual notice.* CMS sets forth the national and regional criteria in the annual notice of prospective payment rates published under § 412.8(b). These criteria are compared to an applying hospital's number of discharges for the same cost reporting period used to develop the regional criteria in this section in determining if the hospital qualifies for referral center status for cost reporting periods beginning on or after October 1 of the Federal fiscal year to which the notice applies.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.96, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.98 [Reserved]

§ 412.100 Special treatment: Kidney transplant programs.

(a) *Adjustments for kidney transplant programs.* (1) CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104 of this chapter) to remove the net costs associated with kidney acquisition.

(2)(i) Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.

(ii) IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

(b) Costs of kidney acquisition. Kidney acquisition costs include allowable costs incurred in the acquisition of a kidney from a living or a deceased donor by the hospital, or from a deceased donor by an organ procurement organization. These costs are listed in § 413.402(b) of this chapter.

[86 FR 73511, Dec. 27, 2021, as amended at 87 FR 72286, Nov. 23, 2022]

§ 412.101 Special treatment: Inpatient hospital payment adjustment for low-volume hospitals.

(a) *Definitions.* Beginning in FY 2011, the terms used in this section are defined as follows:

Medicare discharges means discharge of inpatients entitled to Medicare Part A, including discharges associated with individuals whose inpatient benefits are exhausted or whose stay was not covered by Medicare and also discharges of individuals enrolled in a MA organization under Medicare Part C.

Road miles means ''miles'' as defined in § 412.92(c)(1).

(b) *General considerations.* (1) CMS provides an additional payment to a qualifying hospital for the higher incremental costs associated with a low volume of discharges. The amount of any additional payment for a qualifying hospital is calculated in accordance with paragraph (c) of this section.

(2) In order to qualify for this adjustment, a hospital must meet the following criteria, subject to the provisions of paragraph (e) of this section:

(i) For FY 2005 through FY 2010, the portion of FY 2025 beginning on January 1, 2025 and subsequent fiscal years, a hospital must have fewer than 200 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 25 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(ii) For FY 2011 through FY 2018, a hospital must have fewer than 1,600 Medicare discharges, as defined in paragraph (a) of this section, during the fiscal year, based on the hospital's Medicare discharges from the most recently available MedPAR data as determined by CMS, and be located more than 15 road miles, as defined in paragraph (a) of this section, from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(iii) For FY 2019 through FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024, a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, and be located more than 15 road miles (as defined in paragraph (a) of this section) from the nearest ''subsection (d)'' (section 1886(d) of the Act) hospital.

(3) In order to qualify for the adjustment, a hospital must provide its fiscal intermediary or Medicare administrative contractor with sufficient evidence that it meets the distance requirement specified under paragraph (b)(2) of this section. The fiscal intermediary or Medicare administrative contractor will base its determination of whether the distance requirement is satisfied upon the evidence presented by the hospital and other relevant evidence, such as maps, mapping software, and inquiries to State and local police, transportation officials, or other government officials.

(c) *Determination of the adjustment amount.* The low-volume adjustment for hospitals that qualify under paragraph (b) of this section is as follows for the applicable fiscal year:

(1) For FY 2005 through FY 2010, the portion of FY 2025 beginning on January 1, 2025, and subsequent fiscal years, the adjustment is an additional 25 percent for each Medicare discharge.

(2) For FY 2011 through FY 2018, the adjustment is as follows:

(i) For low-volume hospitals with 200 or fewer Medicare discharges (as defined in paragraph (a) of this section), the adjustment is an additional 25 percent for each Medicare discharge.

(ii) For low-volume hospitals with Medicare discharges (as defined in paragraph (a) of this section) of more than 200 and fewer than 1,600, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(4/14)—(number of Medicare discharges/5600)]. The ''number of Medicare discharges'' is determined as described in paragraph (b)(2)(ii) of this section.

(3) For FY 2019 through FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024, the adjustment is as follows:

(i) For low-volume hospitals with 500 or fewer total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment is an additional 25 percent for each Medicare discharge.

(ii) For low-volume hospitals with more than 500 and fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on the hospital's most recently submitted cost report, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330)−(number of total discharges/13,200)]. ''Total discharges'' is determined as described in paragraph (b)(2)(iii) of this section.

(d) *Eligibility of new hospitals for the adjustment.* For FYs 2005 through 2010 and FY 2019 and subsequent fiscal years, a new hospital will be eligible for a low-volume adjustment under this section once it has submitted a cost report for a cost reporting period that indicates that it meets discharge requirements during the applicable fiscal year and has provided its Medicare administrative contractor with sufficient evidence that it meets the distance requirement, as specified in paragraph (b)(2) of this section.

(e) *Special treatment regarding hospitals operated by the Indian Health Service (IHS) or a Tribe.* (1) For discharges occurring in FY 2018 and subsequent fiscal years—

(i) A hospital operated by the IHS or a Tribe will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital operated by the IHS or a Tribe.

(ii) A hospital, other than a hospital operated by the IHS or a Tribe, will be considered to meet the applicable mileage criterion specified under paragraph (b)(2) of this section if it is located more than the specified number of road miles from the nearest subsection (d) hospital other than a subsection (d)

hospital operated by the IHS or a Tribe.

(2) Subject to the requirements set forth in § 405.1885 of this chapter, a hospital may request the application of the policy described in paragraph (e)(1) of this section for discharges occurring in FY 2011 through FY 2017.

[75 FR 50414, Aug. 16, 2010, as amended at 78 FR 50965, Aug. 19, 2013; 49 FR 15030, Mar. 18, 2014; 79 FR 50352, Aug. 22, 2014; 80 FR 49767, Aug. 17, 2015; 82 FR 38511, Aug. 14, 2017; 83 FR 41702, Aug. 17, 2018; 84 FR 42613, Aug. 16, 2019; 88 FR 59332, Aug. 28, 2023; 89 FR 69911, Aug. 28, 2024]

§ 412.102 Special treatment: Hospitals located in areas that are changing from urban to rural as a result of a geographic redesignation.

An urban hospital that was part of an MSA, but was redesignated as rural as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for 2 successive fiscal years as provided in paragraphs (a) and (b) of this section.

(a) *First year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, the hospital's rural average standardized amount and disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its geographic redesignation and the rural standardized amount and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, the hospital's rural disproportionate share payments as described in § 412.106 are adjusted on the basis of an additional amount that equals two-thirds of the difference between the disproportionate share payments as an urban hospital applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payment otherwise applicable to the Federal fiscal year for which the adjustment is made.

(b) *Second year adjustment.* (1) Effective on or after October 1, 1983 and before October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its rural average standardized amount and disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the urban standardized amount and disproportionate share payments applicable to the hospital before its redesignation and the rural standardized amounts and disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

(2) Effective on or after October 1, 2014, if a hospital's status continues to be rural as a result of geographic redesignation, its disproportionate share payments are adjusted on the basis of an additional amount that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its geographic redesignation to a rural area as a result of implementation of the most recent OMB standards for delineating statistical areas adopted by CMS and the rural disproportionate share payments otherwise applicable to the Federal fiscal year for which the adjustment is made.

[79 FR 50353, Aug. 22, 2014]

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

(a) *General criteria.* A prospective payment hospital that is located in an urban area (as defined in subpart D of this part) may be reclassified as a rural hospital if it submits an application in accordance with paragraph (b) of this section and meets any of the following conditions:

(1) The hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, using the Rural-Urban Commuting Area codes and additional criteria, as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA),

which is available at the web link provided in the most recent FEDERAL REGISTER notice issued by HRSA defining rural areas.

(2) The hospital is located in an area designated by any law or regulation of the State in which it is located as a rural area, or the hospital is designated as a rural hospital by State law or regulation.

(3) The hospital would qualify as a rural referral center as set forth in §412.96, or as a sole community hospital as set forth in §412.92, if the hospital were located in a rural area.

(4) For any period after September 30, 2004 and before October 1, 2006, a CAH in a county that, in FY 2004, was not part of a MSA as defined by the Office of Management and Budget, but as of FY 2005 was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in §485.610(b) of this chapter if it meets any of the requirements in paragraphs (a)(1), (a)(2), or (a)(3) of this section.

(5) For any period after September 30, 2009, and before October 1, 2011, a CAH in a county that, in FY 2009, was not part of an MSA as defined by the Office of Management and Budget, but, as of FY 2010, was included as part of an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on November 20, 2008, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement in §485.610(b) of this chapter if it meets any of the requirements under paragraph (a)(1), (a)(2), or (a)(3) of this section.

(6) For any period on or after October 1, 2014, a CAH in a county that was not in an urban area as defined by the Office of Management and Budget (OMB), but was included in an urban area as a result of the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, may be reclassified as being located in a rural area for purposes of meeting the rural location requirement at §485.610(b) of this chapter for a period of 2 years, beginning with the date of the implementation of the new labor market area delineations, if it meets any of the requirements under paragraph (a)(1), (a)(2), or (a)(3) of this section.

(7) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at §413.65 of this chapter as a main campus and a remote location of a hospital, the hospital is required to demonstrate that the main campus and its remote location(s) each independently satisfy the location conditions specified in paragraphs (a)(1) and (2) of this section.

(8) For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at §413.65 of this chapter as a main campus and a remote location of a hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area (as defined in §412.64(b) and including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act).

(b) *Application requirements*—(1) *Written application.* A hospital seeking reclassification under this section must submit a complete application in writing to CMS in accordance with paragraphs (b)(2) and (b)(3) of this section.

(2) *Contents of application.* An application is complete if it contains an explanation of how the hospital meets the condition that constitutes the basis of the request for reclassification set forth in paragraph (a) of this section, including data and documentation necessary to support the request.

(3) *Submission of application.* An application may be submitted to the CMS Regional Office by the requesting hospital by mail or by facsimile or other electronic means.

(4) *Notification by CMS.* Within 5 business days after receiving the hospital's application, the CMS Regional Office

will send the hospital a letter acknowledging receipt, with a copy to the CMS Central Office.

(5) *Filing date.* The filing date of the application is the date CMS receives the application.

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §412.64(e)(1)(ii), (e)(2) and (4), and (h) for the payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of this section no later than 60 days after the public display date at the Office of the Federal Register of the inpatient prospective payment system proposed rule for the next Federal fiscal year.

(c) *CMS review.* The CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date.

(d) *Effective dates of reclassification.* (1) Except as specified in paragraphs (d)(2) and (3) of this section, CMS will consider a hospital that satisfies any of the criteria set forth in paragraph (a) of this section as being located in the rural area of the State in which the hospital is located as of that filing date.

(2) If a hospital's complete application is received in CMS by September 1, 2000, and satisfies any of the criteria set forth in paragraph (a) of this section, CMS will consider the filing date to be January 1, 2000.

(3) CMS will consider a hospital that satisfies the criteria set forth in paragraph (a)(3) of this section and which qualifies for sole community hospital status in accordance with the requirements of §412.92(b)(2)(vi) as being located in the rural area of the State in which the hospital is located as of the effective date set forth in §412.92(b)(2)(vi).

(e) *Withdrawal of application.* A hospital may withdraw an application at any time prior to the date of CMS's decision as set forth in paragraph (c) of this section.

(f) *Duration of classification.* An approved reclassification under this section remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved.

(g) *Cancellation of classification*—(1) *Hospitals other than rural referral centers.* Except as provided in paragraph (g)(2) of this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of its current cost reporting period.

(ii) The hospital's cancellation of the classification is effective beginning with the next full cost reporting period.

(iii) The provisions of paragraphs (g)(1)(i) and (ii) of this section are effective for all written requests submitted by hospitals before October 1, 2019 to cancel rural reclassifications.

(2) *Hospitals classified as rural referral centers.* For a hospital that was classified as a rural referral center under §412.96 based on rural reclassification under this section—

(i) A hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a Federal fiscal year and after being paid as rural for at least one 12-month cost reporting period.

(ii) The hospital's cancellation of the classification is not effective until it has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the Federal fiscal year following such 12-month cost reporting period.

(iii) The provisions of paragraphs (g)(2)(i) and (ii) of this section are effective for all written requests submitted by hospitals on or after October 1, 2007 and before October 1, 2019, to cancel rural reclassifications.

(3) *Cancellation of rural reclassification on or after October 1, 2019, and before October 1, 2021.* For all written requests submitted by hospitals on or after October, 1, 2019, and before October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 120 days prior to the end of a

Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(4) *Cancellation of rural reclassification on or after October 1, 2021.* For all written requests submitted by hospitals on or after October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification and not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(5) *Special rule for hospitals that opt to receive county out-migration adjustment.* A rural reclassification will be considered canceled effective for the next Federal fiscal year when a hospital, by submitting a request to CMS within 45 days of the date of public display of the proposed rule for the next Federal fiscal year at the Office of the Federal Register, opts to accept and receives its county out-migration wage index adjustment determined under section 1886(d)(13) of the Act in lieu of its geographic reclassification described under section 1886(d)(8)(B) of the Act.

[65 FR 47048, Aug. 1, 2000, as amended at 69 FR 49244, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47486, Aug. 12, 2005; 72 FR 47411, Aug. 22, 2007; 74 FR 43997, Aug. 27, 2009; 79 FR 50353, Aug. 22, 2014; 81 FR 57267, Aug. 22, 2016; 83 FR 41703, Aug. 17, 2018; 84 FR 42613, Aug. 16, 2019; 86 FR 45519, Aug. 13, 2021; 87 FR 49403, Aug. 10, 2022; 88 FR 59332, Aug. 28, 2023; 89 FR 69911, Aug. 28, 2024]

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into any of the following MS–DRGs, where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges:

(1) MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis).

(2) MS–DRGs 650 and 651 (Kidney Transplant with Hemodialysis with MCC, without MCC, respectively).

(3) MS–DRGs 682, 683, and 684 (Renal Failure with MCC, with CC, without CC/MCC, respectively).

(b) *Additional payment.* A hospital that meets the criteria of paragraph (a) of this section is paid an additional payment for each ESRD beneficiary discharge except those excluded under paragraph (a) of this section.

(1) The payment is based on the estimated weekly cost of dialysis and the average length of stay of ESRD beneficiaries for the hospital.

(2)(i) Effective for cost reporting periods beginning before October 1, 2024, the estimated weekly cost of dialysis is the average number of dialysis sessions furnished per week during the 12-month period that ended June 30, 1983, multiplied by the average cost of dialysis for the same period.

(ii) Effective for cost reporting periods beginning on or after October 1, 2024, the estimated weekly cost of dialysis is calculated as 3 dialysis sessions per week multiplied by the applicable ESRD prospective payment system (PPS) base rate (as defined in 42 CFR 413.171) that corresponds with the fiscal year in which the cost reporting period begins.

(3) The average cost of dialysis used for purposes of determining the estimated weekly cost of dialysis for cost reporting periods beginning before October 1, 2024, includes only those costs determined to be directly related to the renal dialysis services. (These costs include salary, employee health and welfare, drugs, supplies, and laboratory services.)

(4) Effective for cost reporting periods beginning before October 1, 2024, the average cost of dialysis is reviewed and adjusted, if appropriate, at the time the composite rate reimbursement for outpatient dialysis is reviewed.

(5) The payment to a hospital equals the average length of stay of ESRD beneficiaries in the hospital, expressed

as a ratio to one week, times the estimated weekly cost of dialysis multiplied by the number of ESRD beneficiary discharges except for those excluded under paragraph (a) of this section. This payment is made only on the Federal portion of the payment rate.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39824, Sept. 1, 1992; 69 FR 49244, Aug. 11, 2004; 73 FR 48755, Aug. 19, 2008; 85 FR 59021, Sept. 18, 2020; 89 FR 69911, Aug. 28, 2024]

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

CMS makes an additional payment to hospitals for indirect medical education costs using the following procedures:

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's ratio of full-time equivalent residents (except as limited under paragraph (f) of this section) to the number of beds (as determined under paragraph (b) of this section).

(i) Except for the special circumstances for Medicare GME affiliated groups, emergency Medicare GME affiliated groups, and new programs described in paragraphs (f)(1)(vi) and (f)(1)(vii) of this section for cost reporting periods beginning on or after October 1, 1997, and for the special circumstances for closed hospitals or closed programs described in paragraph (f)(1)(ix) of this section for cost reporting periods beginning on or after October 1, 2002, and for Rural Track Programs within their 5-year cap building period described in paragraph (f)(1)(x)(B) in cost reporting periods beginning on or after October 1, 2022, this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section, and adding to the capped numerator any dental and podiatric full-time equivalent residents.

(ii)(A) For new programs started prior to October 1, 2012, the exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually for which the full-time equivalent cap may be adjusted based on the period of years equal to the minimum accredited length of each new program.

(B) For new programs started on or after October 1, 2012, the exception for new programs described in paragraph (f)(1)(vii) of this section applies to each new program individually during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(1) of this chapter, and prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with § 413.79(e)(3) of this chapter.

(iii) The exception for closed hospitals and closed programs described in paragraph (f)(1)(ix) of this section applies only through the end of the first 12-month cost reporting period in which the receiving hospital trains the displaced full-time equivalent residents.

(iv) In the cost reporting period following the last year the receiving hospital's full-time equivalent cap is adjusted for the displaced resident(s), the resident-to-bed ratio cap in paragraph (a)(1) of this section is calculated as if the displaced full-time equivalent residents had not trained at the receiving hospital in the prior year.

(2) The hospital's DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs, excluding outlier payments for inpatient operating costs determined under subpart F of this part and additional payments made under the provisions of § 412.106.

(b) *Determination of the number of beds.* For purposes of this section, the number of beds in a hospital is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting

period. This count of available bed days excludes bed days associated with—

(1) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month);

(2) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days;

(3) Beds in excluded distinct part hospital units;

(4) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services.

(5) Beds or bassinets in the healthy newborn nursery; and

(6) Custodial care beds.

(c) *Measurement for teaching activity.* The factor representing the effect of teaching activity on inpatient operating costs equals .405 for discharges occurring on or after May 1, 1986.

(d) *Determination of education adjustment factor.* Each hospital's education adjustment factor is calculated as follows:

(1) *Step one.* A factor representing the sum of 1.00 plus the hospital's ratio of full-time equivalent residents to beds, as determined under paragraph (a)(1) of this section, excluding beds temporarily added during the time frame that the Public Health Emergency as defined in §400.200 of this chapter is in effect, is raised to an exponential power equal to the factor set forth in paragraph (c) of this section.

(2) *Step two.* The factor derived from step one is reduced by 1.00.

(3) *Step three.* The factor derived from completing steps one and two is multiplied by ''c'', and where ''c'' is equal to the following:

(i) For discharges occurring on or after October 1, 1988, and before October 1, 1997, 1.89.

(ii) For discharges occurring during fiscal year 1998, 1.72.

(iii) For discharges occurring during fiscal year 1999, 1.6.

(iv) For discharges occurring during fiscal year 2000, 1.47.

(A) Each hospital receives an amount that is equal in the aggregate to the difference between the amount of payments made to the hospital if ''c'' equaled 1.6, rather than 1.47.

(B) The payment of this amount will not affect any other payments, determinations, or budget neutrality adjustments.

(v) For fiscal year 2001—

(A) For discharges occurring on or after October 1, 2000 and before April 1, 2001, 1.54.

(B) For discharges occurring on or after April 1, 2001 and before October 1, 2001, the adjustment factor is determined as if ''c'' equaled 1.66, rather than 1.54. This payment increase will not apply to discharges occurring after fiscal year 2001 and will not be taken into account in calculating the payment amounts applicable for discharges occurring after fiscal year 2001.

(vi) For discharges occurring during fiscal year 2002, 1.6.

(vii) For discharges occurring on or after October 1, 2002 and before April 1, 2004, 1.35.

(viii) For discharges occurring on or after April 1, 2004 and before October 1, 2004, 1.47.

(ix) For discharges occurring during fiscal year 2005, 1.42.

(x) For discharges occurring during fiscal year 2006, 1.37.

(xi) For discharges occurring during fiscal year 2007, 1.32.

(xii) For discharges occurring during fiscal year 2008 and thereafter, 1.35.

(4) For discharges occurring on or after July 1, 2005, with respect to FTE residents added as a result of increases in the FTE resident cap under paragraph (f)(1)(iv)(C) of this section, the factor derived from completing steps one and two is multiplied by 'c', where 'c' is equal to 0.66.

(e)(1) *Determination of payment amount.* Each hospital's indirect medical education payment under the prospective payment system for inpatient operating costs is determined by multiplying the total DRG revenue for inpatient operating costs, as determined under paragraph (a)(2) of this section,

by the applicable education adjustment factor derived in paragraph (d) of this section.

(2) For discharges occurring on or after July 1, 2005, a hospital that counts additional residents as a result of an increase in its FTE resident cap under paragraph (f)(1)(iv)(C) of this section will receive indirect medical education payments based on the sum of the following two indirect medical education adjustment factors:

(i) An adjustment factor that is calculated using the schedule of formula multipliers in paragraph (d)(3) of this section and the hospital's FTE resident count, not including residents attributable to an increase in its FTE cap under paragraph (f)(1)(iv)(C) under this section; and

(ii) An adjustment factor that is calculated using the applicable formula multiplier under paragraph (d)(4) of this section, and the additional number of FTE residents that are attributable to the increase in the hospital's FTE resident cap under paragraph (f)(1)(iv)(C) in this section.

(f) *Determining the total number of full-time equivalent residents for cost reporting periods beginning on or after July 1, 1991.* (1) For cost reporting periods beginning on or after July 1, 1991, the count of full-time equivalent residents for the purpose of determining the indirect medical education adjustment is determined as follows:

(i) The resident must be enrolled in an approved teaching program. An approved teaching program is one that meets one of the following requirements:

(A) Is approved by one of the national organizations listed in §415.152 of this chapter.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(*1*) The Directory of Graduate Medical Education Programs published by the American Medical Association.

(*2*) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(D) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

(ii) In order to be counted, the resident must be assigned to one of the following areas:

(A) The portion of the hospital subject to the hospital inpatient prospective payment system.

(B) The outpatient department of a hospital that meets provider-based status as defined at §413.65(a)(2) of this subchapter.

(C) The portions of a hospital located in Puerto Rico that are subject to the hospital inpatient prospective payment system, including off-campus outpatient departments that meet provider-based status as defined at §413.65(a)(2) of this subchapter.

(D) The portions of a hospital that are reimbursed under a reimbursement system authorized under section 1814(b)(3) of the Act.

(E) Effective for discharges occurring on or after October 1, 1997, the time spent by a resident in a nonprovider setting in patient care activities, as defined in §413.75(b) of this subchapter, under an approved medical residency training program is counted towards the determination of full-time equivalency if the criteria set forth in §413.78(c), (d), (e), (f), or (g) of this subchapter, as applicable, are met.

(iii)(A) Full-time equivalent status is based on the total time necessary to fill a residency slot. No individual may be counted as more than one full-time equivalent. If a resident is assigned to more than one hospital, the resident counts as a partial full-time equivalent based on the proportion of time worked in any areas of the hospital listed in paragraph (f)(1)(ii) of this section to the total time worked by the resident. A hospital cannot claim the time spent by residents training at another hospital, unless the exception provided at §413.78(i) of this chapter applies. A part-time resident or one working in an area of the hospital other than

those listed under paragraph (f)(1)(ii) of this section (such as a freestanding family practice center or an excluded hospital unit) would be counted as a partial full-time equivalent based on the proportion of time assigned to an area of the hospital listed in paragraph (f)(1)(ii) of this section, compared to the total time necessary to fill a full-time residency slot.

(B) The time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable.

(C) Effective for cost reporting periods beginning on or after January 1, 1983, except for research activities described in paragraph (f)(1)(iii)(B) of this section, the time a resident is training in an approved medical residency program in a hospital setting, as described in paragraphs (f)(1)(ii)(A) through (f)(1)(ii)(D) of this section, must be spent in either patient care activities, as defined in §413.75(b) of this subchapter, or in nonpatient care activities, such as didactic conferences and seminars, to be counted. This provision may not be applied in a manner that would require the reopening of settled cost reports, except those cost reports on which, as of March 23, 2010, there is a jurisdictionally proper appeal pending on direct GME or IME payments.

(D) Effective for cost reporting periods beginning on or after January 1, 1983, the time spent by a resident in an approved medical residency program on vacation, sick leave, or other approved leave that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program is countable. This provision may not be applied in a manner that would require the reopening of settled cost reports, except those cost reports on which, as of March 23, 2010, there is a jurisdictionally proper appeal pending on direct GME or IME payments.

(iv)(A) Effective for discharges occurring on or after October 1, 1997, the total number of FTE residents in the fields of allopathic and osteopathic medicine in either a hospital or a nonhospital setting that meets the criteria listed in paragraph (f)(1)(ii) of this section may not exceed the number of such FTE residents in the hospital (or, in the case of a hospital located in a rural area, effective for discharges occurring on or after April 1, 2000, 130 percent of that number) with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996.

(B)(*1*) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital's otherwise applicable FTE resident cap may be reduced if its reference resident level, as determined under §413.79(c)(1)(ii)(A) of this subchapter, is less than its otherwise applicable FTE resident cap in a reference cost reporting period, in accordance with the provisions of §413.79(c)(3) of this subchapter. The reduction is 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level.

(*2*) Effective for portions of cost reporting periods beginning on or after July 1, 2011, a hospital's otherwise applicable FTE resident cap may be reduced if its reference resident level, as determined under §413.79(c)(1)(ii)(B) of this subchapter, is less than its otherwise applicable FTE resident cap in a reference cost reporting period, in accordance with the provisions of §413.79(m) of this subchapter. The reduction shall take into account the hospital's FTE resident cap as reduced under paragraph (f)(1)(iv)(B)(*1*). The reduction is 65 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level.

(C)(*1*) Effective for portions of cost reporting periods beginning on or after July 1, 2005, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap (up to 25 additional FTEs) if the criteria specified in §413.79(c)(4) of this subchapter are met.

(*2*) Effective for portions of cost reporting periods beginning on or after July 1, 2011, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap (up to 75 additional FTEs) if the criteria specified in §413.79(n) of this subchapter are met.

(*3*) Effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to

receive an increase in its otherwise applicable FTE resident cap if the criteria specified in §413.79(p) of this subchapter are met.

(*4*) Effective for portions of cost reporting periods beginning on or after July 1, 2026, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in §413.79(q) of this subchapter are met.

(D) A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, may retain the increases to its full-time equivalent resident cap that it received under paragraphs (f)(1)(iv)(A) and (f)(1)(vii) of this section while it was located in a rural area. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, the redesignated urban hospital may retain any existing increases to its FTE resident cap that it had received prior to when the redesignation became effective. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, the redesignated urban hospital may receive an increase to its FTE resident cap for a new program, in accordance with paragraph (e) of this section, if it received a letter of accreditation for the new program and/or started training residents in the new program prior to the redesignation becoming effective.

(v)(A) For a hospital's cost reporting periods beginning on or after October 1, 1997, and before October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident counts (subject to the requirements listed in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding cost reporting period.

(B) For a hospital's cost reporting periods beginning on or after October 1, 1998, the total number of full-time equivalent residents for payment purposes is equal to the average of the actual full-time equivalent resident count (subject to the requirements set forth in paragraphs (f)(1)(ii)(C) and (f)(1)(iv) of this section) for that cost reporting period and the preceding two cost reporting periods.

(C) For new programs started prior to October 1, 2012, if a hospital qualified for an adjustment to the limit established under paragraph (f)(1)(iv) of this section for new medical residency programs created under paragraph (f)(1)(vii) of this section, the count of residents participating in new medical residency training programs above the number included in the hospital's full-time equivalent count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in paragraph (f)(1)(v)(B) of this section for a period of years. Residents participating in new medical residency training programs are included in the hospital's full-time equivalent count before applying the averaging rules after the period of years has expired. For purposes of this paragraph, for each new program started, the period of years equals the minimum accredited length for each new program. The period of years for each new program begins when the first resident begins training in each new program.

(D) For new programs started on or after October 1, 2012, for hospitals for which the full-time equivalent cap may be adjusted in accordance with §413.79(e) of this chapter, full-time equivalent residents participating in new medical residency training programs are excluded from the hospital's full-time equivalent count before applying the averaging rules during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with §413.79(e)(1) of this chapter, and prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started, for hospitals for which the full-time equivalent cap may be adjusted in accordance with §413.79(e)(3)

of this chapter. Beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the full-time equivalent cap may be adjusted in accordance with §413.79(e)(1) of this chapter, and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for hospitals for which the full-time equivalent cap may be adjusted in accordance with §413.79(e)(3) of this chapter, full-time equivalent residents participating in new medical residency training programs are included in the hospital's full-time equivalent count before applying the averaging rules in paragraph (f)(1)(v)(B) of this section.

(E) Subject to the provisions of paragraph (f)(1)(ix) of this section, full-time equivalent residents that are displaced by the closure of either another hospital or another hospital's program are added to the full-time equivalent count after applying the averaging rules in paragraph (f)(1)(v)(B) of this section for the receiving hospital for the duration of time that the displaced residents are training at the receiving hospital.

(F) (*1*) Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, and beginning before October 1, 2022, full-time equivalent residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in paragraph (f)(1)(v)(B) of this section.

(*2*) Subject to the provisions of paragraph (f)(1)(x) of this section, for cost reporting periods beginning on or after October 1, 2022, full-time equivalent residents at an urban hospital or rural hospital in a Rural Track Program are excluded from the rolling average calculation described in paragraph (f)(1)(v)(B) of this section during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(vi) Hospitals that are part of the same Medicare GME affiliated group or emergency Medicare GME affiliated group (as defined in §413.75(b) of this subchapter) may elect to apply the limit specified in paragraph (f)(1)(iv) of this section on an aggregate basis, as specified in §413.79(f) of this subchapter. Effective beginning on or after October 1, 2008, home and host hospitals with valid emergency Medicare GME affiliation agreements are exempt from the application of the ratio cap specified in paragraph (a)(1)(i) of this section.

(vii) (A) If a hospital establishes a new medical residency training program, as defined in §413.79(l) of this subchapter, the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of §413.79(e) of this subchapter.

(B)(*1*) A hospital that, as of December 27, 2020, has a full-time equivalent cap of less than 1.0 FTE based on a cost reporting period beginning before October 1, 1997, that begins training residents in a new medical residency training program, as defined at §413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains at least 1.0 FTE in such new medical residency training program(s), to be calculated in accordance with §413.79(e) of this subchapter.

(*2*) A hospital that has a full-time equivalent cap of no more than 3.0 FTEs based on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, that begins training residents in a new medical residency training program, as defined at §413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains more than 3.0 FTE in such new medical residency training program(s), to be calculated in accordance with the provisions of §413.79(e) of this subchapter.

(viii) A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995 and on or before August

5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was completed, may receive an adjustment to its full-time equivalent cap in accordance with the provisions of § 413.79(g) of this subchapter.

(ix)(A) A hospital may receive a temporary adjustment to its FTE resident cap to reflect displaced residents added because of another hospital's closure if the hospital meets the criteria specified in § 413.79(h)(1) and (2) of this subchapter. If a hospital that closes its residency training program agrees to temporarily reduce its FTE resident cap according to the criteria specified in § 413.79(h)(1) and (h)(3)(ii)of this subchapter, another hospital(s) may receive a temporary adjustment to its FTE resident cap to reflect displaced residents added because of the closure of the residency training program if the criteria specified in § 413.79(h)(1) and (h)(3)(i) of this subchapter are met.

(B) A hospital may receive a permanent adjustment to its FTE resident cap as a result of slots that were redistributed from a closed hospital, as defined at § 413.79(h)(1)(i) of this subchapter, if the hospital meets the requirements at § 413.79(o) of this subchapter.

(x) (A) For rural track programs started in a cost reporting period beginning before October 1, 2022, an urban hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.79(k) of this subchapter.

(B) For cost reporting periods beginning on or after October 1, 2022, an urban hospital or rural hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter) that is a Rural Track Program (as defined at § 413.75(b) of this subchapter), or adds an additional site to a Rural Track Program, may include in its FTE count residents in the Rural Track Program in accordance with the applicable provisions of § 413.79(k) of this subchapter.

(xi) Effective for discharges occurring in cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional FTEs to the extent that the additional residents would have been counted as primary care residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence, in accordance with the provisions of § 413.79(i) of this subchapter.

(xii) For discharges occurring on or after October 1, 1997, a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had been previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if the hospital meets the criteria and other provisions of § 413.79(j) of this subchapter.

(xiii) For a hospital that was paid under part 413 of this chapter as a hospital excluded from the hospital inpatient prospective payment system and that subsequently becomes subject to the hospital inpatient prospective payment system, the limit on the total number of FTE residents for payment purposes is determined based on the data from the hospital's most recent cost reporting period ending on or before December 31, 1996.

(xiv) In the case of a merger of a hospital that is excluded from the hospital inpatient prospective payment system and an acute care hospital subject to the hospital inpatient prospective payment system, if the surviving hospital is a hospital subject to the hospital inpatient prospective payment system and no hospital unit that is excluded from the hospital inpatient prospective payment system is created as a result of the merger, the surviving hospital's number of FTE residents for payment purposes is equal to the sum of the FTE resident count of the hospital that is subject to the hospital inpatient prospective payment system as determined under paragraph (f)(1)(ii)(B) of this section and the limit on the total number of FTE residents for the excluded hospital as determined under paragraph (f)(1)(xiii) of this section.

(xv) Effective for discharges occurring on or after October 1, 2005, an urban hospital that reclassifies to a rural area under §412.103 for fewer than 10 continuous years and then subsequently elects to revert back to urban classification will not be allowed to retain the adjustment to its IME FTE resident cap that it received as a result of being reclassified as rural.

(2) To include a resident in the full-time equivalent count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(i) A listing, by specialty, of all residents assigned to the hospital and providing services to the hospital during the cost reporting period.

(ii) The name and social security number of each resident.

(iii) The dates the resident is assigned to the hospital.

(iv) The dates the resident is assigned to other hospitals or other freestanding providers and any nonprovider setting during the cost reporting period.

(v) The proportion of the total time necessary to fill a residency slot that the resident is assigned to an area of the hospital listed under paragraph (f)(1)(ii) of this section.

(3) Fiscal intermediaries must verify the correct count of residents.

(g) *Indirect medical education payment for managed care enrollees.* For portions of cost reporting periods occurring on or after January 1, 1998, a payment is made to a hospital for indirect medical education costs, as determined under paragraph (e) of this section, for discharges associated with individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act or with a Medicare + Choice organization under title XVIII, Part C of the Act during the period, according to the applicable payment percentages described in §§413.76(c)(1) through (c)(5) of this subchapter.

[50 FR 12741, Mar. 29, 1985. Redesignated at 56 FR 43241, Aug. 30, 1991]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.105, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

(a) *General considerations.* (1) The factors considered in determining whether a hospital qualifies for a payment adjustment include the number of beds, the number of patient days, and the hospital's location.

(i) The number of beds in a hospital is determined in accordance with §412.105(b).

(ii) For purposes of this section, the number of patient days in a hospital includes only those days attributable to units or wards of the hospital providing acute care services generally payable under the prospective payment system and excludes patient days associated with—

(A) Beds in excluded distinct part hospital units;

(B) Beds otherwise countable under this section used for outpatient observation services, skilled nursing swing-bed services, or inpatient hospice services;

(C) Beds in a unit or ward that is not occupied to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system at any time during the 3 preceding months (the beds in the unit or ward are to be excluded from the determination of available bed days during the current month); and

(D) Beds in a unit or ward that is otherwise occupied (to provide a level of care that would be payable under the acute care hospital inpatient prospective payment system) that could not be made available for inpatient occupancy within 24 hours for 30 consecutive days.

(iii) The hospital's location, in an urban or rural area, is determined in accordance with the definitions in §412.64, except that a reclassification that results from an urban hospital reclassified as rural as set forth in §412.103 is classified as rural.

(2) The payment adjustment is applied to the hospital's DRG revenue for inpatient operating costs based on DRG-adjusted prospective payment rates for inpatient operating costs, excluding outlier payments for inpatient operating costs under subpart F of this

part and additional payments made under the provisions of § 412.105.

(b) *Determination of a hospital's disproportionate patient percentage*—(1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for patients who were not entitled to Medicare Part A, and who were either eligible for Medicaid on such days as described in paragraph (b)(4)(i) of this section or who were regarded as eligible for Medicaid on such days and the Secretary has determined to include those days in this computation as described in paragraph (b)(4)(ii)(A) or (B) of this section. The fiscal intermediary then divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is eligible for Medicaid on a given day if the patient is eligible on that day for inpatient hospital services under a State Medicaid plan approved under title XIX of the Act, regardless of whether particular items or services were covered or paid for on that day under the State plan.

(ii) For purposes of this computation, a patient is regarded as eligible for Medicaid on a given day if the patient receives health insurance authorized by a demonstration approved by the Secretary under section 1115(a)(2) of the Act for that day, where the cost of such health insurance may be counted as expenditures under section 1903 of the Act, or the patient has health insurance for that day purchased using premium assistance received through a demonstration approved by the Secretary under section 1115(a)(2) of the Act, where the cost of the premium assistance may be counted as expenditures under section 1903 of the Act, and in either case regardless of whether particular items or services were covered or paid for on that day by the health insurance. Of these patients regarded as eligible for Medicaid on a given day, only the days of patients meeting the following criteria on that day may be counted in this second computation:

(A) Patients who are provided by a demonstration authorized under section 1115(a)(2) of the Act health insurance that covers inpatient hospital services; or

(B) Patients who purchase health insurance that covers inpatient hospital services using premium assistance provided by a demonstration authorized under section 1115(a)(2) of the Act and the premium assistance accounts for 100 percent of the premium cost to the patient.

(iii) Patients whose health care costs, including inpatient hospital services costs, for a given day are claimed for

payment by a provider from an uncompensated, undercompensated, or other type of funding pool authorized under section 1115(a) of the Act to fund providers' uncompensated care costs are not regarded as eligible for Medicaid for purposes of paragraph (b)(4)(ii) of this section on that day and the days of such patients may not be included in this second computation.

(iv) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(v) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written notification must specify the methodology the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage.* The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

(c) *Criteria for classification.* A hospital is classified as a ''disproportionate share'' hospital under any of the following circumstances:

(1) The hospital's disproportionate patient percentage, as determined under paragraph (b)(5) of this section, is at least equal to one of the following:

(i) 15 percent, if the hospital is located in an urban area, and has 100 or more beds, or is located in a rural area and has 500 or more beds.

(ii) 30 percent for discharges occurring before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in a rural area and either has more than 100 beds and fewer than 500 beds or is classified as a sole community hospital under §412.92.

(iii) 40 percent for discharges before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in an urban area and has fewer than 100 beds.

(iv) 45 percent for discharges before April 1, 2001, and 15 percent for discharges occurring on or after April 1, 2001, if the hospital is located in a rural area and has 100 or fewer beds.

(2) The hospital is located in an urban area, has 100 or more beds, and can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to indigent patients.

(d) *Payment adjustment factor*—(1) *Method of adjustment.* Subject to the reduction factor set forth in paragraph (e) of this section, if a hospital serves a disproportionate number of low-income patients, its DRG revenues for inpatient operating costs are increased by an adjustment factor as specified in paragraph (d)(2) of this section.

(2) *Payment adjustment factors.* (i) If the hospital meets the criteria of paragraph (c)(1)(i) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is as follows:

(*1*) For discharges occurring on or after April 1, 1990, and before January 1, 1991, 5.62 percent plus 65 percent of the difference between 20.2 percent and

the hospital's disproportionate patient percentage.

(*2*) For discharges occurring on or after January 1, 1991, and before October 1, 1993, 5.62 percent plus 70 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) For discharges occurring on or after October 1, 1993, and before October 1, 1994, 5.88 percent plus 80 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*4*) For discharges occurring on or after October 1, 1994, 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is as follows:

(*1*) For discharges occurring on or after April 1, 1990, and before October 1, 1993, 2.5 percent plus 60 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) For discharges occurring on or after October 1, 1993, 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(ii) If the hospital meets the criteria of paragraph (c)(1)(ii) of this section, the payment adjustment factor is equal to one of the following:

(A) If the hospital is classified as a rural referral center—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001, and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is greater than or equal to 30 percent, the applicable payment adjustment factor is 5.25 percent plus 60 percent of the difference between 30 percent and the hospital's disproportionate patient percentage.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(B) If the hospital is classified as a sole community hospital—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 10 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent and less than 30 percent, the applicable payment adjustment factor is 5.25 percent.

(*iii*) If the hospital's disproportionate patient percentage is equal to or greater than 30 percent, the applicable payment adjustment factor is 10 percent.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15

percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*iii*) The maximum payment adjustment factor is 12 percent.

(C) If the hospital is classified as both a rural referral center and a sole community hospital, the payment adjustment is—

(*1*) For discharges occurring before April 1, 2001, the greater of—

(*i*) 10 percent; or

(*ii*) 4 percent plus 60 percent of the difference between the hospital's disproportionate patient percentage and 30 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the greater of the adjustments determined under paragraphs (d)(2)(ii)(A) or (d)(2)(ii)(B) of this section.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(D) If the hospital is classified as a rural hospital and is not classified as either a sole community hospital or a rural referral center, and has 100 or more beds—

(*1*) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(*2*) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*ii*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(*3*) For discharges occurring on or after April 1, 2004, the following applies:

(*i*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*ii*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*iii*) The maximum payment adjustment factor is 12 percent.

(iii) If the hospital meets the criteria of paragraph (c)(1)(iii) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 5 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*2*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) If the hospital's disproportionate patient percentage is greater than 20.2

percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) The maximum payment adjustment factor is 12 percent.

(iv) If the hospital meets the criteria of paragraph (c)(1)(iv) of this section—

(A) For discharges occurring before April 1, 2001, the payment adjustment factor is 4 percent.

(B) For discharges occurring on or after April 1, 2001 and before April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than 19.3 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between the hospital's disproportionate patient percentage and 15 percent.

(*2*) If the hospital's disproportionate patient percentage is equal to or greater than 19.3 percent, the applicable payment adjustment factor is 5.25 percent.

(C) For discharges occurring on or after April 1, 2004, the following applies:

(*1*) If the hospital's disproportionate patient percentage is less than or equal to 20.2 percent, the applicable payment adjustment factor is 2.5 percent plus 65 percent of the difference between 15 percent and the hospital's disproportionate patient percentage.

(*2*) If the hospital's disproportionate patient percentage is greater than 20.2 percent, the applicable payment adjustment factor is 5.88 percent plus 82.5 percent of the difference between 20.2 percent and the hospital's disproportionate patient percentage.

(*3*) Except as provided in paragraph (d)(2)(iv)(D) of this section, the maximum payment adjustment factor is 12 percent.

(D) Effective for discharges occurring on or after October 1, 2006, for a hospital that is classified as a Medicare-dependent, small rural hospital under § 412.108, the payment adjustment factor limitation specified in paragraph (d)(2)(iv)(C)(3) does not apply.

(v) If the hospital meets the criteria of paragraph (c)(2) of this section, the payment adjustment factor is as follows:

(A) 30 percent for discharges occurring on or after April 1, 1990, and before October 1, 1991.

(B) 35 percent for discharges occurring on or after October 1, 1991.

(e) *Reduction in payments beginning FY 1998.* The amounts otherwise payable to a hospital under paragraph (d) of this section are reduced by the following:

(1) For FY 1998, 1 percent.

(2) For FY 1999, 2 percent.

(3) For FY 2000, 3 percent.

(4) For FY 2001:

(i) For discharges occurring on or after October 1, 2000 and before April 1, 2001, 3 percent.

(ii) For discharges occurring on or after April 1, 2001 and before October 1, 2001, 1 percent.

(5) For FY 2002, 3 percent.

(6) For FYs 2003 and thereafter, 0 percent.

(f) *Empirically justified Medicare DSH payments.* Effective for discharges on or after October 1, 2013, the amounts otherwise payable to a hospital under paragraph (d) of this section are reduced by 75 percent.

(g) *Additional payment for uncompensated care.* (1) *Payment rules.* Hospitals that qualify for payments under this section for fiscal year 2014 and each subsequent year, will receive an additional amount equal to the product of the following three factors:

(i) *Factor 1.* For FY 2014 and each subsequent fiscal year, a factor equal to the difference between:

(A) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that would be made to such hospitals under paragraphs (a) through (e) of this section if paragraph (f) of this section did not apply for the fiscal year; and

(B) The most recently available estimates, as calculated by CMS' Office of the Actuary, of the aggregate amount of payments that are made to such hospitals pursuant to paragraph (f) of this section for the fiscal year.

(ii) *Factor 2.* (A) For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (and subtracting from the factor 0.1 percentage

point for fiscal year 2014 and 0.2 percentage point for each of fiscal years 2015, 2016, and 2017), as determined by comparing—

(*1*) 18 percent, the percent of such individuals who are uninsured in 2013, based on the March 20, 2010, estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office.

(*2*) The percent of such individuals who are uninsured in the applicable fiscal year, based on the most recent estimate of the ''Insured Share of the Nonelderly Population Including All Residents'' by the Congressional Budget Office available at the time of development of the annual final rule for the hospital inpatient prospective payment system.

(B) For FY 2018 and subsequent fiscal years, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured (and subtracting from the factor 0.2 percentage point for each of fiscal years 2018 and 2019), as determined by comparing the percent of individuals who are uninsured in—

(*1*) 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the CMS); and

(*2*) The most recent period for which data is available (as so estimated and certified).

(iii) *Factor 3.* A factor equal to the percent, for each inpatient prospective payment system hospital, that represents the quotient of:

(A) The amount of uncompensated care for such hospital as estimated by CMS.

(B) The aggregate amount of uncompensated care as estimated by CMS for all hospitals that are estimated to receive a payment under this section.

(C)(*1*) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section.

(*2*) For fiscal year 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

(*3*) For fiscal year 2017, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2011, 2012, and 2013 cost reports from the most recent HCRIS database extract, the 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 3 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*4*) For fiscal year 2018, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 and 2013 cost reports from the most recent HCRIS database extract and 2012 cost report data submitted to CMS by IHS or Tribal hospitals and the most recent available 2 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and for hospitals other than Puerto Rico hospitals, IHS or Tribal hospitals, and all-inclusive rate providers, data on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs from 2014 cost reports from the most recent HCRIS database extract.

(*5*) For fiscal year 2019, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available

year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and for hospitals other than Puerto Rico hospitals, IHS or Tribal hospitals, and all-inclusive rate providers, data on uncompensated care costs, defined as charity care costs plus non-Medicare and nonreimbursable Medicare bad debt costs from 2014 and 2015 cost reports from the most recent HCRIS database extract.

(*6*) For fiscal year 2020, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and nonreimbursable Medicare bad debt costs from 2015 cost reports from the most recent HCRIS database extract, except that, for Puerto Rico hospitals and Indian Health Service or Tribal hospitals, CMS will base its estimates on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*7*) For fiscal year 2021, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and nonreimbursable Medicare bad debt costs from 2017 cost reports from the most recent Hospital Cost Report Information System (HCRIS) database extract, except that, for Puerto Rico hospitals and Indian Health Service or Tribal hospitals, CMS will base its estimates on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*8*) For fiscal year 2022, for all eligible hospitals, except Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the most recent cost reporting year for which audits have been conducted.

(*9*) For fiscal year 2022, for Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*10*) For fiscal year 2023, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and nonreimbursable Medicare bad debt costs from cost reports from the two most recent cost reporting years for which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the two most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3, the Medicare administrative contractor (MAC) will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its FY 2023 cost report to the sum of uncompensated care costs for all DSH-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(*11*) For fiscal year 2024 and subsequent fiscal years, for all eligible hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the three most recent cost reporting years for which audits have been conducted. If a hospital is a new hospital (that is, a hospital that began participation in the Medicare program after the three most recent cost reporting years for which audits have been conducted) or if the hospital is treated as a new hospital for purposes of Factor 3, the Medicare administrative contractor (MAC) will determine Factor 3 as the ratio of the hospital's uncompensated care costs from its cost report for the applicable fiscal year to the sum of uncompensated care costs for all disproportionate share hospital (DSH)-eligible hospitals as estimated by CMS from the most recent cost reporting year for which audits have been conducted.

(2) *Preclusion of administrative and judicial review.* There is no administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, of the following:

(i) Any estimate of the Secretary for the purpose of determining the factors in paragraph (g)(1) of this section; and

(ii) Any period selected by the Secretary for such purposes.

(h) *Supplemental payment for Indian Health Service and Tribal hospitals and Puerto Rico hospitals.* (1) For fiscal year 2023 and each subsequent fiscal year, Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that qualify for an additional payment for uncompensated care under paragraph (g) of this section for the applicable fiscal year may also qualify to receive a supplemental payment.

(2) Indian Health Service and Tribal Hospitals and Puerto Rico hospitals that do not have a Factor 3 amount for fiscal year 2022 determined under paragraph (g)(1)(iii)(C)(*9*) of this section are not eligible to receive a supplemental payment under this paragraph (h).

(3) The amount of the supplemental payment for a fiscal year is determined as the difference between the following:

(i) A base year amount defined as the FY 2022 uncompensated care payment determined for the hospital, in accordance with paragraph (g)(1) of this section, adjusted by 1 plus the percent change in the aggregate amount of uncompensated care payments as estimated by CMS in accordance with paragraphs (g)(1)(i) and (ii) of this section between fiscal year 2022 and the applicable fiscal year. If the hospital did not qualify for an additional payment for uncompensated care under paragraph (g) of this section for fiscal year 2022, CMS uses the Factor 3 determined for the hospital under paragraph (g)(1)(iii)(C)(*9*) of this section to estimate the amount of the additional payment for uncompensated care that the hospital would have received in fiscal year 2022 if the hospital had qualified for an additional payment for uncompensated care under paragraph (g)(1) of this section for that fiscal year.

(ii) The additional payment for uncompensated care determined for the hospital for the applicable fiscal year, in accordance with paragraph (g)(1) of this section.

(4) If the base year amount under paragraph (h)(3)(i) of this section is equal to or lower than the additional payment for uncompensated care determined for the hospital for the applicable fiscal year in accordance with paragraph (g)(1) of this section, the hospital will not receive a supplemental payment under paragraph (h) of this section for that fiscal year.

(i) *Manner and timing of payments.* (1) Interim payments are made during the payment year to each hospital that is estimated to be eligible for payments under this section at the time of the annual final rule for the hospital inpatient prospective payment system, subject to the final determination of eligibility at the time of cost report settlement for each hospital. For FY 2025, interim uncompensated care payments are calculated based on an average of the most recent 2 years of available historical discharge data. For FY 2026 and subsequent years, interim uncompensated care payments are calculated based on an average of the most recent

3 years of available historical discharge data.

(2) Final payment determinations are made at the time of cost report settlement, based on the final determination of each hospital's eligibility for payment under this section.

[54 FR 36494, Sept. 1, 1989]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.106, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 412.107 Special treatment: Hospitals that receive an additional update for FYs 1998 and 1999.

(a) *Additional payment update.* A hospital that meets the criteria set forth in paragraph (b) of this section receives the following increase to its applicable percentage amount set forth in § 412.63 (p) and (q):

(1) For FY 1998, 0.5 percent.

(2) For FY 1999, 0.3 percent.

(b) *Criteria for classification.* A hospital is eligible for the additional payment update set forth in paragraph (a) of this section if it meets all of the following criteria:

(1) *Definition.* The hospital is not a Medicare-dependent, small rural hospital as defined in § 412.108(a) and does not receive any additional payment under the following provisions:

(i) The indirect medical education adjustment made under § 412.105.

(ii) The disproportionate share adjustment made under § 412.106.

(2) *State criteria.* The hospital is located in a State in which the aggregate payment made under § 412.112 (a) and (c) for hospitals described in paragraph (b)(1) of this section for their cost reporting periods beginning in FY 1995 is less than the allowable operating costs described in § 412.2(c) for those hospitals.

(3) *Hospital criteria.* The aggregate payment made to the hospital under § 412.112 (a) and (c) for the hospital's cost reporting period beginning in the fiscal year in which the additional payment update described in paragraph (a) of this section is made is less than the allowable operating cost described in § 412.2(c) for that hospital.

[62 FR 46030, Aug. 29, 1997]

§ 412.108 Special treatment: Medicare-dependent, small rural hospitals.

(a) *Criteria for classification as a Medicare-dependent, small rural hospital—*

(1) *General considerations.* For cost reporting periods beginning on or after April 1, 1990, and ending before October 1, 1994, or for discharges occurring on or after October 1, 1997, and before January 1, 2025, a hospital is classified as a Medicare-dependent, small rural hospital if it meets all of the following conditions:

(i) It is located in a rural area (as defined in subpart D of this part) or it is located in a State with no rural area and satisfies any of the criteria under § 412.103(a)(1) or (3) or under § 412.103(a)(2) as of January 1, 2018.

(ii) The hospital has 100 or fewer beds as defined in § 412.105(b) during the cost reporting period.

(iii) The hospital is not also classified as a sole community hospital under § 412.92.

(iv) At least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the hospital's cost reporting period or periods as follows, subject to the provisions of paragraph (a)(1)(v) of this section:

(A) The hospital's cost reporting period ending on or after September 30, 1987 and before September 30, 1988.

(B) If the hospital does not have a cost reporting period that meets the criterion set forth in paragraph (a)(1)(iv)(A) of this section, the hospital's cost reporting period beginning on or after October 1, 1986, and before October 1, 1987.

(C) At least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report.

(v) If the cost reporting period determined under paragraph (a)(1)(iv) of this section is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

(2) *Counting days and discharges.* In counting inpatient days and discharges for purposes of meeting the criteria in paragraph (a)(1)(iii) of this section, only days and discharges from acute

care inpatient hospital stays are counted (including days and discharges from swing beds when used for acute care inpatient hospital services), but not including days and discharges from units excluded from the prospective payment system under §§412.25 through 412.30 or from newborn nursery units. For purposes of this section, a transfer as defined in §412.4(b) is considered to be a discharge.

(3) *Criteria for hospitals that have remote location(s).* For a hospital with a main campus and one or more remote locations under a single provider agreement where services are provided and billed under the inpatient hospital prospective payment system and that meets the provider-based criteria at §413.65 of this chapter as a main campus and a remote location of a hospital, combined data from the main campus and its remote location (s) are required to demonstrate that the criteria in paragraphs (a)(1) and (2) of this section are met. For the location requirement specified in paragraph (a)(1)(i) of this section, the hospital must demonstrate that the main campus and its remote locations each independently satisfy this requirement.

(b) *Classification procedures.* (1) The MAC determines whether a hospital meets the criteria specified in paragraph (a) of this section.

(2) A hospital must submit a written request along with qualifying documentation to its fiscal intermediary to be considered for MDH status based on the criterion under paragraph (a)(1)(iii)(C) of this section.

(3) The MAC will make its determination and notify the hospital within 90 days from the date that it receives the hospital's request and all of the required documentation.

(4) For applications received on or before September 30, 2018, a determination of MDH status made by the MAC is effective 30 days after the date the MAC provides written notification to the hospital. For applications received on or after October 1, 2018, a determination of MDH status made by the MAC is effective as of the date the MAC receives the complete application. An approved MDH status determination remains in effect unless there is a change in the circumstances under which the status was approved.

(i) An approved MDH must notify the MAC if any change occurs that is specified in paragraph (b)(4)(ii) of this section occurs. If CMS determines that an MDH failed to comply with this requirement, CMS will cancel the hospital's classification as an MDH effective with the date that the hospital no longer met the criteria for such status, consistent with the provisions of §405.1885 of this chapter.

(ii) An MDH must report the following to the MAC within 30 days of the event:

(A) The number of beds increases to more than 100.

(B) Its geographic classification changes.

(iii) An MDH must report to the MAC if it becomes aware of any change that would affect its classification as an MDH beyond the events listed in paragraph (b)(4)(ii) of this section within 30 days of the event. If CMS determines that an MDH has failed to comply with this requirement, CMS will cancel the hospital's classification as an MDH effective with the date the hospital became aware of the event that resulted in the MDH no longer meeting the criteria for such classification, consistent with the provisions of §405.1885 of this chapter.

(5) The MAC will evaluate on an ongoing basis, whether or not a hospital continues to qualify for MDH status. This evaluation includes an ongoing review to ensure that the hospital continues to meet all of the criteria specified in paragraph (a) of this section.

(6) If the MAC determines that a hospital no longer qualifies for MDH status, the change in status will become effective 30 days after the date the MAC provides written notification to the hospital.

(7) A hospital may reapply for MDH status following its disqualification only after it has completed another cost reporting period that has been audited and settled. The hospital must reapply for MDH status in writing to its MAC and submit the required documentation.

(8) If a hospital disagrees with an MAC's determination regarding the

hospital's initial or ongoing MDH status, the hospital may notify its MAC and submit other documentable evidence to support its claim that it meets the MDH qualifying criteria.

(9) The MAC's initial and ongoing determination is subject to review under subpart R of Part 405 of this chapter. The time required by the MAC to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

(c) *Payment methodology.* A hospital that meets the criteria in paragraph (a) of this section is paid for its inpatient operating costs the sum of paragraphs (c)(1) and (c)(2) of this section.

(1) The Federal payment rate applicable to the hospital, as determined under subpart D of this part, subject to the regional floor defined in § 412.70(c)(6).

(2) The amount, if any, determined as follows:

(i) For discharges occurring during the first three 12-month cost reporting periods that begin on or after April 1, 1990, 100 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the higher of the following:

(A) The hospital-specific rate as determined under § 412.73.

(B) The hospital-specific rate as determined under § 412.75.

(ii) For discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, and for discharges occurring on or after October 1, 1997 and before October 1, 2006, 50 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the higher of the following:

(A) The hospital-specific rate as determined under § 412.73.

(B) The hospital-specific rate as determined under § 412.75.

(iii) For discharges occurring during cost reporting periods (or portions thereof) beginning on or after October 1, 2006, and before January 1, 2025, 75 percent of the amount that the Federal rate determined under paragraph (c)(1) of this section is exceeded by the highest of the following:

(A) The hospital-specific rate as determined under § 412.73.

(B) The hospital-specific rate as determined under § 412.75.

(C) The hospital-specific rate as determined under § 412.79.

(d) *Additional payments to hospitals experiencing a significant volume decrease.* (1) CMS provides for a payment adjustment for a Medicare-dependent, small rural hospital for any cost reporting period during which the hospital experiences, due to circumstances as described in paragraph (d)(2) of this section, a more than 5 percent decrease in its total inpatient discharges as compared to its immediately preceding cost reporting period. If either the cost reporting period in question or the immediately preceding cost reporting period is other than a 12-month cost reporting period, the MAC must convert the discharges to a monthly figure and multiply this figure by 12 to estimate the total number of discharges for a 12-month cost reporting period.

(2) To qualify for a payment adjustment on the basis of a decrease in discharges, a Medicare-dependent, small rural hospital must submit its request no later than 180 days after the date on the MAC's Notice of Amount of Program Reimbursement and it must—

(i) Submit to the MAC documentation demonstrating the size of the decrease in discharges and the resulting effect on per discharge costs; and

(ii) Show that the decrease is due to circumstances beyond the hospital's control.

(3) The MAC determines a lump sum adjustment amount in accordance with the methodology set forth in § 412.92(e)(3).

(i) In determining the adjustment amount, the MAC considers—

(A) The individual hospital's needs and circumstances, including the reasonable cost of maintaining necessary core staff and services in view of minimum staffing requirements imposed by State agencies;

(B) The hospital's fixed (and semi-fixed) costs, other than those costs paid on a reasonable cost basis under part 413 of this chapter; and

(C) The length of time the hospital has experienced a decrease in utilization.

(ii) The MAC makes its determination within 180 days from the date it

receives the hospital's request and all other necessary information.

(iii) The MAC determination is subject to review under subpart R of part 405 of this chapter. The time required by the MAC to review the request is considered good cause for granting an extension of the time limit for the hospital to apply for that review.

[55 FR 15175, Apr. 20, 1990; 55 FR 32088, Aug. 7, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.108, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§412.109 Special treatment: Essential access community hospitals (EACHs).

(a) *General rule.* For payment purposes, CMS treats as a sole community hospital any hospital that is located in a rural area as described in paragraph (b) of this section and that CMS designated as an EACH under section 1820(i)(1) of the Act as in effect on September 30, 1997, for as long as the hospital continues to comply with the terms, conditions, and limitations that were applicable at the time CMS designated the hospital as an EACH. The payment methodology for sole community hospitals is set forth at §412.92(d).

(b) *Location in a rural area.* For purposes of this section, a hospital is located in a rural area if it—

(1) Is located outside any area that is a Metropolitan Statistical Area as defined by the Office of Management and Budget or that has been recognized as urban under §412.62;

(2) Is not deemed to be located in an urban area under subpart D of this part.

(3) Is not classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board; or

(4) Is not located in a rural county that has been redesignated to an adjacent urban area under §412.232.

(c) *Adjustment to the hospital-specific rate for rural EACH's experiencing increased costs*—(1) *General rule.* CMS increases the applicable hospital-specific rate of an EACH that it treats as a sole community hospital if, during a cost reporting period, the hospital experiences an increase in its Medicare inpatient operating costs per discharge that is directly attributable to activities related to its membership in a rural health network.

(2) *Request and documentation.* In order for a hospital to qualify for an increase in its hospital-specific rate, it must meet the following criteria:

(i) The hospital must submit its request to its intermediary no later than 180 days after the date on the intermediary's notice of program reimbursement.

(ii) The request must include documentation specifically identifying the increased costs resulting from the hospital's participation in a rural health network and show that the increased costs during the cost reporting period will result in increased costs in subsequent cost reporting periods that are not already accounted for under the prospective payment system payment.

(iii) The hospital must show that the cost increases are incremental costs that would not have been incurred in the absence of the hospital's membership in a rural health network.

(iv) The hospital must show that the cost increases do not include amounts for start-up and one-time, nonrecurring costs attributable to its membership in a rural health network.

(3) *Intermediary recommendation.* The intermediary forwards the following material to CMS within 60 days of receipt from the hospital:

(i) The hospital's documentation and the intermediary's verification of that documentation.

(ii) The intermediary's analysis and recommendation of the request.

(iii) The hospital's Medicare cost report for the year in which the increase in costs occurred and the prior year.

(4) *CMS determination.* CMS determines, within 120 days of receiving all necessary information from the intermediary, whether an increase in the hospital-specific rate is warranted and, if it is, the amount of the increase. CMS grants an adjustment only if a hospital's Medicare inpatient operating costs per discharge exceed the hospital's hospital-specific rate. The adjusted hospital-specific rate cannot exceed the hospital's Medicare inpatient

operating costs per discharge for the cost reporting period.

(d) *Termination of EACH designation.* If CMS determines that a hospital no longer complies with the terms, conditions, and limitations that were applicable at the time CMS designated the hospital as an EACH, CMS will terminate the EACH designation of the hospital, effective with discharges occurring on or after 30 days after the date of the determination.

(e) *Review of CMS determination.* A determination by CMS that a hospital's EACH designation should be terminated, is subject to review under part 405, subpart R of this chapter, including the time limits for filing requests for hearings as specified in §§ 405.1811(a) and 405.1841(a)(1) and (b) of this chapter.

[58 FR 30669, May 26, 1993, as amended at 59 FR 45398, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 61 FR 21972, May 13, 1996; 62 FR 46030, Aug. 29, 1997; 70 FR 47486, Aug. 12, 2005]

Subpart H—Payments to Hospitals Under the Prospective Payment Systems

§ 412.110 Total Medicare payment.

Under the prospective payment systems, Medicare's total payment for inpatient hospital services furnished to a Medicare beneficiary by a hospital will equal the sum of the payments listed in §§ 412.112 through 412.115, reduced by the amounts specified in § 412.120.

[50 FR 12741, Mar. 29, 1985, as amended at 57 FR 39824, Sept. 1, 1992]

§ 412.112 Payments determined on a per case basis.

A hospital is paid the following amounts on a per case basis:

(a) The appropriate prospective payment rate for inpatient operating costs for each discharge as determined in accordance with subparts D, E, and G of this part.

(b) Effective for cost reporting periods beginning on or after October 1, 1991, the appropriate prospective payment rate for capital-related costs for each discharge as determined in accordance with subpart M of this part.

(c) The appropriate outlier payment amounts determined under subpart F of this part.

(d) Additional payments for new medical services and technologies determined under subpart F of this part.

[56 FR 43448, Aug. 30, 1991, as amended at 57 FR 39824, Sept. 1, 1992; 68 FR 45470, Aug. 1, 2003]

§ 412.113 Other payments.

(a) *Capital-related costs*—(1) *Payment.* Subject to the reductions described in paragraph (a)(2) of this section, payment for capital-related costs (as described in § 413.130 of this chapter) for cost reporting periods beginning before October 1, 1991 is determined on a reasonable cost basis.

(2) *Reduction to capital-related payments.* (i) Except for sole community hospitals as defined in § 412.92, the amount of capital-related payments for cost-reporting periods beginning before October 1, 1991 (including a return on equity capital as provided under § 413.157 of this chapter) is reduced by—

(A) Three and one-half percent for payments attributable to portions of cost reporting periods occurring during Federal FY 1987;

(B) Seven percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 and before January 1, 1988;

(C) Twelve percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988 occurring on or after January 1, 1988;

(D) Fifteen percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989 and beginning on or after January 1, 1990 and ending on or before September 30, 1991; and

(E) Ten percent for payments attributable to portions of cost-reporting periods occurring on or after October 1, 1991 and before the beginning of the hospital's first cost-reporting period beginning on or after October 1, 1991.

(ii) If a hospital's cost reporting period encompasses more than one Federal fiscal year, the reductions to capital-related payments are determined on a prorated monthly basis.

(3) For cost-reporting periods beginning on or after October 1, 1991, a hospital with a hospital-specific rate above the Federal capital rate is paid a hold-harmless payment for old capital determined in accordance with subpart M of this part.

(b) *Direct medical education costs.* (1) Payment for the direct medical education costs of interns and residents in approved programs for cost reporting periods beginning prior to July 1, 1985, and for approved education activities of nurses and paramedical health professionals is made as described in §413.85 of this chapter.

(2) For cost reporting periods beginning on or after July 1, 1985, payment for the direct medical education costs of interns and residents in approved programs is made as described in §§413.75 through 413.83 of this subchapter.

(3) Except as provided in §413.75(c) of this subchapter, for cost reporting periods during the prospective payment transition period, the costs of medical education must be determined in a manner that is consistent with the treatment of these costs for purposes of determining the hospital-specific portion of the payment rate as provided in subpart E of this part.

(c) *Anesthesia services furnished by hospital or CAH employed nonphysician anesthetists or obtained under arrangements.* (1) For cost reporting periods beginning on or after October 1, 1984 through any part of a cost reporting period occurring before January 1, 1989, payment is determined on a reasonable cost basis for anesthesia services provided in the hospital or CAH by qualified nonphysician anesthetists (certified registered nurse anesthetists and anesthesiologist's assistants) employed by the hospital or CAH or obtained under arrangements.

(2)(i) For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, through any part of a cost reporting period occurring before January 1, 1990, payment is determined on a reasonable cost basis for anesthesia services provided in a hospital or CAH by qualified nonphysician anesthetists employed by the hospital or CAH or obtained under arrangement, if the hospital or CAH demonstrates to its intermediary prior to April 1, 1989 that it meets the following criteria:

(A) The hospital or CAH is located in a rural area as defined in §412.62(f) and is not deemed to be located in an urban area under the provisions of §412.64(b)(3). Effective December 2, 2010, the hospital or CAH is either located in a rural area as defined at §412.62(f) and is not deemed to be located in an urban area under the provisions of §412.64(b)(3) or the hospital or CAH has reclassified as rural under the provisions at §412.103.

(B) The hospital or CAH must have employed or contracted with a qualified nonphysician anesthetist, as defined in §410.69 of this chapter, as of January 1, 1988 to perform anesthesia services in that hospital or CAH. The hospital or CAH may employ or contract with more than one anesthetist; however, the total number of hours of service furnished by the anesthetists may not exceed 2,080 hours per year.

(C) The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 250 procedures. For purposes of this section, a *surgical procedure requiring anesthesia services* means a surgical procedure in which the anesthesia is administered and monitored by a qualified nonphysician anesthetist, a physician other than the primary surgeon, or an intern or resident.

(D) Each qualified nonphysician anesthetist employed by or under contract with the hospital or CAH has agreed in writing not to bill on a reasonable charge basis for his or her patient care to Medicare beneficiaries in that hospital or CAH.

(ii) To maintain its eligibility for reasonable cost payment under paragraph (c)(2)(i) of this section in calendar years after 1989, a qualified hospital or CAH must demonstrate prior to January 1 of each respective year that for the prior year its volume of surgical procedures requiring anesthesia service did not exceed 500 procedures; or, effective October 1, 2002, did not exceed 800 procedures.

(iii) A hospital or CAH that did not qualify for reasonable cost payment for nonphysician anesthetist services furnished in calendar year 1989 can qualify in subsequent years if it meets the criteria in paragraphs (c)(2)(i)(A), (B), and (D) of this section, and demonstrates to its intermediary prior to the start of the calendar year that it met these criteria. The hospital or CAH must provide data for its entire patient population to demonstrate that, during calendar year 1987 and the year immediately preceding its election of reasonable cost payment, its volume of surgical procedures (inpatient and outpatient) requiring anesthesia services did not exceed 500 procedures, or, effective October 1, 2002, did not exceed 800 procedures.

(iv) For administrative purposes for the calendar years after 1990, the volume of surgical procedures for the immediately preceding year is the sum of the surgical procedures for the nine month period ending September 30, annualized for the twelve month period.

(d) *Organ acquisition.* Payment for organ acquisition costs as specified in part 413, subpart L, incurred by hospitals with approved transplant programs is made on a reasonable cost basis.

(e) *Allogeneic hematopoietic stem cell acquisition.* For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis.

(1) An allogeneic hematopoietic stem cell transplant is the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.

(2) Allogeneic hematopoietic stem cell acquisition costs recognized under this paragraph (e) are costs of acquiring hematopoietic stem cells from a donor. These costs are as follows:

(i) Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.

(ii) Tissue typing of donor and recipient.

(iii) Donor evaluation.

(iv) Physician pre-admission/pre-procedure donor evaluation services.

(v) Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services), and transportation costs of stem cells if the recipient hospital incurred or paid such costs.

(vi) Post-operative/post-procedure evaluation of donor.

(vii) Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

(3) A subsection (d) hospital that furnishes inpatient allogeneic hematopoietic stem cell transplants is required to hold all allogeneic hematopoietic stem cell acquisition charges and bill them to Medicare using the appropriate revenue code, when the transplant occurs.

(4) A subsection (d) hospital must maintain an itemized statement that identifies, for all costs defined in paragraph (e)(2) of this section, the services furnished in collecting hematopoietic stem cells including all invoices or statements for purchased services for all donors and their service charges. Records must be for the person receiving the services (donor or recipient; for all donor sources, the hospital must identify the prospective recipient), and the recipient's Medicare beneficiary identification number.

(f) *Additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators.* (1) For cost reporting periods beginning on or after January 1, 2023, a payment adjustment to a hospital for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95 respirators is made as described in paragraph (f)(2) of this section.

(2) 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.

(g) *Additional resource costs of establishing and maintaining access to buffer stocks of essential medicines.* (1) Essential medicines are the 86 medicines prioritized in the report Essential Medicines Supply Chain and Manufacturing Resilience Assessment developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022, and any subsequent revisions to that list of medicines. A buffer stock of essential medicines for a hospital is a supply, for no less than a 6-month period of one or more essential medicines.

(2) The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients or arrange contractually for such a buffer stock to be held by another entity for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves.

(3) For cost reporting periods beginning on or after October 1, 2024, a payment adjustment to a small, independent hospital for the additional resource costs of establishing and maintaining access to buffer stocks of essential medicines is made as described in paragraph (g)(4) of this section. For purposes of this section, a small, independent hospital is a hospital with 100 or fewer beds as defined in §412.105(b) during the cost reporting period that is not part of a chain organization, defined as a group of two or more health care facilities which are owned, leased, or through any other device, controlled by one organization.

(4) The payment adjustment is based on the estimated reasonable cost incurred by the hospital for establishing and maintaining access to buffer stocks of essential medicines during the cost reporting period.

[50 FR 12741, Mar. 29, 1985]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.113, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§412.115 Additional payments.

(a) *Bad debts.* An additional payment is made to each hospital in accordance with §413.89 of this chapter for bad debts attributable to deductible and coinsurance amounts related to covered services received by beneficiaries.

(b) *Administration of blood clotting factor.* For discharges occurring on or after June 19, 1990, and before October 1, 1994, and for discharges occurring on or after October 1, 1997, an additional payment is made to a hospital for each unit of blood clotting factor furnished to a Medicare inpatient who is a hemophiliac. For discharges occurring on or after October 1, 2005, the additional payment is made based on the average sales price methodology specified in subpart K, part 414 of this chapter and the furnishing fee specified in §410.63 of this subchapter.

(c) *QIO reimbursement for cost of sending requested patient records to the QIO.* An additional payment is made to a hospital in accordance with §476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

[50 FR 12741, Mar. 29, 1985, as amended at 51 FR 34793, Sept. 30, 1986; 55 FR 15175, Apr. 20, 1990; 56 FR 43448, Aug. 30, 1991; 57 FR 39825, Sept. 1, 1992; 57 FR 47787, Oct. 20, 1992; 58 FR 46339, Sept. 1, 1993; 62 FR 46030, Aug. 29, 1997; 68 FR 67960, Dec. 5, 2003; 70 FR 47486, Aug. 12, 2005; 85 FR 59022, Sept. 18, 2020]

§412.116 Method of payment.

(a) *General rules.* (1) Unless the provisions of paragraphs (b) and (c) of this section apply, hospitals are paid for hospital inpatient operating costs and capital-related costs for each discharge

based on the submission of a discharge bill.

(2) Payments for inpatient hospital services furnished by an excluded psychiatric unit of a hospital (or by an excluded rehabilitation unit of a hospital for cost reporting periods beginning before January 1, 2002) are made as described in §§ 413.64(a), (c), (d), and (e) of this chapter.

(3) For cost reporting periods beginning on or after January 1, 2005, payments for inpatient hospital services furnished by an inpatient psychiatric facility that meets the conditions of § 412.404 are made as described in § 412.432.

(4) For cost reporting periods beginning on or after January 1, 2002, payments for inpatient hospital services furnished by a rehabilitation hospital or a rehabilitation unit that meets the conditions of § 412.604 are made as described in § 412.632.

(5) For cost reporting periods beginning on or after October 1, 2002, payments for inpatient hospital services furnished by a long-term care hospital that meets the conditions for payment of §§ 412.505 through 412.511 are made as described in § 412.521.

(b) *Periodic interim payments*—(1) *Criteria for receiving periodic interim payments.* Effective with claims received on or after July 1, 1987, a hospital that meets the criteria in § 413.64(h) of this chapter may request in writing to receive periodic interim payments as described in this paragraph. A hospital that is receiving periodic interim payments also receives payment on this basis for inpatient hospital services furnished by its excluded psychiatric or rehabilitation unit.

(i) *Failure of intermediary to make prompt payment.* Beginning with claims received in April 1987, the hospital's fiscal intermediary does not meet the requirements of section 1816(c)(2) of the Act, which provides for prompt payment of claims under Medicare Part A, for three consecutive calendar months. The hospital may continue to receive periodic interim payments until the intermediary meets the requirements of section 1816 (c)(2) of the Act for three consecutive calendar months. For purposes of this paragraph, a hospital that is receiving periodic interim payments as of June 30, 1987 and meets the requirements of § 413.64(h) of this chapter may continue to receive payment on this basis until the hospital's intermediary meets the requirements of section 1816(c)(2) of the Act for three consecutive calendar months beginning with April 1987.

(ii) *Hospitals that serve a disproportionate share of low-income patients.* The hospital is receiving periodic interim payments as of June 30, 1987 and has a disproportionate share payment adjustment factor of at least 5.1 percent as determined under § 412.106(c) for purposes of establishing the average standardized amounts for discharges occurring on or after October 1, 1986 and before October 1, 1987. The hospital's request must be made by a date prior to July 1, 1987, specified by the intermediary.

(iii) *Small rural hospitals.* The hospital is receiving periodic interim payments as of June 30, 1987, makes its request by a date prior to July 1, 1987, specified by the intermediary, and, on July 1, 1987, the hospital—

(A) Is located in a rural area as defined in § 412.62(f); and

(B) Has 100 or fewer beds available for use.

(2) *Frequency of payment.* The intermediary estimates a hospital's prospective payments as described in paragraph (b)(3) of this section and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. Each payment is made two weeks after the end of a biweekly period of service, as described in § 413.64(h)(5) of this chapter. These payments are subject to final settlement.

(3) *Amount of payment.* (i) The biweekly interim payment amount is based on the total estimated Medicare discharges for the reporting period multiplied by the hospital's estimated average prospective payment amount as described in paragraph (b)(3)(ii) of this paragraph. These interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a hospital receives interim payments for less than a full reporting period.

(ii) For purposes of determining periodic interim payments under this paragraph, a hospital's estimated average prospective payment amount is computed as follows:

(A) If a hospital has no payment experience under the prospective payment system for operating costs, the intermediary computes the hospital's estimated average prospective payment amount for operating costs by multiplying its payment rates as determined under §412.70(c), but without adjustment by a DRG weighting factor, by the hospital's case-mix index, and subtracting from this amount estimated deductibles and coinsurance.

(B) Effective for cost-reporting periods beginning on or after October 1, 1991, the intermediary computes a hospital's estimated average prospective payment amount for capital-related costs by multiplying its prospective payment rate as determined under §412.340 or §412.344(a), as applicable, and under §412.308 for cost reporting periods beginning on or after October 1, 2001 but without adjustment by a DRG weighting factor, by the hospital's case-mix index. The intermediary may take into account estimated additional payments per discharge under §412.348. If the hospital is paid under §412.344(a)(1), the intermediary includes an estimated payment for old capital costs per discharge.

(C) If a hospital has payment experience under the prospective payment system for operating costs, and, for cost reporting periods beginning on or after October 1, 1991, for inpatient capital-related costs, the intermediary computes a hospital's estimated average prospective payment amount for operating costs and capital-related costs based on that payment experience, adjusted for projected changes, and subtracts from this amount estimated deductibles and coinsurance.

(4) *Termination of periodic interim payments*—(i) *Request by the hospital.* A hospital receiving periodic interim payments may convert to payments on a per discharge basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates periodic interim payments if—

(A) A hospital no longer meets the requirements of §413.64(h);

(B) A hospital is receiving payment under the criterion in paragraph (b)(1)(i) of this section and the intemediary meets the prompt payment requirements of section 1816(c)(2) of the Act for three consecutive calendar months; or

(C) A hospital that is receiving payment under the criterion set forth in paragraph (b)(1)(iii) of this section no longer meets the criterion.

(iii) *Limitation on reelection.* If a hospital that is receiving periodic interim payments under the criterion set forth in paragraph (b)(1)(ii) or (b)(1)(iii) of this section is removed from that method of payment at its own request, it may reelect to receive periodic interim payments only under the criterion set forth in paragraph (b)(1)(i) of this section. However, if the hospital is removed from that method of payment by its intermediary because it no longer meets the requirements of §413.64(h) of this chapter, that hospital may subsequently reelect to receive periodic interim payments if it qualifies under the provisions of paragraph (b)(1)(ii) or (b)(1)(iii) of this section, subject to the requirements in §413.64(h) of this chapter.

(c) *Special interim payments for certain costs.* For capital-related costs for cost-reporting periods beginning before October 1, 1991, and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items for cost-reporting periods beginning before October 1, 1991, and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Medicare Part A and for kidney acquisition costs in hospitals with approved kidney transplant programs) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made 2 weeks after the end of

a biweekly period of services, as described in §413.64(h)(5) of this subchapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

(d) *Special interim payment for unusually long lengths of stay*—(1) *First interim payment.* A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment after a Medicare beneficiary has been in the hospital at least 60 days. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments.* A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph (d).

(e) *Outlier payment and additional payments for new medical services and technologies.* Payments for outlier cases and additional payments for new medical services and technologies (described in subpart F of this part) are not made on an interim basis.

(f) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to a hospital that is not receiving periodic interim payments under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A hospital's request for an accelerated payment must be approved by the intermediary and CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as hospital bills are processed or by direct payment by the hospital.

[53 FR 1627, Jan. 21, 1988, as amended at 53 FR 38532, Sept. 30, 1988; 54 FR 36495, Sept. 1, 1989; 56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992; 59 FR 36712, July 19, 1994; 59 FR 45400, Sept. 1, 1994; 66 FR 41387, Aug. 7, 2001; 67 FR 56049, Aug. 30, 2002; 68 FR 45470, Aug. 1, 2003; 69 FR 66977, Nov. 15, 2004; 71 FR 48140, Aug. 18, 2006; 86 FR 73512, Dec. 27, 2021]

§ 412.120 Reductions to total payments.

(a) *Deductible and coinsurance.* Subject to paragraph (a)(2) of this section, the total Medicare payments otherwise payable to a hospital are reduced by the applicable deductible and coinsurance amounts related to inpatient hospital services as determined in accordance with §§409.82, 409.83, and 409.87 of this chapter.

(b) *Payment by workers' compensation, automobile medical, no-fault or liability insurance or an employer group health plan primary to Medicare.* If workers' compensation, automobile medical, no-fault, or liability insurance or an employer group health plan which is primary to Medicare pays in full or in part, the Medicare payment is determined in accordance with the following guidelines:

(1) If workers' compensation pays, in accordance with the applicable provisions of §§405.316 through 405.321 of this chapter.

(2) If automobile medical, no-fault, or liability insurance pays, in accordance with the applicable provisions of §§405.322 through 405.325 of this chapter.

(3) If an employer group health plan which is primary to Medicare pays for services to ESRD beneficiaries, in accordance with the applicable provisions of §§405.326 through 405.329 of this chapter.

(4) If an employer group health plan which is primary to Medicare pays for services to employees age 65–69 and their spouses age 65–69, in accordance with the applicable provisions of

§§405.340 through 405.344 of this chapter.

[50 FR 12741, Mar. 29, 1985, as amended at 55 FR 36071, Sept. 4, 1990; 56 FR 573, Jan. 7, 1991; 57 FR 39825, Sept. 1, 1992]

§412.125 Effect of change of ownership on payments under the prospective payment systems.

When a hospital's ownership changes, as described in §489.18 of this chapter, the following rules apply:

(a) Payment for the operating and capital-related costs of inpatient hospital services for each patient, including outlier payments, as provided in §412.112, and payments for hemophilia clotting factor costs under §412.115(b), are made to the entity that is the legal owner on the date of discharge. Payments are not prorated between the buyer and seller.

(1) The owner on the date of discharge is entitled to submit a bill for all inpatient hospital services furnished to a beneficiary regardless of when the beneficiary's coverage began or ended during a stay, or of how long the stay lasted.

(2) Each bill submitted must include all information necessary for the intermediary to compute the payment amount, whether or not some of that information is attributable to a period during which a different party legally owned the hospital.

(b) Other payments under §412.113 and payments for bad debts as described in §412.115(a), are made to each owner or operator of the hospital (buyer and seller) in accordance with the principles of reasonable cost reimbursement.

[50 FR 12741, Mar. 29, 1985, as amended at 56 FR 43449, Aug. 30, 1991]

§412.130 Retroactive adjustments for incorrectly excluded hospitals and units.

(a) *Hospitals for which adjustment is made.* The intermediary makes the payment adjustment described in paragraph (b) of this section for the following hospitals:

(1) A hospital that was excluded from the prospective payment systems specified in §412.1(a)(1) or paid under the prospective payment system specified in §412.1(a)(3), as a new rehabilitation hospital for a cost reporting period beginning on or after October 1, 1991 based on a certification under §412.29(c) regarding the inpatient population the hospital planned to treat during that cost reporting period, if the inpatient population actually treated in the hospital during that cost reporting period did not meet the requirements of §412.29(b).

(2) A hospital that has a unit excluded from the prospective payment systems specified in §412.1(a)(1) or paid under the prospective payment system specified in §412.1(a)(3), as a new rehabilitation unit for a cost reporting period beginning on or after October 1, 1991, based on a certification under §412.29(c) regarding the inpatient population the hospital planned to treat in that unit during the period, if the inpatient population actually treated in the unit during that cost reporting period did not meet the requirements of §412.29(b).

(3) A hospital that added new beds to its existing rehabilitation unit for a cost reporting period beginning on or after October 1, 1991 based on a certification under §412.29(c) regarding the inpatient population the hospital planned to treat in these new beds during that cost reporting period, if the inpatient population actually treated in the new beds during that cost reporting period did not meet the requirements of §412.29(b).

(b) *Adjustment of payment.* (1) For cost reporting periods beginning before January 1, 2002, the intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(i) The intermediary calculates the difference between the amounts actually paid during the cost reporting period for which the hospital, unit, or beds were first excluded as a new hospital, new unit, or newly added beds under subpart B of this part, and the amount that would have been paid under the prospective payment systems specified in §412.1(a)(1) for services furnished during that period.

(ii) The intermediary makes a retroactive adjustment for the difference between the amount paid to the hospital based on the exclusion and the amount that would have been paid under the

prospective payment systems specified in § 412.1(a)(1).

(2) For cost reporting periods beginning on or after January 1, 2002, the intermediary adjusts the payment to the hospitals described in paragraph (a) of this section as follows:

(i) The intermediary calculates the difference between the amounts actually paid under subpart P of this part during the cost reporting period for which the hospital, unit, or beds were first classified as a new hospital, new unit, or newly added beds under subpart B of this part, and the amount that would have been paid under the prospective payment systems specified in § 412.1(a)(1) for services furnished during that period.

(ii) The intermediary makes a retroactive adjustment for the difference between the amount paid to the hospital under subpart P of this part and the amount that would have been paid under the prospective payment systems specified in § 412.1(a)(1).

[56 FR 43241, Aug. 30, 1991, as amended at 57 FR 39825, Sept. 1, 1992; 59 FR 45400, Sept. 1, 1994; 60 FR 45848, Sept. 1, 1995; 66 FR 41387, Aug. 7, 2001; 70 FR 66977, Nov. 15, 2005; 78 FR 47934, Aug. 6, 2013]

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

(a) *Participation in the Hospital IQR Program.* In order to participate in the Hospital IQR Program, a section 1886(d) of the hospital must–

(1) Register on QualityNet website, before it begins to report data;

(2) Identify and register a QualityNet security official as part of the registration process under paragraph (a)(1) of this section; and

(3) Submit a completed Notice of Participation Form to CMS if the hospital is participating in the program for the first time, has previously withdrawn from the program and would like to participate again, or has received a new CMS Certification Number (CCN).

(i) A hospital that would like to participate in the program for the first time (and to which paragraph (a)(3)(ii) of this section does not apply), or that previously withdrew from the program and would now like to participate again, must submit to CMS a completed Notice of Participation Form by December 31 of the calendar year preceding the first quarter of the calendar year in which data submission is required for any given fiscal year.

(ii) A hospital that has received a new CCN and would like to participate in the program must submit a completed Notice of Participation Form to CMS no later than 180 days from the date identified as the open date on the approved CMS Quality Improvement Evaluation System (QIES).

(b) *Withdrawal from the Hospital IQR Program.* CMS will accept Hospital IQR Program withdrawal forms from hospitals on or before—

(1) Prior to the FY 2016 payment determination, August 15 of the fiscal year preceding the fiscal year for which a Hospital IQR determination will be made.

(2) Beginning with the FY 2016 payment determination, May 15 of the fiscal year preceding the fiscal year for which a Hospital IQR payment determination will be made.

(c) *Submission and validation of Hospital IQR Program data.* (1) *General rule.* Except as provided in paragraph (c)(2) of this section, subsection (d) hospitals that participate in the Hospital IQR Program must submit to CMS data on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. A hospital must begin submitting data on the first day of the quarter following the date that the hospital submits a completed Notice of Participation form under paragraph (a)(3) of this section.

(2) *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. CMS may grant an exception as follows:

(i) For circumstances not relating to the reporting of electronic clinical quality measure data, a hospital participating in the Hospital IQR Program that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that

the extraordinary circumstances occurred. For circumstances relating to the reporting of electronic clinical quality measures, a hospital participating in the Hospital IQR Program that wishes to request an exception must submit its request to CMS by April 1 following the end of the reporting calendar year in which the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on QualityNet website.

(ii) CMS may grant an exception to one or more hospitals that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the hospital to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

(d) *Validation of Hospital IQR Program data.* CMS may validate one or more measures selected under section 1886(b)(3)(B)(viii) of the Act by reviewing patient charts submitted by selected participating hospitals.

(1) Upon written request by CMS or its contractor, a hospital must submit to CMS a sample of patient charts 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 patient charts to CMS or its contractor within 30 days of the date identified on the written request.

(2)(i) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(ii)(A) Prior to the FY 2028 payment determination, a hospital meets the eCQM validation requirement with respect to a fiscal year if it submits 100 percent of sampled eCQM measure medical records in a timely and complete manner, as determined by CMS.

(B) For the FY 2028 payment determination and later years, a hospital meets the eCQM validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

(e) *Reconsiderations and appeals of Hospital IQR Program decisions.* (1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital IQR Program for a particular fiscal year. Except as provided in paragraph (c)(2) of this section, a hospital must submit a reconsideration request to CMS no later than 30 days from the date identified on the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter provided to the hospital.

(2) A reconsideration request must contain the following information:

(i) The hospital's CMS Certification Number (CCN);

(ii) The name of the hospital;

(iii) Contact information for the hospital's chief executive officer and QualityNet security official, including each individual's name, e-mail address, telephone number, and physical mailing address;

(iv) A summary of the reason(s), as set forth in the Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter, that CMS concluded the hospital did not meet the requirements of the Hospital IQR Program;

(v) A detailed explanation of why the hospital believes that it complied with the requirements of the Hospital IQR Program for the applicable fiscal year;

(vi) Any evidence that supports the hospital's reconsideration request, including copies of patient charts, e-mails and other documents; and

(vii) If the hospital has requested reconsideration on the basis that CMS concluded it did not meet the validation requirement set forth in paragraph (d) of this section, the reconsideration request must contain a detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(A) A copy of each patient chart that the hospital timely submitted to CMS or its contractor in response to a request made under paragraph (d)(1) of this section; and

(B) A detailed explanation identifying which data the hospital believes was improperly validated by CMS and why the hospital believes that such data are correct.

(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.

(f) *Patient experience of care data (HCAHPS survey).* HCAHPS is the Hospital Consumer Assessment of Healthcare Providers and Systems survey that measures patient experience of care after a recent hospital stay.

(1) Approved HCAHPS survey vendors and self-administering hospitals must fully comply with all HCAHPS oversight activities, including allowing CMS and its HCAHPS Project Team to perform site visits at the hospitals' and survey vendors' company locations.

(2) CMS approves an application for an entity to administer the HCAHPS survey as an approved HCAHPS survey vendor on behalf of one or more hospitals when an applicant has met the Minimum Survey Requirements and Rules of Participation that can be found on the official HCAHPS On-Line Web site, and agree to comply with the current survey administration protocols that can be found on the official HCAHPS On-Line Web site. An entity must be an approved HCAHPS survey vendor in order to administer and submit HCAHPS data to CMS on behalf of one or more hospitals.

(g) *Retention and removal of quality measures under the Hospital IQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital IQR 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 (g)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure raises specific patient safety concerns, CMS will immediately remove a quality measure from the Hospital IQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital IQR Program ListServ and the QualityNet website, as applicable.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (g)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital IQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove a measure 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'' measure).

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(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 IQR Program, a measure is considered to be topped-out under paragraph (g)(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 2 times the standard error of the full data set).

(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 IQR Program will be assessed on a case-by-case basis.

[76 FR 51782, Aug. 18, 2011, as amended at 77 FR 53674, Aug. 31, 2012; 78 FR 50966, Aug. 19, 2013; 79 FR 50354, Aug. 22, 2014; 81 FR 57267, Aug. 22, 2016; 82 FR 38511, Aug. 14, 2017; 86 FR 45520, Aug. 13, 2021; 87 FR 49404, Aug. 10, 2022; 88 FR 59332, Aug. 28, 2023; 89 FR 69912, Aug. 28, 2024]

Subpart I—Adjustments to the Base Operating DRG Payment Amounts Under the Prospective Payment Systems for Inpatient Operating Costs

SOURCE: 77 FR 53674, Aug. 31, 2012, unless otherwise noted.

§412.150 Basis and scope of subpart.

(a) Section 1886(q) of the Act requires the Secretary to establish a Hospital Readmissions Reduction program, under which payments to applicable hospitals are reduced in order to account for certain excess readmissions, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Readmission Reductions Program are specified in §§412.152 and 412.154.

(b) Section 1886(o) of the Act requires the Secretary to establish a Value-Based Purchasing (VBP) Program for inpatient hospitals (Hospital VBP Program), which requires CMS to make value-based incentive payments to hospitals that meet performance standards for applicable performance periods, effective for discharges beginning on October 1, 2012. The rules for determining the payment adjustment under the Hospital Value-Based Purchasing Program are specified in §§412.160 through 412.167.

(c) Section 1886(p) of the Act requires the Secretary to establish an adjustment to hospital payments for hospital-acquired conditions, or a Hospital-Acquired Condition Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions, effective for discharges beginning on October 1, 2014. The rules for determining the payment adjustment under the Hospital-Acquired Condition Reduction Program are specified in §§412.170 and 412.172.

[77 FR 53674, Aug. 31, 2012, as amended at 78 FR 50966, Aug. 19, 2013]

PAYMENT ADJUSTMENTS UNDER THE HOSPITAL READMISSIONS REDUCTION PROGRAM

§412.152 Definitions for the Hospital Readmissions Reduction Program.

As used in this section and in §412.154, the following definitions apply:

Aggregate payments for all discharges is, for a hospital for the applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.

Aggregate payments for excess readmissions is, for a hospital for the applicable period, the sum, for the applicable conditions, of the product for each applicable condition of:

(1) The base operating DRG payment amount for the hospital for the applicable period for such condition or procedure;

(2) The number of admissions for such condition or procedure for the hospital for the applicable period;

(3) The excess readmission ratio for the hospital for the applicable period minus the peer-group median excess readmission ratio (ERR); and

(4) The neutrality modifier, a multiplicative factor that equates total Medicare savings under the current stratified methodology to the previous non-stratified methodology.

Applicable condition is a condition or procedure selected by the Secretary—

(1) Among the conditions and procedures for which—

(i) Readmissions represent conditions or procedures that are high volume or high expenditures; and

(ii) Measures of such readmissions have been endorsed by the entity with a contract under section 1890(a) of the Act and such endorsed measures have exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital); or

(2) Among other conditions and procedures as determined appropriate by the Secretary. In expanding the applicable conditions, the Secretary will seek endorsement of the entity with a contract under section 1890(a) of the Act, but may apply such measures without such an endorsement 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 as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

(1) The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020; and

(2) Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary.

Applicable period for dual eligibility is the 3-year data period corresponding to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise established by the Secretary.

Base operating DRG payment amount is the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Value-Based Purchasing Program, as specified under § 412.162. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, and a low volume of discharges under § 412.101. With respect to a sole community hospital that receives payments under § 412.92(d) this amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part. With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c), this amount includes the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part. With respect to a hospital that is paid under section 1814(b)(3) of the Act, this amount is an amount equal to the wage-adjusted DRG payment amount plus new technology payments that would be paid to such hospitals, absent the provisions of section 1814(b)(3) of the Act.

Dual-eligible—(1) For payment adjustment factor calculations prior to the FY 2021 program year, is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Authorization Act (MMA) files for the month the beneficiary was discharged from the hospital; and

(2) For payment adjustment factor calculations beginning in the FY 2021 program year, is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, which will be identified using the previous month's data as sourced from the State MMA files.

Excess readmissions ratio is a hospital-specific ratio for each applicable condition for an applicable period, which is the ratio (but not less than 1.0) of risk-adjusted readmissions based on actual readmissions for an applicable hospital for each applicable condition to the risk-adjusted expected readmissions for the applicable hospital for the applicable condition.

Floor adjustment factor is the value that the readmissions adjustment factor cannot be less than for a given fiscal year. The floor adjustment factor is set at 0.99 for FY 2013, 0.98 for FY 2014,

and 0.97 for FY 2015 and subsequent fiscal years.

Proportion of dual-eligibles is the number of dual-eligible patients among all Medicare Fee-for-Service and Medicare Advantage stays during the applicable period.

Readmission is the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period of 30 days from the date of such discharge.

Readmissions adjustment factor is equal to the greater of:

(1) 1 minus the ratio of the aggregate payments for excess readmissions to aggregate payments for all discharges; or

(2) The floor adjustment factor.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for resource utilization by the applicable MS–DRG relative weight and adjusted for differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii). This amount includes an applicable payment adjustment for transfers under §412.4(f).

[77 FR 53674, Aug. 31, 2012, as amended at 78 FR 50967, Aug. 19, 2013; 83 FR 41704, Aug. 17, 2018; 84 FR 42613, Aug. 16, 2019l 85 FR 59022, Sept. 18, 2020]

§412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

(a) *Scope*. This section sets forth the requirements for determining the payment adjustments under the Hospital Readmissions Reduction Program for applicable hospitals to account for excess readmissions in the hospital.

(b) *Payment adjustment*. (1) *General*. To account for excess readmissions, except as provided for in paragraph (d) of this section, an applicable hospital's base operating DRG payment amount is adjusted for each discharge occurring during the fiscal year. The payment adjustment for each discharge is determined by subtracting the product of the base operating DRG payment amount (as defined in §412.152) for such discharge by the hospital's readmission payment adjustment factor for the fiscal year (determined under paragraph (c) of this section) from the base operating DRG payment amount for such discharge.

(2) *Special treatment for sole community hospitals*. In the case of a sole community hospital that receives payments under §412.92(d) based on the hospital-specific rate, the difference between the hospital-specific rate payment and the Federal rate payment determined under subpart D of this part is not affected by this payment adjustment.

(c) *Methodology to calculate the readmissions payment adjustment factor*. A hospital's readmissions payment adjustment factor is the higher of the ratio described in paragraph (c)(1) of this section or the floor adjustment factor set forth in paragraph (c)(2) of this section.

(1) *Ratio*. The ratio is equal to 1 minus the ratio of the aggregate payments for excess readmissions as defined in §412.152 and the aggregate payments for all discharges as defined in §412.152.

(2) *Floor adjustment factor*. The floor adjustment factor is:

(i) For FY 2013, 0.99;

(ii) For FY 2014, 0.98; and

(iii) For FY 2015 and subsequent fiscal years, 0.97.

(d) [Reserved]

(e) *Limitations on review*. There is no administrative or judicial review under this subpart of the following:

(1) The determination of base operating DRG payment amounts.

(2) The methodology for determining the adjustment factor under paragraph (c) of this section, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges.

(3) The applicable period.

(4) The neutrality modifier.

(5) The proportion of dual-eligibles.

(6) The applicable conditions.

(f) *Reporting of hospital-specific information*. CMS will make information available to the public regarding readmissions rates of each applicable hospital (as defined in §412.152) under the Hospital Readmissions Reduction Program.

(1) To ensure that an applicable hospital has the opportunity to review and

submit corrections for its excess readmission ratios for the applicable conditions for a fiscal year that are used to determine its readmissions payment adjustment factor under paragraph (c) of this section, CMS will provide each applicable hospital with confidential hospital-specific reports and discharge level information used in the calculation of its excess readmission ratios.

(2) Applicable hospitals will have a period of 30 days after receipt of the information provided in paragraph (f)(1) of this section to review and submit corrections for the excess readmission ratios for each applicable condition that are used to calculate the readmissions payment adjustment factor under paragraph (c) of this section for the fiscal year.

(3) The administrative claims data used to calculate an applicable hospital's excess readmission ratios for the applicable conditions for a fiscal year are not subject to review and correction under paragraph (f)(1) of this section.

(4) CMS posts the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the Hospital Compare website or successor website(s).

[77 FR 53674, Aug. 31, 2012, as amended at 78 FR 50967, Aug. 19, 2013; 79 FR 50354, Aug. 22, 2014; 84 FR 42614, Aug. 16, 2019; 86 FR 45520, Aug. 13, 2021]

§§ 412.155–412.159 [Reserved]

INCENTIVE PAYMENTS UNDER THE HOSPITAL VALUE-BASED PURCHASING PROGRAM

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

As used in this section and in §§ 412.161 through 412.168:

Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

Applicable percent means the following:

(1) For FY 2013, 1.0 percent;

(2) For FY 2014, 1.25 percent;

(3) For FY 2015, 1.50 percent;

(4) For FY 2016, 1.75 percent; and

(5) For FY 2017 and subsequent fiscal years, 2.0 percent.

Base operating DRG payment amount means the following:

(1) With respect to a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount is determined without regard to any payment adjustments under the Hospital Readmissions Reduction Program, as specified under § 412.154. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101.

(2) With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) or a sole community hospital that receives payments under § 412.92(d), the wage-adjusted DRG operating payment plus any applicable new technology add-on payments under subpart F of this part. This amount does not include any additional payments for indirect medical education under § 412.105, the treatment of a disproportionate share of low-income patients under § 412.106, outliers under subpart F of this part, or a low volume of discharges under § 412.101. With respect to a Medicare-dependent, small rural hospital that receives payments under § 412.108(c) (for discharges occurring in FY 2013) or a sole community hospital that receives payments under § 412.92(d), this amount also does not include the difference between the hospital-specific payment rate and the Federal payment rate determined under subpart D of this part.

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal

year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least three surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction. CMS assigns an immediate jeopardy citation to a performance period as follows:

(1) If the Form CMS–2567 only contains one or more EMTALA-related immediate jeopardy citations, CMS uses the date that the Form CMS–2567 is issued to the hospital;

(2) If the Form CMS–2567 only contains one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN; and

(3) If the Form CMS–2567 contains both one or more EMTALA-related immediate jeopardy citations and one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN.

Domain means a grouping of measures used for purposes of calculating the Total Performance Score for each hospital with respect to a fiscal year.

Domain score means the total number of points awarded to a hospital for a domain.

Health equity adjustment bonus points means the points that a hospital can earn for a fiscal year based on its performance and proportion of inpatient stays for patients with dual eligibility status.

Hospital means a hospital described in section 1886(d)(1)(B) of the Act, but does not include a hospital, with respect to a fiscal year, for which one or more of the following applies:

(1) The hospital is subject to the payment reduction under section 1886(b)(3)(B)(viii)(I) of the Act for the fiscal year;

(2) The Secretary cited the hospital for deficiencies that pose immediate jeopardy to the health or safety of patients during the performance period that applies with respect to the fiscal year;

(3) There are not a minimum number of measures that apply to the hospital for the performance period for the fiscal year; or

(4) There are not a minimum number of cases for the measures that apply to the hospital for the performance period for the fiscal year.

Immediate jeopardy has the same meaning as that term is defined in §489.3 of this chapter.

Improvement threshold (or improvement performance standard) means an individual hospital's performance level on a measure during the baseline period with respect to a fiscal year.

Linear Exchange Function is the means to translate a hospital's total performance score into a value-based incentive payment percentage such that:

(1) Each eligible hospital's value-based incentive payment percentage is based on its total performance score; and

(2) The total amount of value-based incentive payments to all hospitals in a fiscal year is equal to the total amount available for value-based incentive payments in such fiscal year.

Measure performance scaler means the sum of the points awarded to a hospital for each domain for the fiscal year based on the hospital's performance on the measures in those domains.

Performance period means the time period during which data are collected for the purpose of calculating hospital performance on measures with respect to a fiscal year.

Performance standards are the levels of performance that hospitals must meet or exceed in order to earn points under the Hospital VBP Program, and are calculated with respect to a measure for a fiscal year no later than 60 days prior to the start of the performance period for that measure for that fiscal year. The performance standards for a measure may be updated as follows:

(1) To make a single correction to correct a calculation error, data issue,

or other problem that would significantly change the performance standards; or

(2) To incorporate nonsubstantive technical updates made to the measure between the time that CMS first displays the performance standards for that measure for a fiscal year and the time that CMS calculates hospital performance on that measure at the conclusion of the performance period for that measure for a fiscal year.

Total Performance Score means the numeric score awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of hospital inpatient stays for patients in the underserved population out of the hospital's total Medicare inpatient population during the calendar year that is 2 years prior to the applicable fiscal year.

Underserved population, as used in this section, means hospital inpatients who are Medicare beneficiaries and also dually eligible for full Medicaid benefits during the month of discharge or, if a patient died during that month, during the previous month.

Value-based incentive payment adjustment factor is the number that will be multiplied by the base operating DRG payment amount for each discharge from a hospital, during a fiscal year, in order to adjust the hospital's payment as a result of its performance under the Hospital VBP Program.

Value-based incentive payment percentage means the percentage of the base operating DRG payment amount for each discharge that a hospital has earned with respect to a fiscal year, based on its Total Performance Score for that fiscal year.

Wage-adjusted DRG operating payment is the applicable average standardized amount adjusted for—

(1) Resource utilization by the applicable MS-DRG relative weight;

(2) Differences in geographic costs by the applicable area wage index (and by the applicable cost-of-living adjustment for hospitals located in Alaska and Hawaii); and

(3) Any applicable payment adjustment for transfers under § 412.4(f).

[77 FR 53674, Aug. 31, 2012, as amended at 78 FR 50967, Aug. 19, 2013; 79 FR 50354, Aug. 22, 2014; 81 FR 57268, Aug. 22, 2016; 86 FR 45520, Aug. 13, 2021; 88 FR 59333, Aug. 28, 2023]

§ 412.161 Applicability of the Hospital Value-Based Purchasing (VBP) Program.

The Hospital VBP Program applies to hospitals, as that term is defined in § 412.160.

[79 FR 50355, Aug. 22, 2014]

§ 412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

(a) *General.* If a hospital meets or exceeds the performance standards that apply to the Hospital VBP Program for a fiscal year, CMS will make value-based incentive payments to the hospital under the requirements and conditions specified in this section.

(b) *Value-based incentive payment amount.* (1) *Available amount.* The value-based incentive payment amount for a discharge is the portion of the payment amount that is attributable to the Hospital VBP Program. The total amount available for value based incentive payments to all hospitals for a fiscal year is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(2) *Calculation of the value-based incentive payment amount.* The value-based incentive payment amount is calculated by multiplying the base operating DRG payment amount by the value-based incentive payment percentage.

(3) *Calculation of the value-based incentive payment percentage.* The value-based incentive payment percentage is calculated as the product of all of the following:

(i) The applicable percent as defined in § 412.160.

(ii)(A) For fiscal years before FY 2026, the hospital's Total Performance Score divided by 100; or

(B) Beginning with FY 2026, the hospital's Total Performance Score divided by 110; and

(iii) The linear exchange function slope.

(c) *Methodology to calculate the value-based incentive payment adjustment factor*. The value-based incentive payment adjustment factor for each discharge is determined by subtracting the applicable percent as specified in §412.160 from the value-based incentive payment percentage and then adding that difference to one.

[77 FR 53674, Aug. 31, 2012, as amended at 88 FR 59333, Aug. 28, 2023]

§412.163 Process for making hospital-specific performance information under the Hospital Value-Based Purchasing (VBP) Program available to the public.

(a) CMS will make information available to the public regarding the performance of each hospital under the Hospital VBP Program.

(b) To ensure that a hospital has the opportunity to review and submit corrections for the information to be made public under this section, CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its performance with respect to each measure, condition, and domain, and the calculation of its Total Performance Score.

(c) Hospitals will have a period of 30 days after CMS provides the information specified in paragraph (b) of this section to review and submit corrections for the information.

(d) CMS will post the information specified in paragraph (b) for each hospital on the the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*.

[50 FR 12741, Mar. 29, 1985, as amended at 86 FR 45520, Aug. 13, 2021]

§412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

(a) CMS will select measures, other than measures of readmissions, for purposes of the Hospital VBP Program. The measures will be selected from the measures specified under section 1886(b)(3)(B)(viii) of the Act (the Hospital Inpatient Quality Reporting Program).

(b) CMS will post data on each measure on the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*, for at least 1 year prior to the beginning of a performance period for the measure under the Hospital VBP Program.

(c)(1) *Updating of measure specifications*. CMS uses rulemaking to make substantive updates to the specifications of measures used in the Hospital VBP Program. CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

(2) *Measure retention*. All measures selected under paragraph (a) of this section remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors*—(i) *General rule*. CMS may remove or replace a measure based on one of 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), defined as: statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10.

(B) *Factor 2*. A measure does not align with current clinical guidelines or practice.

(C) *Factor 3*. The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4*. Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5*. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6*. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Application of measure removal factors.* CMS assesses the benefits of removing a measure from the Hospital VBP Program on a case-by-case basis.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for hospitals to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the Hospital VBP measure set. CMS will, upon removal of the measure—

(A) Provide notice to hospitals and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if hospitals continued to submit data on the measure; and

(B) Provide notice of the removal in the FEDERAL REGISTER.

[77 FR 53674, Aug. 31, 2012, as amended at 83 FR 41704, Aug. 17, 2018; 86 FR 45520, Aug. 13, 2021; 88 FR 59333, Aug. 28, 2023]

§ 412.165 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

(a) *Points awarded based on hospital performance.* (1) CMS will award points to hospitals for performance on each measure for which the hospital reports the applicable minimum number of cases during the applicable performance period. The applicable minimum number of cases are set forth as follows:

TABLE 1 TO PARAGRAPH (a)(1)—MINIMUM CASE NUMBER REQUIREMENTS FOR HOSPITAL VBP PROGRAM

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed Hospital Consumer Assessment of Healthcare providers and Systems (HCAHPS) surveys.
Clinical Outcomes Domain	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
COMP–HIP–KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the Centers for Disease Control and Prevention (CDC).
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI.	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
SEP–1	Hospitals must report a minimum number of 25 cases.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

(2) CMS will award from 1 to 9 points for achievement to each hospital whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark for that measure.

(3) CMS will award from 0 to 9 points for improvement to each hospital whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(4) CMS will award 10 points to a hospital whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(b) *Calculation of the Total Performance Score.* The hospital's Total Performance Score for a program year is calculated as follows:

(1) CMS will calculate a domain score for a hospital when it reports the minimum number of measures in the domain.

(2) CMS will sum all points awarded for each measure in a domain to calculate an unweighted domain score.

(3) CMS will normalize each domain score to ensure that it is expressed as a percentage of points earned out of 100.

(4) CMS will weight the domain scores with the finalized domain weights for each fiscal year.

(5) Beginning with FY 2026, CMS will calculate the number of health equity adjustment bonus points the hospital has earned for the fiscal year as follows:

(i) Calculating the measure performance scaler for each domain in which the hospital reported the minimum number of cases by—

(A) Awarding 4 points where the hospital's performance on the domain for the fiscal year meets or exceeds the top third of performance of all hospitals on the domain for the same fiscal year;

(B) Awarding 2 points where the hospital's performance on the domain for the fiscal year meets or exceeds the middle third of performance, but is less than the top third of performance, of all hospitals on the domain for the same fiscal year;

(C) Awarding 0 points where the hospital's performance on the domain is less than the middle third of performance of all hospitals on the domain for the fiscal year; and

(D) Summing the points awarded under paragraph (b)(5)(i) of this section to calculate the measure performance scaler for the hospital.

(ii) Calculating the underserved multiplier for the hospital.

(iii) Multiplying the measure performance scaler calculated under paragraph (b)(5)(i) of this section by the underserved multiplier and, if the resulting product is greater than 10, capping that product at 10.

(6) The hospital's Total Performance Score for the fiscal year is as follows:

(i) For fiscal years before FY 2026, the sum of the weighted domain scores up to a maximum score of 100.

(ii) Beginning with FY 2026, the sum of the weighted domain scores and the health equity adjustment bonus points up to a maximum score of 110.

(c) *Extraordinary circumstances exception.* (1) A hospital may request and CMS may grant exceptions to the Hospital VBP Program's requirements under this section when there are certain extraordinary circumstances beyond the control of the hospital.

(2) A hospital may request an exception within 90 calendar days of the date that the extraordinary circumstances occurred by submitting a completed Extraordinary Circumstances Request Form (available on the Hospital Value-Based Purchasing (HVBP) Program section of the QualityNet website (*https://qualitynet.cms.gov/*)), and any available evidence of the impact of the extraordinary circumstances on the hospital's quality measure performance. The form must be sent via secure file transfer via the *QualityNet Secure portal*, secure fax, email, or conventional mail.

(3) Following receipt of the request form, CMS will provide a written acknowledgement using the contact information provided in the request, to the CEO and any additional designated personnel, notifying them that the hospital's request has been received, and provide a written response to the CEO and any additional designated personnel using the contact information provided in the request.

(4) CMS may grant an exception to one or more hospitals that have not requested an exception if CMS determines that an extraordinary circumstance has affected an entire region or locale, which may include the entire United States. CMS will notify hospitals that it has granted an exception under this paragraph via multiple methods, which may include memos,

emails, and notices posted on the public QualityNet website (*https://qualitynet.cms.gov/*).

[50 FR 12741, Mar. 29, 1985, as amended at 85 FR 27621, May, 8, 2020; 86 FR 45520, Aug. 13, 2021; 88 FR 59333, Aug. 28, 2023]

§ 412.167 Appeal under the Hospital Value-Based Purchasing (VBP) Program.

(a) A hospital may appeal the following issues:

(1) CMS' decision to deny a hospital's correction request that the hospital submitted under the review and corrections process;

(2) Whether the achievement/improvement points were calculated correctly;

(3) Whether CMS properly used the higher of the achievement/improvement points in calculating the hospital's measure/dimension score;

(4) Whether CMS correctly calculated the domain scores, including the normalization calculation;

(5) Whether CMS used the proper lowest dimension score in calculating the hospital's HCAHPS consistency points;

(6) Whether CMS calculated the HCAHPS consistency points correctly;

(7) Whether the correct domain scores were used to calculate the Total Performance Score;

(8) Whether each domain was weighted properly;

(9) Whether the weighted domain scores were properly summed to arrive at the Total Performance Score; and,

(10) Whether the hospital's open/closed status (including mergers and acquisitions) is properly specified in CMS' systems.

(b) Appeals must be submitted within 30 days of CMS' decision to deny a corrections request under § 412.163 or within 30 days of the conclusion of the review and corrections period, as applicable, and must contain the following information:

(1) Hospital's CMS Certification Number (CCN).

(2) Hospital name.

(3) Hospital's basis for requesting an appeal. This must identify the hospital's specific reason(s) for appealing the hospital's Total Performance Score or performance assessment with respect to the performance standards.

(4) CEO contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(5) QualityNet security official contact information, including name, email address, telephone number, and mailing address (must include the physical address, not just the post office box).

(c) If a hospital is dissatisfied with CMS' decision on an appeal request submitted under paragraph (b) of this section, the hospital may request an independent CMS review of that decision.

(d) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the amount of the value-based incentive payment under section 1886(o)(6) of the Act and the determination of such amount.

(2) The determination of the amount of funding available for value-based incentive payments under section 1886(o)(7)(A) of the Act and the payment reduction under section 1886(o)(7)(B)(i) of the Act.

(3) The establishment of the performance standards under section 1886(o)(3) of the Act and the performance period under section 1886(o)(4) of the Act.

(4) The measures specified under section 1886(b)(3)(B)(viii) of the Act and the measures selected under section 1886(o)(2) of the Act.

(5) The methodology developed under section 1886(o)(5) of the Act that is used to calculate hospital performance scores and the calculation of such scores.

(6) The validation methodology that is specified under section 1886(b)(3)(B)(viii)(XI) of the Act.

[50 FR 12741, Mar. 29, 1985, as amended at 78 FR 75196, Dec. 10, 2013; 86 FR 45520, Aug. 13, 2021]

§ 412.168 Special rules for FY 2022 and FY 2023.

(a) This section sets forth the scoring and payment methodology for each of fiscal years 2022 and 2023Hospital VBP Program.

(b) CMS calculates a measure rate for all measures selected under § 412.164(a)

for fiscal year 2022 but only applies § 412.165(a) to the measures included in the Clinical Outcomes Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI).

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF).

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort)).

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD).

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG).

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE).

(c) CMS calculates a domain score for the measures described in paragraph (b)(1) of this section for hospitals that report the minimum number of measures in the Clinical Outcomes Domain.

(d) CMS does not award a Total Performance Score to any hospital.

(e) The total amount available for value-based incentive payments for fiscal year 2022 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(f) CMS awards value-based incentive payment percentages (as defined in § 412.160) for all hospitals to ensure that each hospital receives an incentive payment amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

(g) CMS calculates a measure rate for all measures selected under § 412.164(a) for fiscal year 2023 but only applies § 412.165(a) to the measures included in the Clinical Outcomes Domain and the Efficiency and Cost Reduction Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI).

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF).

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort)).

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD).

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG).

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE).

(7) Medicare Spending Per Beneficiary (MSPB)—Hospital.

(h) CMS calculates—

(1) A Clinical Outcomes Domain score for fiscal year 2023 for hospitals that report the minimum number of cases and measures with respect to the measures described in paragraphs (g)(1) through (6) of this section; and

(2) An Efficiency and Cost Reduction Domain score for fiscal year 2023 for hospitals that report the minimum number of cases with respect to the measure described in paragraph (g)(7) of this section.

(i) CMS does not award a Total Performance Score to any hospital for fiscal year 2023.

(j) The total amount available for value-based incentive payments for fiscal year 2023 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(k) CMS awards a value-based incentive payment percentage (as defined in § 412.160) for fiscal year 2023 to all hospitals to ensure that each hospital receives a value-based incentive payment

amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

[86 FR 45520, Aug. 13, 2021, as amended at 87 FR 49404, Aug. 10, 2022]

§ 412.169 [Reserved]

PAYMENT ADJUSTMENTS UNDER THE HOSPITAL-ACQUIRED CONDITION REDUCTION PROGRAM

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

As used in this section and § 412.172, the following definitions apply:

Applicable hospital is a hospital described in section 1886(d)(1)(B) of the Act (including a hospital in Maryland that is paid under the waiver under section 1814(b)(3) of the Act and that, absent the waiver specified by section 1814(b)(3) of the Act, would have been paid under the hospital inpatient prospective payment system) as long as the hospital meets the criteria specified under § 412.172(e).

Applicable period is, unless otherwise specified by the Secretary, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

(1) The applicable period for FY 2022—

(i) For the CMS PSI 90 measure, is the 24-month period from July 1, 2018 through June 30, 2020; and

(ii) For the CDC NHSN HAI measures, is the 24-month period from January 1, 2019 through December 31, 2020.

(2) Beginning with the FY 2023 program year, the applicable period is the 24-month period advanced by 1-year from the prior fiscal year's period from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program, unless otherwise specified by the Secretary.

CDC NHSN HAI stands for Centers for Disease Control and Prevention National Healthcare Safety Network healthcare-associated infection measures.

CMS PSI 90 stands for Patient Safety and Adverse Events Composite for Selected Indicators (modified version of PSI 90).

Hospital-acquired condition is a condition as described in section 1886(d)(4)(D)(iv) of the Act and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.

[78 FR 50967, Aug. 19, 2013, as amended at 81 FR 57268, Aug. 22, 2016; 85 FR 59022, Sept. 18, 2020]

§ 412.172 Payment adjustments under the Hospital-Acquired Condition Reduction Program.

(a) *Scope.* This section sets forth the requirements for determining the payment adjustments under the Hospital-Acquired Condition Reduction Program for hospitals that meet the criteria described under paragraph (e) of this section.

(b) *Payment adjustment.* With respect to all discharges from an applicable hospital occurring during FY 2015 or a subsequent year, the amount of payment under this section, or section 1814(b)(3) of the Act as applicable, for such discharges during the fiscal year will be equal to 99 percent of the amount of payment that would otherwise apply to these discharges under this section or section 1814(b)(3) of the Act (determined after the application of the payment adjustment under the Hospital Readmissions Reduction Program under § 412.154 and the adjustment made under the Hospital Value-Based Purchasing Program under § 412.162 and section 1814(l)(4) of the Act but without regard to section 1886(p) of the Act).

(c) [Reserved]

(d) *Risk adjustment.* In carrying out the provisions of paragraph (e) of this section, CMS will establish and apply an appropriate risk-adjustment methodology.

(e) *Criteria for applicable hospitals.* (1) *General.* With respect to a subsection (d) hospital, CMS will identify the top quartile of all subsection (d) hospitals with respect to hospital-acquired conditions as measured during the applicable period.

(2) *Use of total hospital-acquired condition scores.* CMS will use total hospital-acquired condition scores to identify applicable hospitals. CMS will identify the 25 percent of hospitals with the highest total scores.

(3) *Methodology for calculating total hospital-acquired condition scores.* CMS will calculate the total hospital-acquired condition scores by weighing the selected measures according to the established methodology.

(f) *Reporting of hospital-specific information.* CMS will make information available to the public regarding hospital-acquired condition rates of all hospitals under the Hospital-Acquired Condition Reduction Program.

(1) CMS will provide each hospital with confidential hospital-specific reports and discharge level information used in the calculation of its total hospital-acquired condition score.

(2) Hospitals will have a period of 30 days after the receipt of the information provided under paragraph (f)(1) of this section to review and submit corrections for the hospital-acquired condition program scores for each condition that is used to calculate the total hospital-acquired condition score for the fiscal year.

(3) The administrative claims data used to calculate a hospital's total hospital-acquired condition score for a condition for a fiscal year are not subject to review and correction under paragraph (f)(2) of this section.

(4) CMS posts the total hospital-acquired condition score, the domain score, and the score on each measure for each hospital on the Hospital Compare website or successor website.

(g) *Limitations on review.* There is no administrative or judicial review under § 412.170 and this section for the following:

(1) The criteria describing applicable hospitals.

(2) The applicable period.

(3) The specification of hospital-acquired conditions.

(4) The provision of reports to hospitals and the information made available to the public.

[78 FR 50967, Aug. 19, 2013, as amended at 79 FR 50355, Aug. 22, 2014; 84 FR 42614, Aug. 16, 2019; 86 FR 45520, Aug. 13, 2021]

§ 412.190 Overall Hospital Quality Star Rating.

(a) *Purpose.* (1) The Overall Hospital Quality Star Rating (Overall Star Rating) is a summary of certain publicly reported hospital measure data for the benefit of stakeholders, such as patients, consumers, and hospitals.

(2) The guiding principles of the Overall Star Rating are as follows. In developing and maintaining the Overall Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with *Hospital Compare* or its successor website and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Star Rating; and

(iv) Be responsive to stakeholder input.

(b) *Data included in Overall Star Rating*—(1) *Source of data.* The Overall Star Rating is calculated based on measure data collected and publicly reported on *Hospital Compare* or its successor site under the following CMS hospital inpatient and outpatient programs:

(i) Hospital Inpatient Quality Reporting (IQR) Program—section 1886(b)(3)(B)(viii)(VII) of the Act.

(ii) Hospital-Acquired Condition Reduction Program—section 1886(p)(6)(A) of the Act.

(iii) Hospital Value-based Purchasing Program—section 1886(o)(10)(A) of the Act.

(iv) Hospital Readmissions Reduction Program—section 1886(q)(6)(A) of the Act.

(v) Hospital Outpatient Quality Reporting (OQR) Program—section 1833(t)(17)(e) of the Act.

(2) *Hospitals included in Overall Star Rating.* Subsection (d) hospitals subject to the CMS quality programs specified in paragraph (b)(1) of this section that also have their data publicly reported on one of CMS' websites are included in the Overall Star Rating.

(3) *Critical Access Hospitals.* Critical Access Hospitals (CAHs) that wish to be voluntarily included in the Overall Star Rating must have elected to—

(i) Voluntarily submit quality measures included in and as specified under CMS hospital programs; and

(ii) Publicly report their quality measure data on *Hospital Compare* or its successor site.

(c) Frequency of publication and data used. The Overall Star Rating are published once annually using data publicly reported on Hospital Compare or its successor website from a quarter within the previous 12 months.

(d) *Methodology*—(1) *Selection of measures*. Measures are selected from those publicly reported on *Hospital Compare* or its successor website through certain CMS quality programs under paragraph (b)(1) of this section.

(i) From this group of measures, measures falling into one or more of the exclusions in paragraphs (d)(1)(i)(A) through (E) of this section will be removed from consideration:

(A) Measures that 100 hospitals or less publicly report. These measures would not produce reliable measure group scores based on too few hospitals;

(B) Measures that cannot be standardized to a single, common scale and otherwise not amenable to inclusion in a summary score calculation alongside process and outcome measures or measures that cannot be combined in a meaningful way. This includes measures that cannot be as easily combined with other measures captured on a continuous scale with more granular data;

(C) Non-directional measures for which it is unclear whether a higher or lower score is better. These measures cannot be standardized to be combined with other measures and form an aggregate measure group score;

(D) Measures not required for reporting on *Hospital Compare* or its successor websites through CMS programs; or

(E) Measures that overlap with another measure in terms of cohort or outcome, including component measures that are part of an already-included composite measure.

(ii) [Reserved]

(2) *Measure score standardization*. All measure scores are standardized by calculating Z-scores so that all measures are on a single, common scale to be consistent in terms of direction (that is, higher scores are better) and numerical magnitude. This is calculated by subtracting the national mean measure score from each hospital's measure score and dividing the difference by the measure standard deviation in order to standardize measures.

(3) *Grouping measures*. Measures are grouped into one of the five clinical groups as follows:

(i) Mortality.

(ii) Safety of Care.

(iii) Readmission.

(iv) Patient Experience.

(v) Timely and Effective Care.

(4) *Calculate measure group scores*. A score is calculated for each measure group for which a hospital has measure data using a simple average of measure scores, as follows:

(i) Each measure group score is standardized by calculating Z-scores for each measure group so that all measure group scores are centered near zero with a standard deviation of one.

(ii) We take 100 percent divided by the number of measures reported in a measure group to determine the percentage of each measure's weight.

(iii) The measure weight is then multiplied by the standardized measure score to calculate the measure's weighted score.

(iv) Then, all of the individual measure weighted scores within a measure group are added together to calculate the measure group score.

(5) *Reporting thresholds*. In order to receive an Overall Star Rating, a hospital must report at least three measures within at least three measure groups, one of which must specifically be the Mortality or Safety of Care outcome group.

(6) *Hospital summary score*. A summary score is calculated by multiplying the standardized measure group scores by the assigned measure group weights and then summing the weighted measure group scores.

(i) *Standard measure group weighting*. (A) Each of the Mortality, Safety of Care, Readmission, and Patient Experience groups are weighted 22 percent; and

(B) The Timely and Effective Care group is weighted 12 percent.

(ii) *Reweighting*. (A) Hospitals may have too few cases to report particular measures and, in those cases, may not

report enough measures in one or more measure groups.

(B) When a hospital does not have enough measures in one or more measure groups due to too few cases CMS may re-distribute one or more of the missing measure group's weight proportionally across the remaining measure groups by subtracting the standard weight percentage of the group or groups with insufficient measures from 100 percent; and then dividing the resulting percentage across the remaining measure groups, giving new re-proportioned weights.

(7) *Peer grouping.* Hospitals are assigned to one of three peer groups based on the number of measure groups for which they report at least three measures: three, four, or five measure groups.

(8) *Star ratings assignment.* Hospitals in each peer group are then assigned between one and five stars where one star is the lowest and five stars is the highest using k-means clustering to complete convergence.

(e) *Preview period prior to publication.* CMS provides hospitals the opportunity to preview their Overall Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Star Rating*—(1) *Subsection (d) hospitals.* CMS may consider suppressing Overall Star Rating for subsection (d) hospitals only under extenuating circumstances that affect numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Star Rating calculation; or

(iii) If a Public Health Emergency, as defined in § 400.200 of this chapter, substantially affects the underlying measure data.

(2) *CAHs.* (i) CAHs may request to withhold their Overall Star Rating from publication on *Hospital Compare* or its successor website so long as the request for withholding is made, at the latest, during the Overall Star Rating preview period.

(ii) CAHs may request to have their Overall Star Rating withheld from publication on *Hospital Compare* or its successor website, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the *Hospital Compare* refresh data used to calculate the Overall Star Ratings.

[85 FR 86300, Dec. 29, 2020, as amended at 87 FR 72287, Nov. 23, 2022]

Subpart J [Reserved]

Subpart K—Prospective Payment System for Inpatient Operating Costs for Hospitals Located in Puerto Rico

SOURCE: 52 FR 33058, Sept. 1, 1987, unless otherwise noted.

§ 412.200 General provisions.

Beginning with discharges occurring on or after October 1, 1987, hospitals located in Puerto Rico are subject to the rules governing the prospective payment system for inpatient operating costs. Except as provided in this subpart, the provisions of subparts A, B, C, F, G, and H of this part apply to hospitals located in Puerto Rico. Except for § 412.60, which deals with DRG classification and weighting factors, or as otherwise specified, the provisions of subparts D and E, which describe the methodology used to determine prospective payment rates for inpatient operating costs for hospitals, do not apply to hospitals located in Puerto Rico. Instead, the methodology for determining prospective payment rates for inpatient operating costs for these hospitals is set forth in §§ 412.204 through 412.212.

[83 FR 41704, Aug. 17 2018]

§ 412.204 Payment to hospitals located in Puerto Rico.

(a) *FY 1988 through FY 1997.* For discharges occurring on or after October 1, 1987 and before October 1, 1997, payments for inpatient operating costs to hospitals located in Puerto Rico that

are paid under the prospective payment system are equal to the sum of—

(1) 75 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 25 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(b) *FY 1998 through March 31, 2004.* For discharges occurring on or after October 1, 1997 and before April 1, 2004, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 50 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 50 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(c) *Period of April 1, 2004 through September 31, 2004.* For discharges occurring on or after April 1, 2004 and before October 1, 2004, payment for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 37.5 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.210; and

(2) 62.5 percent of the national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(d) *FY 2005 through December 31, 2015.* For discharges occurring on or after October 1, 2004 and before January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

(1) 25 percent of the Puerto Rico prospective payment rate for inpatient operating costs, as determined under § 412.208 or § 412.211; and

(2) 75 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

(e) *January 1, 2016 and thereafter.* For discharges occurring on or after January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to 100 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

[62 FR 46030, Aug. 29, 1997, as amended at 69 FR 49247, Aug. 11, 2004; 81 FR 57268, Aug. 22, 2016]

§ 412.208 Puerto Rico rates for Federal fiscal year 1988.

(a) *General rule.* CMS determines the Puerto Rico adjusted DRG prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal year 1988 for a prospective payment hospital. These rates are determined as described in paragraphs (b) through (i) of this section.

(b) *Determining target amounts.* For each hospital subject to the prospective payment system for inpatient operating costs, CMS determines the Medicare target amount, as described in § 413.40(c) of this chapter, for the hospital's cost reporting period beginning in fiscal year 1987. Revisions in the target amounts made subsequent to establishment of the standardized amounts under paragraph (d) of this section do not affect the standardized amounts.

(c) *Updating the target amounts for fiscal year 1988.* CMS updates each target amount determined under paragraph (b) of this section for fiscal year 1988 by prorating the applicable percentage increase (as defined in § 412.63(f) of this chapter) for fiscal year 1988 to the midpoint of fiscal year 1988 (April 1, 1988).

(d) *Standardizing amounts.* CMS standardizes the amount updated under paragraph (c) of this section for each hospital by—

(1) Adjusting for variations in case mix among hospitals;

(2) Excluding an estimate of indirect medical education costs;

(3) Adjusting for area variations in hospital wage levels; and

(4) Excluding an estimate of the payments for hospitals that serve a disproportionate share of low-income patients.

(e) *Computing urban and rural averages.* CMS computes separate discharge-weighted averages of the standardized amounts determined under paragraph (d) of this section for urban and rural hospitals in Puerto Rico.

(f) *Geographic classification.* (1) For purposes of this paragraph (e) of this section, the following definitions apply:

(i) The term *urban area* means a Metropolitan Statistical Area (MSA), as defined by the Executive Office of Management and Budget.

(ii) The term *large urban area* means an MSA with a population of more than 1,000,000.

(iii) The term *rural area* means any area outside an urban area.

(2) A hospital classified as rural is deemed to be urban and receives the urban Puerto Rico payment amount if the county in which it is located meets the following criteria:

(i) At least 95 percent of the perimeter of the rural county is contiguous with urban counties.

(ii) The county was reclassified from an urban area to a rural area after April 20, 1983, as described in §412.62(f)(1)(iv).

(iii) At least 15 percent of employed workers in the county commute to the central county of one of the adjacent MSAs.

(g) *Reducing for value of outlier payments.* CMS reduces each of the average standardized amounts determined under paragraphs (c) through (e) of this section by a proportion equal to the proportion (estimated by CMS) of the total amount of payments based on DRG prospective payment rates that are additional payments to hospitals located in Puerto Rico for outlier cases under subpart F of this part.

(h) *Computing Puerto Rico rates established under the prospective payment system for inpatient operating costs for urban and rural hospitals.* For each discharge classified within a DRG, CMS establishes a Puerto Rico prospective payment rate, as follows:

(1) For hospitals located in an urban area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in an urban area; and

(ii) The weighting factor determined under §412.60(b) for that DRG.

(2) For hospitals located in a rural area, the rate equals the product of—

(i) The average standardized amount (computed under paragraphs (c) through (g) of this section) for hospitals located in a rural area; and

(ii) The weighting factor determined under §412.60(b) for that DRG.

(i) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Puerto Rico rates computed under paragraph (h) of this section that are attributable to wages and labor-related costs, for area differences in hospital wage levels, by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (f) of this section) of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987; 52 FR 35350, Sept. 18, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992]

§412.210 Puerto Rico rates for Federal fiscal years 1989 through 2003.

(a) *General rule.* (1) CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal years 1989 through 2003 that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(2) The rate is determined for hospitals located in large urban, other urban, or rural areas within Puerto Rico, as described in paragraphs (b) through (e) of this section.

(b) *Geographic classifications.* (1) For purposes of this section, the definitions set forth in §412.208(f)(1) apply.

(2) For discharges occurring on or after October 1, 1988, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the Federal payment amount for the urban area to which the greatest number of workers in the county commute if the

rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final standards for classification of MSAs published in the FEDERAL REGISTER on January 3, 1980 (45 FR 956), and available from CMS, East High Rise Building, Room 132, 6325 Security Boulevard, Baltimore, Maryland 21207.

(3) For discharges occurring on or after October 1, 1988, for hospitals that consist of two or more separately located inpatient hospital facilities, the national adjusted prospective payment rate for inpatient operating costs is based on the geographic location of the hospital at which the discharge occurs.

(c) *Updating previous standardized amounts.* CMS computes separate average standardized amounts for hospitals in large urban, other urban, and rural areas within Puerto Rico equal to the respective average standardized amount computed for fiscal year 1988 under § 412.208(e)—

(1) Increased by the applicable percentage changes determined under § 412.63 (g) and (h); and

(2) Reduced by a proportion equal to the proportion (estimated by CMS) of the total amount of prospective payments that are additional payment amounts to hospitals located in Puerto Rico attributable to outlier cases under subpart F of this part.

(d) *Computing Puerto Rico rates for large urban, other urban, and rural hospitals.* For each discharge classified within a DRG, CMS establishes for the fiscal year a Puerto Rico prospective payment rate for inpatient operating costs as follows:

(1) For hospitals located in a large urban or other urban area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a large urban or other urban area; and

(ii) The weighting factor determined under § 412.60(b) for that DRG.

(2) For hospitals located in a rural area in Puerto Rico, the rate equals the product of—

(i) The average standardized amount (computed under paragraph (c) of this section) for the fiscal year for hospitals located in a rural area; and

(ii) The weighting factor (determined under § 412.60(b)) for that DRG.

(e) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of Puerto Rico rates computed under paragraph (d) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the Peurto Rico average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992; 62 FR 46030, Aug. 29, 1997; 69 FR 49247, Aug. 11, 2004]

§ 412.211 Puerto Rico rates for Federal fiscal year 2004 and subsequent fiscal years.

(a) *General rule.* CMS determines the Puerto Rico adjusted prospective payment rate for inpatient operating costs for each inpatient hospital discharge occurring in Federal fiscal year 2004 and subsequent fiscal years that involves inpatient hospital services of a hospital in Puerto Rico subject to the prospective payment system for which payment may be made under Medicare Part A.

(b) *Geographic classifications.* (1) For purposes of this section, the following definitions apply:

(i) The term *urban area* means a Metropolitan Statistical Area (MSA) as defined by the Executive Office of Management and Budget.

(ii) The term *rural area* means any area outside of an urban area.

(2) For discharges occurring on or after October 1, 2004, a hospital located in a rural county adjacent to one or more urban areas is deemed to be located in an urban area and receives the

Federal payment amount for the urban area to which the greater number of workers in the county commute if the rural county would otherwise be considered part of an urban area, under the standards for designating MSAs if the commuting rates used in determining outlying counties were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or central counties of all adjacent MSAs. These EOMB standards are set forth in the notice of final revised standards for classification of MSAs published in the FEDERAL REGISTER on December 27, 2000 (65 FR 82228), announced by EOMB on June 6, 2003, and available from CMS, 7500 Security Boulevard, Baltimore, Maryland 21244.

(c) *Computing the standardized amount.* CMS computes a Puerto Rico standardized amount that is applicable to all hospitals located in all areas. The applicable percentage change for updating the Puerto Rico specific standardized amount is as follows:

(1) For fiscal year 2004 through fiscal year 2009, increased by the applicable percentage change specified in §412.64(d)(1)(ii)(A).

(2) For fiscal year 2010, increased by the market basket index for prospective payment hospitals (as defined in §413.40(a) of this subchapter) for hospitals in all areas.

(3) For fiscal year 2011, increased by the applicable percentage change specified in §412.64(d)(1)(iii).

(4) For fiscal year 2012 and subsequent fiscal years, the applicable percentage increase specified in §412.64(d).

(d) *Computing Puerto Rico Federal rates for inpatient operating costs for hospitals located in all areas.* For each discharge classified within a DRG, CMS establishes for the fiscal year a Puerto Rico prospective payment rate for inpatient operating costs equal to the product of—

(1) The average standardized amount for the fiscal year for hospitals located in all areas; and

(2) The weighting factor determined under §412.60(b) for that DRG.

(e) *Adjusting for different area wage levels.* CMS adjusts the proportion of the Puerto Rico rate for inpatient operating costs that are attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS based on survey data) reflecting the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined under the provisions of paragraph (b) of this section) of the hospital compared to the Puerto Rico average level of hospital wages and wage-related costs. The adjustment specified in this paragraph (e) also takes into account the earnings and paid hours of employment by occupational category.

(1) The wage index is updated annually.

(2) CMS determines the proportion of the Puerto Rico rate that is attributable to wages and labor-related costs from time to time, employing a methodology that is described in the annual update of the prospective payment system for payment of inpatient hospital operating costs published in the FEDERAL REGISTER.

(3) For discharges occurring on or after October 1, 2004, CMS employs 62 percent as the proportion of the rate that is adjusted for the relative level of hospital wages and wage-related costs, unless employing that percentage would result in lower payments for the hospital than employing the proportion determined under the methodology described in paragraph (e)(2) of this section.

(f) *Adjusting the wage index to account for commuting patterns of hospital workers*—(1) *General criteria.* For discharges occurring on or after October 1, 2004, CMS adjusts the hospital wage index for hospitals located in qualifying areas to recognize the commuting patterns of hospital employees. A qualifying area is an area that meets all of the following criteria:

(i) Hospital employees in the area commute to work in an MSA (or MSAs) with a wage index (or wage indices) higher than the wage index of the area.

(ii) At least 10 percent of the county's hospital employees commute to an MSA (or MSAs) with a higher wage index (or wage indices).

(iii) The 3-year average hourly wage of the hospital(s) in the area equals or exceeds the 3-year average hourly wage

of all hospitals in the MSA or rural area in which the county is located.

(2) *Amount of adjustment.* A hospital located in an area that meets the criteria under paragraphs (f)(1)(i) through (f)(1)(iii) of this section will receive an increase in its wage index that is equal to a weighted average of the difference between the prereclassified wage index of the MSA (or MSAs) with the higher wage index (or wage indices) and the prereclasssified wage index of the qualifying area, weighted by the overall percentage of the hospital employees residing in the qualifying area who are employed in any MSA with a higher wage index.

(3) *Process for determining the adjustment.* (i) CMS will use the most accurate data available, as determined by CMS, to determine the out-migration percentage for each area.

(ii) CMS will include, in its annual proposed and final notices of updates to the hospital inpatient prospective payment system, a listing of qualifying areas and the hospitals that are eligible to receive the adjustment to their wage indexes for commuting hospital employees, and the wage index increase applicable to each qualifying area.

(iii) Any wage index adjustment made under this paragraph (f) is effective for a period of 3 fiscal years, except that hospitals in a qualifying county may elect to waive the application of the wage index adjustment. A hospital may waive the application of the wage index adjustment by notifying CMS in writing within 45 days of the date of public display of the annual notice of proposed rulemaking for the hospital inpatient prospective payment system at the Office of the **Federal Register.**

(iv) A hospital in a qualifying area that receives a wage index adjustment under this paragraph (f) is not eligible for reclassification under Subpart L of this part.

[69 FR 49248, Aug. 11, 2004, as amended at 75 FR 50414, Aug. 16, 2010; 76 FR 51783, Aug. 18, 2011; 82 FR 38512, Aug. 14, 2017]

§ 412.212 National rate.

(a) *General rule.* For purposes of payment to hospitals located in Puerto Rico, the national prospective payment rate for inpatient operating costs is determined as described in paragraphs (b) through (d) of this section.

(b) *Computing Puerto Rico standardized amounts.* (1) For Federal fiscal years before FY 2004, CMS computes a discharge-weighted average of the—

(i) National urban adjusted standardized amount determined under § 412.63(j)(1); and

(ii) National rural adjusted average standardized amount determined under § 412.63(j)(2)(i).

(2) For fiscal years 2004 and subsequent fiscal years, CMS computes a discharge-weighted average of the national adjusted standardized amount determined under § 412.64(e).

(c) *Computing a national rate.* For each discharge classified within a DRG, the national rate equals the product of—

(1) The national average standardized amount computed under paragraph (b) of this section; and

(2) The weighting factor (determined under § 412.60(b)) for that DRG.

(d) *Adjusting for different area wage levels.* CMS adjusts the proportion (as estimated by CMS from time to time) of the national rate computed under paragraph (c) of this section that is attributable to wages and labor-related costs for area differences in hospital wage levels by a factor (established by CMS) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

[52 FR 33058, Sept. 1, 1987, as amended at 53 FR 38533, Sept. 30, 1988; 57 FR 39825, Sept. 1, 1992; 69 FR 49248, Aug. 11, 2004]

§ 412.220 Special treatment of certain hospitals located in Puerto Rico.

Subpart G of this part sets forth rules for special treament of certain facilities under the prospective payment system for inpatient operating costs. The following sections in subpart G of this part do not apply to hospitals located in Puerto Rico:

(a) Section 412.92, sole community hospitals.

(b) Section 412.96, referral centers.

[52 FR 33058, Sept. 1, 1987, as amended at 57 FR 39825, Sept. 1, 1992]

Subpart L—The Medicare Geographic Classification Review Board

SOURCE: 55 FR 36766, Sept. 6, 1990, unless otherwise noted.

CRITERIA AND CONDITIONS FOR REDESIGNATION

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

(a) *General*—(1) *Purposes.* Except as specified in paragraph (a)(5)—

(i) For fiscal years prior to fiscal year 2005, an individual hospital may be redesignated from a rural area to an urban area, from a rural area to another rural area, or from an urban area to another urban area for the purposes of using the other area's standardized amount for inpatient operating costs, the wage index value, or both.

(ii) Effective for fiscal year 2005 and subsequent fiscal years, an individual hospital may be redesignated from an urban area to another urban area, from a rural area to another rural area, or from a rural area to another urban area for the purposes of using the other area's wage index value.

(iii) An urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located in the rural area of the state for the purposes of this section.

(2) *Proximity.* Except as provided in paragraph (a)(3) of this section, to be redesignated to another rural area or an urban area, a hospital must demonstrate a close proximity to the area to which it seeks redesignation by meeting the criteria in paragraph (b) of this section, and submitting data requested under paragraph (c) of this section.

(3) *Special rules for sole community hospitals and rural referral centers.* To be redesignated under the special rules in this paragraph, a hospital must be approved as a sole community hospital or a rural referral center as of the date of the MGCRB's review.

(i) A hospital that is approved as a rural referral center or a sole community hospital, or both, does not have to demonstrate a close proximity to the area to which it seeks redesignation.

(ii) If a hospital that is approved as a rural referral center or a sole community hospital, or both, qualifies for urban redesignation, it is redesignated to the urban area that is closest to the hospital or to the hospital's geographic home area. If the hospital is closer to another rural area than to any urban area, it may seek redesignation to either the closest rural area or the closest urban area.

(iii) If a sole community hospital or rural referral center loses its special status as a result of redesignation, the hospital is considered to retain its special status for the purpose of applicability of the special rules in paragraph (a)(3) of this section.

(iv) A hospital that is redesignated under paragraph (a)(3) of this section may not be redesignated in the same fiscal year under paragraph (a)(2) of this section.

(4) *Application of criteria.* In applying the numeric criteria contained in paragraphs (b)(1) and (2) and (d)(1)(iii) and (iv) of this section, rounding of numbers to meet the mileage or qualifying percentage standards is not permitted.

(5) *Limitations on redesignation.* The following limitations apply to redesignation:

(i) An individual hospital may not be redesignated to another area for purposes of the wage index if the pre-reclassified average hourly wage for that area is lower than the pre-reclassified average hourly wage for the area in which the hospital is located. An urban hospital that has been granted redesignation as rural under § 412.103 is considered to be located either in its geographic area or in the rural area of the State for the purposes of this paragraph (a)(5)(i).

(ii) A hospital may not be redesignated to more than one area, except for an urban hospital that has been granted redesignation as rural under § 412.103 and receives an additional reclassification by the MGCRB.

(iii) Beginning with wage index reclassification applications for FY 2003, if a hospital is already reclassified to a given geographic area for wage index purposes for a 3-year period, and submits an application for reclassification

to the same area for either the second or third year of the 3-year period, that application will not be approved.

(b) *Proximity criteria.* A hospital demonstrates a close proximity with the area to which it seeks redesignation if one of the following conditions applies:

(1) The distance from the hospital to the area is no more than 15 miles for an urban hospital and no more than 35 miles for a rural hospital.

(2) At least 50 percent of the hospital's employees reside in the area.

(c) *Appropriate proximity data.* For redesignation to an area, the hospital must submit appropriate data relating to its proximity to that area.

(1) To demonstrate proximity to the area, the hospital must submit evidence of the shortest route over improved roads to the area and the distance of that route.

(2) For employee address data, the hospital must submit current payroll records that include information that establishes the home addresses by zip code of its employees.

(d) *Use of urban or other rural area's wage index*—(1) *Criteria for use of area's wage index.* Except as provided in paragraphs (d)(3) and (d)(4) of this section, to use an area's wage index, a hospital must demonstrate the following:

(i) The hospital's incurred wage costs are comparable to hospital wage costs in an urban or other rural area;

(ii) The hospital has the necessary geographic relationship as specified in paragraphs (a) and (b) of this section;

(iii) One of the following conditions apply:

(A) With respect to redesignations for Federal fiscal years 1994 through 2001, the hospital's average hourly wage is at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located;

(B) With respect to redesignations for Federal fiscal years 2002 through 2005, the hospital's average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of hospitals in the area in which the hospital is located; or

(C) With respect to redesignations for Federal fiscal year 2006 and subsequent years, the hospital's average hourly wage is, in the case of a hospital located in a rural area, at least 106 percent and in the case of a hospital located in an urban area, at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located;

(iv) One of the following conditions apply:

(A) For redesignations effective before fiscal year 1999, the hospital's average hourly wage weighted for occupational categories is at least 90 percent of the average hourly wages of hospitals in the area to which it seeks redesignation.

(B) With respect to redesignations for fiscal year 1994 through 2001, the hospital's average hourly wage is equal to at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(C) With respect to redesignations for fiscal years 2002 through 2009, the hospital's average hourly wage is equal to, in the case of a hospital located in a rural area, at least 82 percent, and in the case of a hospital located in an urban area, at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(D) With respect to redesignations for fiscal year 2010, the hospital's average hourly wage is equal to, in the case of a hospital located in a rural area, at least 84 percent, and in the case of a hospital located in an urban area, at least 86 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(E) With respect to redesignations for fiscal year 2011 and later fiscal years, the hospital's average hourly wage is equal to, in the case of a hospital located in a rural area, at least 82 percent, and in the case of a hospital located in an urban area, at least 84 percent of the average hourly wage of hospitals in the area to which it seeks redesignation.

(2) *Appropriate wage data.* For a wage index change, the hospital must submit appropriate wage data as follows:

(i) For redesignations effective through FY 2002:

(A) For hospital-specific data, the hospital must provide data from the

CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospital requests reclassification.

(B) For data for other hospitals, the hospital must provide data concerning the average hourly wage in the area in which the hospital is located and the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospital requests reclassification.

(ii) For redesignations effective beginning FY 2003:

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(*1*) For the limited purpose of qualifying for geographic reclassification based on wage data from cost reporting periods beginning prior to FY 2000, a hospital may request that its wage data be revised if the hospital is in an urban area that was subject to the rural floor for the period during which the wage data the hospital wishes to revise were used to calculate its wage index.

(*2*) Once a hospital has accumulated at least 1 year of wage data in the applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data.

(B) For data for other hospitals, the hospital must provide a weighted 3-year average of the average hourly wage in the area in which the hospital is located and a weighted 3-year average of the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(iii) For applications submitted for reclassifications effective in FYs 2006 through 2008, a campus of a multicampus hospital may seek reclassification only to a CBSA in which another campus(es) is located. If the campus is seeking reclassification to a CBSA in which another campus(es) is located, as part of its reclassification request, the requesting entity must submit the composite wage data for the entire multicampus hospital as its hospital-specific data.

(iv) For purposes of this paragraph (d)(2), if a new owner does not accept assignment of the existing hospital's provider agreement in accordance with § 489.18 of this chapter, the hospital will be treated as a new provider with a new provider number. In this case, the wage data associated with the previous hospital's provider number cannot be used in calculating the new hospital's 3-year average hourly wage. Once a new hospital has accumulated at least 1 year of wage data, it is eligible to apply for reclassification on the basis of those data.

(v) For applications submitted for reclassification effective in FY 2009 and thereafter, a campus of a multicampus hospital that is located in a geographic area different from the area associated with the provider number of the entire multicampus hospital may seek reclassification to another CBSA using the composite wage data of the entire multicampus hospital as its hospital-specific data.

(3) *Rural referral center exceptions.* (i) If a hospital was ever approved as a rural referral center, it does not have to demonstrate that it meets the average hourly wage criterion set forth in paragraph (d)(1)(iii) of this section.

(ii) If a hospital was ever approved as a rural referral center, it is required to meet only the criterion that applies to rural hospitals under paragraph (d)(1)(iv) of this section, regardless of its actual location in an urban or rural area.

(4) *Special dominating hospital exception.* The requirements of paragraph (d)(1)(i) and (d)(1)(iii) of this section do not apply if a hospital meets the following criteria:

(i) Its average hourly wage is at least 108 percent of the average hourly wage of all other hospitals in the area in which the hospital is located.

(ii) It pays at least 40 percent of the adjusted uninflated wages in the MSA.

(iii) It was approved for redesignation under this paragraph (d) for each year from fiscal year 1992 through fiscal year 1997.

(5) *Single hospital MSA exception.* The requirements of paragraph (d)(1)(iii) of this section do not apply if a hospital is the single hospital in its MSA with published 3-year average hourly wage data included in the current fiscal year inpatient prospective payment system final rule.

[55 FR 36766, Sept. 6, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 412.230, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 412.232 Criteria for all hospitals in a rural county seeking urban redesignation.

(a) *Criteria.* For all hospitals in a rural county to be redesignated to an urban area, the following conditions must be met:

(1) The county in which the hospitals are located—

(i) For fiscal years prior to fiscal year 2006, must be adjacent to the MSA or NECMA to which they seek redesignation.

(ii) For fiscal years beginning with fiscal year 2006, must be adjacent to the MSA to which they seek redesignation.

(2) All hospitals in a rural county must apply for redesignation as a group.

(3) The hospitals must demonstrate that the rural county in which they are located currently meets the criteria for metropolitan character under paragraph (b) of this section and the wage criteria under paragraph (c) of this section.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2006, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(b) *Metropolitan character.* (1) For fiscal years prior to FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA or an NECMA as an outlying county that were published in the FEDERAL REGISTER on March 30, 1990 (55 FR 12154) using Bureau of the Census data or Bureau of Census estimates made after 1990.

(2) For fiscal years beginning with FY 2005, the group of hospitals must demonstrate that the county in which the hospitals are located meets the standards for redesignation to an MSA as an outlying county using the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data.

(c) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage for fiscal years before fiscal year 2010*—(i) *Aggregate hourly wage.* With respect to redesignations effective beginning fiscal year 1999 and before fiscal year 2010, the aggregate average hourly wage for all hospitals in the rural county must be equal to at least 85 percent of the average hourly wage in the adjacent urban area.

(ii) *Aggregate hourly wage weighted for occupational mix.* For redesignations effective before fiscal year 1999, the aggregate hourly wage for all hospitals in the rural county, weighed for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban area.

(2) *Aggregate hourly wage for fiscal year 2010.* With respect to redesignations effective for fiscal year 2010, the aggregate average hourly wage for all hospitals in the rural county must be equal to at least 86 percent of the average hourly wage in the adjacent urban area.

(3) *Aggregate hourly wage for fiscal year 2011 and later fiscal years.* With respect to redesignations effective for fiscal year 2011 and later fiscal years, the aggregate average hourly wage for all

hospitals in the rural county must be equal to at least 85 percent of the average hourly wage in the adjacent urban area.

(d) *Appropriate data*—(1) *Metropolitan character*. (i) To meet the criteria in paragraph (b) of this section, the hospitals may submit data, estimates, or projections, made by the Bureau of the Census concerning population density or growth, or changes in designation of urban areas.

(ii) The MGCRB only considers data developed by the Bureau of the Census.

(2) *Appropriate wage data*. The hospitals must submit appropriate data as follows:

(i) For redesignations effective through FY 2002:

(A) For hospital-specific data, the hospitals must provide data from the CMS wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospitals request reclassification.

(B) For data for other hospitals, the hospitals must provide the following:

(*1*) The average hourly wage in the adjacent area, which is taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes during the fiscal year prior to the fiscal year for which the hospitals request reclassification.

(*2*) Occupational-mix data to demonstrate the average occupational mix for each employment category in the adjacent area. Occupational-mix data can be obtained from surveys conducted by the American Hospital Association.

(ii) For redesignations effective beginning FY 2003:

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(B) For data for other hospitals, the hospital must provide a weighted 3-year average of the average hourly wage in the area in which the hospital is located and a weighted 3-year average of the average hourly wage in the area to which the hospital seeks reclassification. The wage data are taken from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(iii) For redesignations effective beginning FY 2009, the wage data of an individual campus of a multicampus hospital will be determined by allocating, on the basis of full-time equivalent staff or discharges, the wage data of the entire multicampus hospital between or among the individual campuses of the multicampus hospital. The provision of this paragraph (d)(2)(iii) applies only in the case where an individual campus is located in a geographic area different from the area associated with the provider number of the entire multicampus hospital.

[55 FR 36766, Sept. 6, 1990, as amended at 57 FR 39826, Sept. 1, 1992; 58 FR 46339, Sept. 1, 1993; 59 FR 45399, Sept. 1, 1994; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 66 FR 39934, Aug. 1, 2001; 69 FR 49249, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 72 FR 47412, Aug. 22, 2007; 73 FR 48756, Aug. 19, 2008; 75 FR 50415, Aug. 16, 2010; 79 FR 50355, Aug. 22, 2014]

§ 412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) *General criteria*. For all prospective payment hospitals in an .urban county to be redesignated to another urban area, the following conditions must be met:

(1) All hospitals in an urban county must apply for redesignation as a group.

(2) The county in which the hospitals are located must be adjacent to the urban area to which they seek redesignation.

(3)(i) For Federal fiscal years before fiscal year 2006, the counties in which the hospitals are located must be part of the Consolidated Metropolitan Statistical Area (CMSA) that includes the urban area to which they seek redesignation.

(ii) For Federal fiscal year 2006, hospitals located in counties that are in the same Combined Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation; or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the

urban area to which they seek designation qualify as meeting the proximity requirements for reclassification to the urban area to which they seek redesignation.

(iii) For Federal fiscal year 2007, hospitals located in counties that are in the same Combined Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(iv) For Federal fiscal year 2008 and thereafter, hospitals located in counties that are in the same Combined Statistical Area (CSA) or Core-Based Statistical Area (CBSA) (under the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(b) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage for fiscal years before fiscal year 2010*—(i) *Aggregate hourly wage.* With respect to redesignations effective beginning fiscal year 1999 and before fiscal year 2010, the aggregate average hourly wage for all hospitals in the urban county must be at least 85 percent of the average hourly wage in the urban area to which the hospitals in the county seek reclassification.

(ii) *Aggregate hourly wage weighted for occupational mix.* For redesignations effective before fiscal year 1999, the aggregate hourly wage for all hospitals in the county, weighed for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban area.

(2) *Aggregate hourly wage for fiscal year 2010.* With respect to redesignations effective for fiscal year 2010, the aggregate average hourly wage for all hospitals in the urban county must be at least 86 percent of the average hourly wage in the urban area to which the hospitals in the county seek reclassification.

(3) *Aggregate hourly wage for fiscal year 2011 and later fiscal years.* With respect to redesignations effective for fiscal year 2011 and later fiscal years, the aggregate average hourly wage for all hospitals in the urban county must be at least 85 percent of the average hourly wage in the urban area to which the hospitals in the county seek reclassification.

(c) *Appropriate wage data.* (1) The hospitals must submit appropriate wage data as provided for in § 412.230(d)(2).

(2) For redesignations effective beginning FY 2009, the appropriate wage data of an individual campus located in a geographic area different from the area associated with the provider number of the entire multicampus hospital are the wage data described in § 412.232(d)(2)(iii).

[56 FR 25488, June 4, 1991, as amended at 57 FR 39826, Sept. 1, 1992; 58 FR 46339, Sept. 1, 1993; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 69 FR 49249, Aug. 11, 2004; 70 FR 47487, Aug. 12, 2005; 71 FR 48140, Aug. 18, 2006; 72 FR 47412, Aug. 22, 2007; 73 FR 48756, Aug. 19, 2008; 75 FR 50415, Aug. 16, 2010; 79 FR 50355, Aug. 22, 2014]

§ 412.235 Criteria for all hospitals in a State seeking a statewide wage index redesignation.

(a) *General criteria.* For all prospective payment system hospitals in a State to be redesignated to a statewide wage index, the following conditions must be met:

(1) All prospective payment system hospitals in the State must apply as a group for reclassification to a statewide wage index through a signed single application.

(2) All prospective payment system hospitals in the State must agree to the reclassification to a statewide wage index through a signed affidavit on the application.

(3) All prospective payment system hospitals in the State must agree, through an affidavit, to withdrawal of an application or to termination of an approved statewide wage index reclassification.

(4) All hospitals in the State must waive their rights to any wage index classification that they would otherwise receive absent the statewide wage index classification, including a wage index that any of the hospitals might have received through individual geographic reclassification.

(5) New hospitals that open within the State prior to the deadline for submitting an application for a statewide wage index reclassification (September 1), regardless of whether a group application has already been filed, must agree to the use of the statewide wage index as part of the group application. New hospitals that open within the State after the deadline for submitting a statewide wage index reclassification application or during the approved reclassification period will be considered a party to the statewide wage index application and reclassification.

(b) *Effect on payments.* (1) An individual hospital within the State may receive a wage index that could be higher or lower under the statewide wage index reclassification in comparison to its otherwise redesignated wage index.

(2) Any new prospective payment system hospital that opens in the State during the effective period of an approved statewide wage index reclassification will be designated to receive the statewide wage index for the duration of that period.

(c) *Terms of the decision.* (1) A decision by the MGCRB on an application for a statewide wage index reclassification will be effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the hospitals filed a complete application.

(2) The procedures and timeframes specified in §412.273 apply to withdrawals of applications for redesignation to a statewide wage index and terminations of approved statewide wage index reclassifications, including the requirement that, to withdraw an application or terminate an approved reclassification, the request must be made in writing by all hospitals that are party to the application, except hospitals reclassified into the State for purposes of receiving the statewide wage index.

[66 FR 39935, Aug. 1, 2001]

COMPOSITION AND PROCEDURES

§ 412.246 MGCRB members.

(a) *Composition.* The Medicare Geographical Classification Review Board (MGCRB) consists of five members, including a Chairman, all of whom are appointed by the Secretary. The members include two members who are representative of prospective payment system hospitals located in rural areas, and at least one individual who is knowledgeable in analyzing the costs of inpatient hospital services.

(b) *Term of office.* The term of office for an MGCRB member may not exceed 3 years. A member may serve more than one term. The Secretary may terminate a member's tenure prior to its full term.

[55 FR 36766, Sept. 6, 1990, as amended at 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

§ 412.248 Number of members needed for a decision or a hearing.

(a) *A quorum.* A quorum, consisting of at least a majority of the MGCRB members, one of whom is representative of rural hospitals if possible, is required for making MGCRB decisions.

(b) *Number of members for a hearing.* If less than a quorum is present for an oral hearing, the chairman with the consent of the hospital may allow those members present to conduct the hearing and to prepare a recommended decision, which is then submitted to a quorum.

§ 412.250 Sources of MGCRB's authority.

(a) *Compliance.* The MGCRB, in issuing decisions under section 1886(d)(10)(C) of the Act, complies with

all the provisions of title XVIII and related provisions of the Act and implementing regulations, including the criteria and conditions located at § 412.230 through § 412.236, issued by the Secretary under the authority of section 1886(d)(10)(D) of the Act; and CMS Rulings issued under the authority of the Administrator.

(b) *Affords great weight.* The MGCRB affords great weight to other interpretive rules, general statements of policy and rules of agency organization, procedure, and practice established by CMS.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991]

§ 412.252 Applications.

(a) *By one hospital.* An individual prospective payment system hospital seeking redesignation to a different rural or urban area has the right to submit an application to the MGCRB.

(b) *By a group of hospitals.* A group of hospitals has the right to submit an application to the MGCRB requesting redesignation of all prospective payment hospitals in a county if all prospective payment hospitals located in a county agree to the request.

[55 FR 36766, Sept. 6, 1990, as amended at 69 FR 49250, Aug. 11, 2004]

§ 412.254 Proceedings before MGCRB.

(a) *On-the-record decision.* The MGCRB will ordinarily issue an on-the-record decision without conducting an oral hearing. The MGCRB will issue a decision based upon all documents, data, and other written evidence and comments submitted timely to the MGCRB by the parties.

(b) *Oral hearing.* The MGCRB may hold an oral hearing on its own motion or if a party demonstrates to the MGCRB's satisfaction that an oral hearing is necessary.

§ 412.256 Application requirements.

(a) *Written application.* A request for reclassification must be in writing and must constitute a complete application in accordance with paragraph (b) of this section.

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB.

(2) A complete application must be received not later than the first day of the 13-month period preceding the Federal fiscal year for which reclassification is requested.

(3) The filing date of an application is the date the application is received by the MGCRB.

(b) *Criteria for a complete application.* An application is complete if the application from an individual hospital or from all hospitals in a county includes the following information:

(1) The Federal fiscal year for which the hospital is applying for redesignation.

(2) Which criteria constitute the basis of the request for reclassification.

(3) An explanation of how the hospital or hospitals meet the relevant criteria in §§ 412.230 through 412.236, including any necessary data to support the application.

(c) *Opportunity to complete a submitted application.* (1) The MGCRB will review an application within 15 days of receipt to determine if the application is complete. If the MGCRB determines that an application is incomplete, the MGCRB will notify the hospital, with a copy to CMS, within the 15 day period, that it has determined that the application is incomplete and may dismiss the application if a complete application is not filed by September 1.

(2) At the request of the hospital, the MGCRB may, for good cause, grant a hospital that has submitted an application by September 1, an extension beyond September 1 to complete its application.

(d) *Appeal of MGCRB dismissal.* (1) The hospital may appeal the MGCRB dismissal to the Administrator within 15 days of the date of the notice of dismissal.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator will affirm the dismissal or reverse the dismissal and remand the case to the MGCRB to determine whether reclassification is appropriate.

(e) *Notification of complete application.* When the MGCRB determines that the hospital's application contains all the necessary elements for a complete application, it notifies the hospital in writing, with a copy to CMS, that the application is complete and that the

case may proceed to an MGCRB decision.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25488, June 4, 1991; 62 FR 46031, Aug. 29, 1997; 63 FR 26357, May 12, 1998; 64 FR 41541, July 30, 1999; 81 FR 57268, Aug. 22, 2016; 84 FR 42614, Aug. 16, 2019]

§ 412.258 Parties to MGCRB proceeding.

(a) The party or parties to an MGCRB proceeding are the hospital or group of hospitals requesting a change in geographic designation.

(b) CMS has 30 days from the date of receipt of notice of a complete application to submit written comments and recommendations (with a copy to the hospital) for consideration by the MGCRB.

(c) The hospital has 15 days from the date of receipt of CMS's comments to submit written comments to the MGCRB, with a copy to CMS, for the purpose of responding to CMS's comments.

§ 412.260 Time and place of the oral hearing.

If the MGCRB decides that an oral hearing is necessary, it sets the time and place for the hearing and notifies the parties in writing, with a copy to CMS, not less than 10 days before the time scheduled for the hearing. The MGCRB may reschedule, adjourn, postpone, or reconvene the hearing provided that reasonable written notice is given to the parties, with a copy to CMS.

§ 412.262 Disqualification of an MGCRB member.

(a) *Grounds for disqualification.* An MGCRB member may not participate in any decision in a case in which he or she may be prejudiced or partial with respect to a party or has any other interest in the case.

(b) *Request for disqualification.* If a party believes that an MGCRB member should not participate in a decision, the party submits the objection in writing to the MGCRB at its earliest opportunity, explaining the grounds for the request. CMS may also submit such a suggestion to the MGCRB.

(c) *Consideration by the MGCRB member.* The MGCRB member will consider the objection and, at his or her discretion, either will proceed or withdraw.

(d) *Consideration by the MGCRB* If the member does not withdraw, a party may petition the MGCRB for withdrawal and the MGCRB will consider the objection and rule on whether the member may participate in the decision before it decides the case.

§ 412.264 Evidence and comments in MGCRB proceeding.

(a) *Submission by the parties.* Before a decision is issued and during an oral hearing, the parties may present evidence or comments to the MGCRB regarding the matters at issue in the case.

(b) *Content of evidence and comments.* The MGCRB may receive evidence and comments without regard for the rules of evidence applicable to court procedures.

(c) *Ex parte communications.* (1) The members of the MGCRB and its staff may not consult or be consulted by an individual representing the interests of an applicant hospital or by any other individual on any matter in issue before the MGCRB without notice to the hospital or CMS. If such communication occurs, the MGCRB will disclose it to the hospital or CMS, as appropriate, and make it part of the record after the hospital or CMS has had an opportunity to comment. MGCRB members and staff may not consider any information outside the record about matters concerning a hospital's application for reclassification.

(2) The provisions in paragraph (c)(1) of this section do not apply to the following:

(i) Communications among MGCRB members and staff.

(ii) Communications concerning the MGCRB's administrative functions or procedures.

(iii) Requests from the MGCRB to a party or CMS for a document.

(iv) Material that the MGCRB includes in the record after notice and an opportunity to comment.

(d) *MGCRB rulings on evidence and comments.* The MGCRB rules upon the admissibility of evidence and comments and excludes irrelevant, immaterial, or unduly repetitious evidence and comments.

§ 412.266 Availability of wage data.

A hospital may obtain the average hourly wage data necessary to prepare its application to the MGCRB from FEDERAL REGISTER documents published in accordance with the provisions of § 412.8(b).

[60 FR 45849, Sept. 1, 1995]

§ 412.268 Subpoenas.

(a) *In general.* When reasonably necessary for the full presentation of a case, and only after a pre-decision request for information or data has failed to produce the necessary evidence, either upon its own motion or upon the request of a party, the MGCRB may issue subpoenas for the attendance and testimony of witnesses, for an oral hearing or the production of books, records, correspondence, papers, or other documents that are relevant and material to any matter at issue.

(b) *Content of request.* The request must designate which witnesses or documents are to be produced, and describe addresses or locations with sufficient particularly to permit these witnesses or documents to be found. The request for a subpoena must state the pertinent facts that the party expects to establish by the requested witnesses or documents and whether these facts could be established by other evidence without the use of a subpoena.

(c) *Issuance.* Subpoenas are issued as provided in section 205(d) of the Act.

(d) *Payment for subpoena cost.* CMS pays for the cost of issuing subpoenas and the fees and mileage of any witness who is subpoenaed, as provided in section 205(d) of the Act.

§ 412.270 Witnesses.

Witnesses at an oral hearing testify under oath or affirmation, unless excused by the MGCRB for cause. The MGCRB may examine the witnesses and may allow the parties or their representatives to also examine any witnesses called.

§ 412.272 Record of proceedings before the MGCRB.

A complete record of the proceedings before the MGCRB is made in all cases. The record will not be closed until a decision has been issued by the MGCRB. A transcription of an oral hearing will be made at a party's request, at the expense of the requesting party.

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or canceling a previous withdrawal or termination.

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

Termination refers to the termination of an already existing 3-year MGCRB reclassification where such reclassification has already been in effect for 1 or 2 years, and there are 1 or 2 years remaining on the 3-year reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered.

Withdrawal refers to the withdrawal of a 3-year MGCRB reclassification that has not yet gone into effect or where the MGCRB has not yet issued a decision on the application.

(b) *General rule.* The MGCRB allows a hospital, or group of hospitals, to withdraw its application or to terminate an already existing 3-year reclassification, in accordance with this section.

(c) *Timing.* (1) A request for withdrawal must be received by the MGCRB—

(i) At any time before the MGCRB issues a decision on the application; or

(ii) After the MGCRB issues a decision, provided that the request for withdrawal is received by the MCGRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.278, whichever is later concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed.

(2) A request for termination must be received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a

decision of the Administrator's in accordance with §412.278, whichever is later concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the termination is to apply.

(d) *Reapplication within the approved 3-year period, cancellations of terminations and withdrawals, and prohibition on overlapping reclassification approvals*—(1) *Cancellation of terminations or withdrawals.* Subject to the provisions of this section, a hospital (or group of hospitals) may cancel a withdrawal or termination in a subsequent year and request the MGCRB to reinstate the wage index reclassification for the remaining fiscal year(s) of the 3-year period. (Withdrawals may be cancelled only in cases where the MGCRB issued a decision on the geographic reclassification request.)

(2) *Timing and process of cancellation request.* Cancellation requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in §412.256(a)(2).

(3) *Reapplications.* A hospital may apply for reclassification to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer cancel a withdrawal or termination of another 3-year reclassification, regardless of whether the withdrawal or termination request is made within 3 years from the date of the withdrawal or termination.

(4) *Termination of existing 3-year reclassification.* In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1.

(e) *Written request only.* (1) A request to withdraw an application must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by all hospitals that are party to the application.

(2) A request to terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB by an individual hospital or by an individual hospital that is party to a group classification.

(f) *Appeal of the MGCRB's denial of a hospital's request for withdrawal or termination, or for cancellation of a withdrawal or termination.* (1) A hospital may file an appeal of the MGCRB's denial of its request for withdrawal or termination, or of the MGCRB's denial of its request for a cancellation of such withdrawal or termination, to the Administrator. The appeal must be received within 15 days of the date of the notice of the denial.

(2) Within 20 days of receipt of the hospital's request for appeal, the Administrator affirms or reverses the denial.

[75 FR 50415, Aug. 16, 2010, as amended at 82 FR 38512, Aug. 14, 2017; 87 FR 49404, Aug. 10, 2022; 89 FR 69912, Aug. 28, 2024]

§412.274 Scope and effect of an MGCRB decision.

(a) *Scope of decision.* The MGCRB may affirm or change a hospital's geographic designation. The MGCRB's decision is based upon the evidence of record, including the hospital's application and other evidence obtained or received by the MGCRB.

(b) *Effective date and term of the decision.* (1) For reclassifications prior to fiscal year 2005, a standardized amount classification change is effective for 1 year beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year following the Federal fiscal year in which the complete application is filed and ending effective at the end of that Federal fiscal year (the end of the next September 30).

(2) A wage index classification change is effective for 3 years beginning with discharges occurring on the first day (October 1) of the second Federal fiscal year in which the complete application is filed.

[55 FR 36766, Sept. 6, 1990, as amended at 62 FR 46031, Aug. 29, 1997; 66 FR 39935, Aug. 1, 2001; 69 FR 49250, Aug. 11, 2004]

§ 412.276 Timing of MGCRB decision and its appeal.

(a) *Timing.* The MGCRB notifies the parties in writing, with a copy to CMS, and issues a decision within 180 days after the first day of the 13-month period preceding the Federal fiscal year for which a hospital has filed a complete application. The hospital has 15 days from the date of the decision to request Administrator review.

(b) *Appeal.* The decision of the MGCRB is final and binding upon the parties unless it is reviewed by the Administrator and the decision is changed by the Administrator in accordance with § 412.278.

[55 FR 36766, Sept. 6, 1990, as amended at 64 FR 41541, July 30, 1999]

§ 412.278 Administrator's review.

(a) *Hospitals requests for review.* A hospital or group of hospitals dissatisfied with the MGCRB's decision regarding its geographic designation may request the Administrator to review the MGCRB decision. (A hospital or group of hospitals may also request that the Administrator review the MGCRB's dismissal of an application as untimely filed or incomplete, as provided in § 412.256(d).)

(b) *Procedures for hospital's request for review.*(1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

(2) The request for review may contain proposed findings of fact and conclusions of law, exceptions to the MGCRB's decision, and supporting reasons therefor.

(3) Within 15 days of receipt of the hospital's request for review, CMS may submit to the Administrator, in writing, with a copy to the party, comments and recommendations concerning the hospital's submission.

(4) Within 10 days of receipt of CMS's submission, the hospital may submit in writing, with a copy to CMS, a response to the Administrator.

(c) *Discretionary review by the Administrator.* (1) The Administrator may, at his or her discretion, review any final decision of the MGCRB.

(2) The Administrator promptly notifies the hospital that he or she has decided to review a decision of the MGCRB. The notice of review indicates the particular issues to be considered and includes copies of any comments submitted to the Administrator by CMS staff concerning the MGCRB decision.

(3) Within 15 days of the receipt of the Administrator's notice of review, the hospital may submit a response in writing to the Administrator, with a copy of CMS.

(d) *Criteria for discretionary review.* In deciding whether to review an MGCRB decision, the Administrator normally considers whether it appears that any of the following situations apply:

(1) The MGCRB made an erroneous interpretation of law, regulation, or CMS Ruling.

(2) The MGCRB's decision is not supported by substantial evidence.

(3) The case presents a significant policy issue having a basis in law and regulations, and review is likely to lead to issuance of a CMS Ruling or other directive needed to clarify a provision in the law or regulations.

(4) The decision of the MGCRB requires clarification, amplication, or an alternative legal basis.

(5) The MGCRB has incorrectly extended its authority to a degree not provided for by law, regulation, or CMS Ruling.

(e) *Communication procedures.* All communications between CMS staff and the Administrator concerning the Administrator's review of an MGCRB decision must be in writing. As specified in paragraphs (b) and (c) of this section, copies of comments by CMS staff are sent to applicant hospitals within 15 days of receipt of a hospital's request for review, or, in cases in which the Administrator decides to review a case at his or her discretion, are included with the Administrator's notice of review. In the event there are additional communications between CMS staff and the Administrator concerning

MGCRB decisions reviewed by the Administrator under paragraphs (b) or (c) of this section, CMS furnishes copies of the communications to the hospital or group of hospitals.

(f) *Administrator's decision.* (1) The Administrator may not receive or consider any new evidence and must issue a decision based only upon the record as it appeared before the MGCRB and comments submitted under paragraphs (b)(2), (b)(3), (b)(4), (c)(2), and (c)(3) of this section.

(2) The Administrator issues a decision in writing to the party with a copy to CMS—

(i) Not later than 90 days following receipt of the party's request for review, except the Administrator may, at his or her discretion, for good cause shown, toll such 90 days; or

(ii) Not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days.

(3) The Administrator's decision issued under §412.278 (a) or (c) is the final Departmental decision, unless it is amended under §412.278(g). The final Departmental decision is not subject to judicial review.

(4) The Administrator's decision is not subject to judicial review.

(g) *Amendment of Administrator decision*—(1) *Hospital's request for amendment.* The hospital may request the Administrator to amend the decision for the limited purpose of correcting mathematical or computational errors, or to correct the decision if the evidence that was considered in making the decision clearly shows on its face that an error was made. The following procedure is followed:

(i) The hospital's request for amendment must be received by the Administrator within 10 days after the date the Administrator issues a decision. The request for amendment must be in writing, with a copy to CMS.

(ii) The Administrator promptly reviews the hospital's request and amends the decision, if necessary, within 5 days following receipt of the hospital's request for amendment.

(2) *Discretionary review by the Administrator.* Within 15 days following the issuance of the Administrator's decision, the Administrator, at his or her discretion, may amend the decision to correct mathematical or computational errors, or to correct the decision if the evidence that was considered in making the decision clearly shows on its face that an error was made. The Administrator's amended decision is final and is not subject to judicial review.

[55 FR 36766, Sept. 6, 1990, as amended at 56 FR 25489, June 4, 1991; 57 FR 39826, Sept. 1, 1992; 68 FR 45471, Aug. 1, 2003; 70 FR 47487, Aug. 12, 2005; 85 FR 59023, Sept. 18, 2020; 86 FR 45520, Aug. 13, 2021]

§ 412.280 Representation.

(a) *General.* A party may be represented by legal counsel or by any other person appointed to act as its representative at any proceeding before the MGCRB or the Administrator.

(b) *Rights of a representative.* A representative appointed by a party may accept or give on behalf of the party any request or notice connected with any proceeding before the MGCRB or the Administrator. A representative is entitled to present evidence and argument as to facts and law in any MGCRB proceeding affecting the party represented and to obtain information to the same extent as the party represented. Notice of any action or decision sent to the representative of a party has the same effect as if it had been sent to the party itself.

Subpart M—Prospective Payment System for Inpatient Hospital Capital Costs

SOURCE: 56 FR 43449, Aug. 30, 1991, unless otherwise noted.

GENERAL PROVISIONS

§ 412.300 Scope of subpart and definition.

(a) *Purpose.* This subpart implements section 1886(g)(1)(A) of the Act by establishing a prospective payment system for inpatient hospital capital-related costs. Under this system, payment is made on the basis described in §412.304 through §412.374 for inpatient hospital capital-related costs furnished by hospitals subject to the prospective

payment system under subpart B of this part.

(b) *Definition.* For purposes of this subpart, a new hospital means a hospital that has operated (under previous or present ownership) for less than 2 years. The following hospitals are not new hospitals:

(1) A hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(2) A hospital that closes and subsequently reopens.

(3) A hospital that has been in operation for more than 2 years but has participated in the Medicare program for less than 2 years.

(4) A hospital that changes its status from a hospital that is excluded from the prospective payment systems to a hospital that is subject to the capital prospective payment systems.

[56 FR 43449, Aug. 30, 1991, as amended at 57 FR 39827, Sept. 1, 1992]

§ 412.302 Introduction to capital costs.

(a) *New capital costs.* New capital costs are allowable Medicare inpatient hospital capital-related costs under subpart G of part 413 of this chapter that are related to assets that were first put in use for patient care after December 31, 1990 (except for such costs deemed to be old capital costs based on prior obligations as described in paragraph (c) of this section) and those allowable capital-related costs related to assets in use prior to December 31, 1990 that are excluded from the definition of old capital costs described in paragraphs (b) (2) through (5) of this section, or are betterment or improvement costs related to those old capital assets.

(b) *Old capital costs.* Except as provided in paragraph (c) of this section with respect to capital obligations that qualify for recognition as old capital, old capital costs are allowable capital-related costs for land and depreciable assets that were put in use for patient care on or before December 31, 1990. However, for a new hospital as defined in § 412.300(b), old capital costs are defined as those allowable capital-related costs for land and depreciable assets that were put in use for patient care on or before the later of December 31, 1990 or the last day of the hospital's base year cost reporting period under § 412.328(a)(2). Old capital costs include the following:

(1) Allowable depreciation on assets based on the useful life guidelines used to determine depreciation expense in the hospital's base period.

(2) Allowable capital-related interest expense. Except as provided below, the amount of allowable capital-related interest expense that will be recognized as old capital is limited to the amount the hospital was legally obligated to pay as of December 31, 1990. Any allowable interest expense in excess of this limitation will be recognized as new capital.

(i) An increase in interest expense is recognized if the increase is due to periodic fluctuations of rates in variable interest rate loans or at the time of conversion from a variable rate loan to a fixed rate loan when no other changes in the terms of the loan are made.

(ii) If the terms of a debt instrument are revised after December 31, 1990, the amount of interest that will be recognized as old capital during the transition cannot exceed the amount that would have been recognized during the same period prior to the revision of the debt instrument.

(iii) If short-term financing was used to acquire old capital assets and the debt is extended or ''rolled-over'', a portion of the extended debt will be recognized as old capital. The portion will equal the ratio of the net book value as of the beginning of the applicable cost reporting period for depreciable assets that were in use in the base year, to the net book value as of the beginning of the base year cost reporting period for those assets. The net book value for the base year will not be adjusted to exclude assets that have been fully depreciated or removed from service since the base year. If the debt is related to specific assets, the ratio will be determined based on the values for those assets. The ratio will exclude assets that were acquired with other identifiable debt instruments. For purposes of this paragraph, short term financing is a debt that becomes due in

no later than the earlier of 5 years or half of the average useful life of the assets to which the debt is related.

(iv) If old capital indebtedness is commingled with new capital debt, the allowable interest expense will be apportioned to old capital costs based on the ratio of the portion of the loan principal related to old capital indebtedness to the total loan principal.

(v) Investment income, excluding income from funded depreciation accounts, is used to reduce old capital interest expense based on the ratio of total old capital interest expense to total allowable interest expense in each cost reporting period.

(3) Allowable capital-related lease and rental costs for land and depreciable assets that were obligated as of December 31, 1990.

(i) Lease renewals up to the annual lease payment level obligated as of December 31, 1990 are recognized provided the same asset remains in use, the asset has a useful life of at least 3 years, and the annual lease payment is $1,000 or more for each item or service.

(ii) If a hospital-owned asset is sold or given to another party and that same asset is then leased back by the hospital, the amount of allowable capital-related costs recognized as old capital costs is limited to the amount allowed for that asset in the last cost reporting period that it was owned by the hospital.

(iii) If an entire hospital is leased without assumption of the hospital's asset costs after December 31, 1990, the amount of allowable capital-related costs recognized as old capital costs is limited to the amount allowed for old capital costs in the base year or the last cost reporting period these costs were recognized under this subpart, whichever is later.

(4) The portion of allowable costs for other capital-related expenses (including but not limited to, taxes, insurance, license and royalty fees on depreciable assets) resulting from applying the ratio of the hospital's gross old asset value to total asset value in each cost reporting period.

(5) The appropriate portion of the capital-related costs of related organizations under §413.17 that would be recognized as old capital costs if these costs had been incurred directly by the hospital.

(6) Obligated capital costs that are recognized as old capital costs in accordance with paragraph (c) of this section.

(7) If a hospital had nonreimbursable costs applicable to an old capital asset as of December 31, 1990 that subsequently become allowable inpatient capital-related costs, the allowable costs for such an asset that are attributable to inpatient hospital services are recognized as old capital costs if a portion of the asset was in use for inpatient hospital care on December 31, 1990 and the costs meet all other provisions for recognition of old capital costs contained in this section.

(c) *Obligated capital costs*—(1) *General rule.* Under the conditions described below, capital-related costs attributable to assets that are put in use after December 31, 1990 may be recognized as old capital costs. Any allowable capital-related costs for these assets that are not recognized as old capital costs are recognized as new capital costs.

(i) *Fixed assets.* The costs of capital-related items and services defined in subpart G of part 413 for which there was a contractual obligation entered into by a hospital or related party with an outside, unrelated party for the construction, reconstruction, lease, rental, or financing of a fixed asset may be recognized as old capital costs if all the following conditions are met:

(A) The obligation must arise from a binding written agreement that was executed on or before December 31, 1990 and that obligates the hospital on or before December 31, 1990.

(B) The capital asset must be put in use for patient care before October 1, 1994 except as provided in paragraph (c)(1)(iv) of this section.

(C) The hospital notifies the intermediary of the existence of obligated capital costs as provided in paragraph (c)(1)(v) of this section.

(D) The amount that is recognized as old capital cost is limited to the lesser of the actual allowable costs when the asset is put in use or the estimated costs of the capital expenditure at the time it was obligated as provided in paragraph (c)(1)(vi) of this section.

(ii) *Moveable equipment.* Moveable equipment is recognized as old capital only if all of the conditions specified in paragraphs (c)(1)(i) (B) through (D) of this section are met and one of the following conditions is met:

(A) There was a binding contractual agreement that was executed on or before December 31, 1990 and obligates the hospital on or before December 31, 1990 for the lease or purchase of the item of equipment on or before December 31, 1990.

(B) There was a binding contractual agreement that was executed on or before December 31, 1990 and obligates the hospital on or before December 31, 1990 for financing the acquisition of the equipment; the item of equipment costs at least $100,000; and the item was specifically listed in an equipment purchase plan approved by the Board of Directors on or before December 31, 1990.

(iii) *Agreements not recognized.* Agreements for planning, design or feasibility that do not commit the hospital to undertake a project are not recognized as obligating capital expenditures for purposes of this subsection.

(iv) *Extension of deadline.* CMS may extend the deadline in paragraph (c)(1)(i)(B) of this section, under which an asset must be put in use for patient care before October 1, 1994, to no later than September 30, 1996 for extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a construction strike or atypically severe weather that significantly delayed completion of a construction project. Normal construction delays do not constitute extraordinary circumstances.

(A) The hospital must submit its request for an extended deadline with documentation of the extraordinary circumstances by the later of January 1, 1993 or 180 days after the extraordinary circumstance.

(B) The intermediary reviews the request and verifies the hospital's documentation, and forwards the request to CMS within 60 days. Within 90 days, CMS notifies the intermediary of its decision and, if an extension is granted, of the revised deadline for putting the asset in use for patient care service.

(v) The hospital must submit to its intermediary the binding agreement and supporting documents that relate to the obligated capital expenditure by the later of October 1, 1992, or within 90 days after the start of the hospital's first cost reporting period beginning on or after October 1, 1991. This documentation must include a project description (including details of any phased construction or financing) and an estimate of costs that were prepared no later than December 31, 1990.

(vi) *Cost limitation*—(A) *Leases, rentals or purchases.* The amount of obligated capital costs recognized as old capital costs cannot exceed the amount specified in the lease, rental, or purchase agreement. If moveable equipment is recognized as old capital under paragraph (c)(1)(ii)(B) of this section, the amount recognized as old capital costs cannot exceed the estimated cost identified in the equipment purchase plan approved by the hospital's Board of Directors.

(B) *Construction contracts.* The amount of obligated capital costs recognized as old capital costs cannot exceed the estimated construction costs for the project as of December 31, 1990. Additional costs will be recognized as old capital costs only if the additional costs are directly attributable to changes in life safety codes or other building requirements established by government ordinance that occurred after the project was obligated.

(C) *Financing costs.* The amount of obligated interest expense that will be recognized as old capital costs cannot exceed the amount for which the hospital was legally obligated as of December 31, 1990 or, in the case of financing that is arranged after December 31, 1990 for a capital acquisition that was legally obligated as of December 31, 1990, the amount specified in a detailed financing plan approved by the hospital's Board of Directors prior to January 1, 1991.

(vii) *Determining old capital costs.* (A) The intermediary determines whether the applicable criteria are met for recognition of obligated capital costs as old capital costs and the maximum allowable cost that will be recognized as old capital costs.

(B) The intermediary advises the hospital of its determination by the later of the end of the hospital's first cost reporting period subject to the capital prospective payment system or 9 months after the receipt of the hospital's notification under paragraph (c)(1)(v) of this section.

(C) The actual amount that will be recognized as old capital costs is based on the lesser of the allowable costs for the asset when it is put into patient use or the amounts determined under paragraph (c)(1)(vi) of this section.

(viii) *Multi-phase project.* If the hospital has a multi-phase capital project, the provisions of paragraphs (c)(1) (i) through (vii) of this section apply independently to each phase of the project.

(2) *Lengthy certificate-of-need process.* (i) If a hospital does not meet the criteria under paragraph (c)(1)(i) or paragraph (c)(1)(ii) of this section, but meets all of the following criteria, the estimated cost for the project as of December 31, 1990 may be recognized as old capital costs:

(A) The hospital is required under State law to obtain preapproval of the capital project or acquisition by a designated State or local planning authority in the State in which it is located.

(B) The hospital filed an initial application for a certificate of need on or before December 31, 1989 that includes a detailed description of the project and its estimated cost and had not received approval or disapproval on or before September 30, 1990. If the hospital received conditional approval on or before September 30, 1990, the hospital's intermediary assesses the nature of the conditions. The hospital will be considered to have received approval for the project as of September 30, 1990 if the intermediary determines that the hospital received sufficient approval for the project to proceed without significant delay.

(C) The hospital expended the lesser of $750,000 or 10 percent of the estimated cost of the project on or before December 31, 1990; and

(D) The hospital put the asset into patient use on or before the later of September 30, 1996 or 4 years from the date the certificate of need was approved.

(ii) The provisions of paragraphs (c)(1) (iv) through (viii) of this section apply to projects that meet the criteria in paragraph (c)(2)(i) of this section.

(3) *Construction in process.* (i) If a hospital that initiates construction on a capital project does not meet the requirements of paragraphs (c)(1)(i) or (ii) or (c)(2)(i) of this section, the project costs may be recognized as old capital costs if all the following conditions are met:

(A) The hospital received any required certificate of need approval on or before December 31, 1990.

(B) The hospital's Board of Directors formally authorized the project with a detailed description of its scope and costs on or before December 31, 1990.

(C) The estimated cost of the project as of December 31, 1990 exceeds 5 percent of the hospital's total patient revenues during its base year.

(D) The capitalized cost that had been incurred for the project as of December 31, 1990 exceeded the lesser of $750,000 or 10 percent of the estimated project cost.

(E) The hospital began actual construction or renovation (''groundbreaking'') on or before March 31, 1991.

(F) The project is completed before October 1, 1994.

(ii) The provisions of paragraphs (c)(1) (iv) through (viii) of this section apply to projects that meet the criteria in paragraph (c)(3)(i) of this section.

(d) *Consistency in cost reporting*—(1) *General rule.* For cost reporting periods beginning on or after October 1, 1991, and before October 1, 2001, the hospital must follow consistent cost finding methods for classifying and allocating capital-related costs, except as otherwise provided in paragraph (d)(4) of this section.

(2) *Old capital costs.* Unless there is a change of ownership, the hospital must continue the same cost finding methods for old capital costs, including its practices for the direct assignment of capital-related costs and its cost allocation bases, that were in effect in the hospital's last cost reporting period ending on or before October 1, 1991. If there is a change of ownership, the new owners may request that the intermediary approve a change in order to

be consistent with their established cost finding practices.

(3) *New capital costs.* If a hospital desires to change its cost finding methods for new capital costs, the request for change must be made in writing to the intermediary prior to the beginning of the cost reporting period for which the change is to apply. The request must include justification as to why the change will result in more accurate and more appropriate cost finding. The intermediary will not approve the change unless it determines that there is reasonable justification for the change.

(4) Hospitals may elect the simplified cost allocation methodology under the terms and conditions provided in the instructions for CMS Form 2552.

[56 FR 43449, Aug. 30, 1991, as amended at 57 FR 3016, Jan. 27, 1992; 57 FR 39827, Sept. 1, 1992; 57 FR 46510, Oct. 9, 1992; 59 FR 45399, Sept. 1, 1994; 61 FR 46224, Aug. 30, 1996; 61 FR 51217, Oct. 1, 1996]

§ 412.304 Implementation of the capital prospective payment system.

(a) *General rule.* As described in §§ 412.312 through 412.370, effective with cost reporting periods beginning on or after October 1, 1991, CMS pays an amount determined under the capital prospective payment system for each inpatient hospital discharge as defined in § 412.4. This amount is in addition to the amount payable under the prospective payment system for inpatient hospital operating costs as determined under subpart D of this part.

(b) *Cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001.* For cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001, the capital payment amount is based on either a combination of payments for old capital costs and new capital costs or a fully prospective rate, as determined under § 412.324 through § 412.348.

(c) *Cost reporting periods beginning on or after October 1, 2001*—(1) *General.* Except as provided in paragraph (c)(2) of this section, for cost reporting periods beginning on or after October 1, 2001, the capital payment amount is based solely on the Federal rate determined under §§ 412.308(a) and (b) and updated under § 412.308(c).

(2) *Payment to new hospitals.* For cost reporting periods beginning on or after October 1, 2002—

(i) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost report ending at least 2 years after the hospital accepts its first patient, unless the new hospital elects to be paid under the capital prospective payment system based on 100 percent of the Federal rate.

(A) If the new hospital elects to be paid based on 100 percent of the Federal rate, the new hospital must submit a written request to the fiscal intermediary by the later of December 1, 2002 or 60 days before the beginning of its cost reporting period.

(B) Once a new hospital elects to be paid based on 100 percent of the Federal rate, it may not revert to payment at 85 percent of its allowable Medicare inpatient hospital capital-related costs.

(ii) For the third year and subsequent years, the hospital is paid based on the Federal rate as described under § 412.312.

(d) *Interim payments.* Interim payments are made to the hospital as provided in § 412.116.

[56 FR 43449, Aug. 30, 1991, as amended at 67 FR 50113, Aug. 1, 2002; 70 FR 47487, Aug. 12, 2005]

Basic Methodology for Determining the Federal Rate for Capital-Related Costs

§ 412.308 Determining and updating the Federal rate.

(a) *FY 1992 national average cost per discharge.* CMS determines the FY 1992 estimated national average cost per discharge by updating the discharge weighted national average Medicare inpatient hospital capital-related cost per discharge for FY 1989 by the estimated increase in Medicare inpatient hospital capital costs per discharge.

(b) *Standard Federal rate.* The standard Federal rate is used to determine the Federal rate for each fiscal year in accordance with the formula specified in paragraph (c) of this section.

(1) CMS determines the standard Federal rate by adjusting the FY 1992 updated national average cost per discharge by a factor so that estimated aggregate payments based on the standard Federal rate adjusted by the payment adjustments described in §412.312(b) equal estimated aggregate payments based solely on the national average cost per discharge.

(2) Effective FY 1994, the standard Federal rate used to determine the Federal rate each year under paragraph (c) of this section is reduced by 7.4 percent.

(3) Effective FY 1996, the standard Federal rate used to determine the Federal rate each year under paragraph (c) of this section is reduced by 0.28 percent to account for the effect of the revised policy for payment of transfers under §412.4(d).

(4) Effective FY 1998, the unadjusted standard Federal capital payment rate in effect on September 30, 1997, used to determine the Federal rate each year under paragraph (c) of this section is reduced by 15.68 percent.

(5) For discharges occurring on or after October 1, 1997 through September 30, 2002, the unadjusted standard Federal capital payment rate as in effect on September 30, 1997, used to determine the Federal rate each year under paragraph (c) of this section is further reduced by 2.1 percent.

(6) For discharges occurring on or after October 1, 2002, the 2.1 percent reduction provided for under paragraph (b)(5) of this section is eliminated from the unadjusted standard Federal rate in effect on September 30, 2002, used to determine the Federal rate each year under paragraph (c) of this section.

(c) *The Federal rate.* CMS determines the Federal rate each year by adjusting the standard Federal rate by the following factors.

(1) *Update factor.* After FY 1992, CMS updates the standard Federal rate as follows:

(i) *FY 1993 through FY 1995.* For FY 1993 through FY 1995, the standard Federal rate is updated based on a moving two-year average of actual increases in capital-related costs per discharge for the period three and four years before the fiscal year in question, excluding the portion of the increase attributable to changes in case mix.

(ii) *Effective FY 1996.* Effective FY 1996, the standard Federal rate is updated based on an analytical framework. The framework includes a capital input price index, which measures the annual change in the prices associated with capital-related costs during the year. CMS adjusts the capital input price index rate of change to take into account forecast errors, changes in the case mix index, the effect of changes to DRG classification and relative weights, and allowable changes in the intensity of hospital services.

(2) *Outlier payment adjustment factor.* CMS reduces the updated standard Federal rate by an adjustment factor equal to the estimated additional payments under the Federal rate for outlier cases under subpart F of this part, determined as a proportion of total capital payments under the Federal rate.

(3) *Exceptions payment adjustment factor.* CMS reduces the updated standard Federal rate by an adjustment factor equal to the estimated additional payments for exceptions under §412.348 determined as a proportion of total payments under the hospital-specific rate and Federal rate.

(4) *Budget neutrality adjustment factor.* (i) For FY 1992 through FY 1995, CMS adjusts the updated standard Federal rate by a budget neutrality factor determined under §412.352.

(ii) CMS makes an adjustment to the Federal rate so that estimated aggregate payments for the fiscal year based on the Federal rate after any changes resulting from the annual reclassification and recalibration of the DRG weight in accordance with §412.60(e) and in the geographic adjustment factors described in §412.312(b)(2) equal estimated aggregate payments based on the Federal rate that would have been made without such changes.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992, as amended at 58 FR 46339, Sept. 1, 1993; 59 FR 45399, Sept. 1, 1994; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997; 67 FR 50113, Aug. 1, 2002]

§412.312 Payment based on the Federal rate.

(a) *General.* The payment amount for each discharge based on the Federal

rate determined under § 412.308(c) is determined under the following formula: [Federal rate × DRG weight × Geographic adjustment factor × Large urban add-on × (1 + Capital disproportionate share adjustment factor + capital indirect medical education adjustment factor) × (for hospitals located in Alaska and Hawaii, a cost-of-living adjustment factor)] + (Any applicable outlier payment).

(b) *Payment adjustments*—(1) *DRG weights.* The relative resource requirements of the discharge are taken into account by applying the DRG weighting factor that is assigned to the discharge under § 412.60.

(2) *Geographic adjustment factors*—(i) *Local cost variation.* A geographic adjustment factor is applied that takes into account geographic variation in costs.

(ii) *Large urban add-on.* An additional adjustment is made for hospitals located in a large urban area to reflect the higher costs incurred by hospitals located in those areas. For purposes of the payment adjustment under this paragraph, the definition of large urban area set forth at § 412.63(c)(6) continues to be in effect for discharges occurring on or after September 30, 2004.

(iii) *Cost-of-living adjustment.* An additional adjustment is made for hospitals located in Alaska and Hawaii to account for the higher cost-of-living in those States.

(3) *Disproportionate share adjustment.* For hospitals with at least 100 beds located in an urban area and serving low-income patients, a disproportionate share adjustment factor is applied that reflects the higher costs attributable to furnishing services to low income patients.

(4) *Indirect medical education adjustment.* An additional adjustment is made based on the ratio of residents to the average daily patient census of the hospital to account for the indirect costs of medical education.

(c) *Additional payment for outlier cases.* Payment is made for day outlier cases as provided for in § 412.82 and for cost outlier cases if both capital-related and operating-related costs exceed the cost outlier threshold as provided for in § 412.84.

(d) *Payment for transfer cases.* Payment is made for transfer cases as provided for in § 412.4.

(e) *Payment for extraordinary circumstances.* For cost reporting periods beginning on or after October 1, 2001—

(1) Payment for extraordinary circumstances is made as provided for in § 412.348(f).

(2) Although no longer independently in effect, the minimum payment levels established under § 412.348(c) continue to be used in the calculation of exception payments for extraordinary circumstances, according to the formula in § 412.348(f).

(3) Although no longer independently in effect, the offsetting amounts established under § 412.348(e) continue to be used in the calculation of exception payments for extraordinary circumstances. However, for cost reporting periods beginning during FY 2005 and subsequent fiscal years, the offsetting amounts in § 412.348(e) are determined based on the lesser of—

(i) The preceding 10-year period; or

(ii) The period of time under which the hospital is subject to the prospective payment system for capital-related costs.

(f) *Payment adjustment for certain clinical trial or expanded access use immunotherapy cases.* For discharges occurring on or after October 1, 2020, in determining the payment amount under this section for certain clinical trial or expanded access use immunotherapy cases as described in § 412.85(b), the DRG weighting factor described in paragraph (b)(1) of this section is adjusted as described in § 412.85(c).

[56 FR 43449, Aug. 30, 1991, as amended at 67 FR 50113, Aug. 1, 2002; 69 FR 49250, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 85 FR 59023, Sept. 18, 2020]

§ 412.316 Geographic adjustment factors.

(a) *Local cost variation.* CMS adjusts for local cost variation based on the hospital wage index value that is applicable to the hospital under subpart D of this part. The adjustment factor equals the hospital wage index value applicable to the hospital raised to the .6848 power and is applied to 100 percent of the Federal rate.

(b) *Large urban location.* For discharges occurring on or before September 30, 2007, CMS provides an additional payment to a hospital located in a large urban area equal to 3.0 percent of what would otherwise be payable to the hospital based on the Federal rate.

(1) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location for the purpose of receiving payment under §412.63(a). The term ''large urban area'' is defined under §412.63(c)(6).

(2) For discharges occurring on or after October 1, 2004, and before October 1, 2007, the definition of large urban areas under §412.63(c)(6) continues be in effect for purposes of the payment adjustment under this section, based on the geographic classification under §412.64, except as provided for in paragraph (b)(3) of this section.

(3) For purposes of this section, the geographic classifications specified under §412.64 apply, except that, effective for discharges occurring on or after October 1, 2006, and before October 1, 2007, for an urban hospital that is reclassified as rural as set forth in §412.103, the geographic classification is rural.

(c) *Cost-of-living adjustment.* CMS provides an additional payment to a hospital located in Alaska and Hawaii equal to [0.3152 × (the cost-of-living adjustment factor used to determine payments under subpart D of this part − 1)] percent.

[56 FR 43449, Aug. 30, 1991, Aug. 11, 2004, as amended at 69 FR 49250, Aug. 11, 2004; 71 FR 48140, Aug. 18, 2006; 72 FR 47412, Aug. 22, 2007]

§412.320 Disproportionate share adjustment factor.

(a) *Criteria for classification.* A hospital is classified as a ''disproportionate share hospital'' for the purposes of capital prospective payments if either of the following conditions is met:

(1) The hospital is located in an urban area, has 100 or more beds as determined in accordance with §412.105(b), and serves low-income patients as determined under §412.106(b).

(i) For discharges occurring on or before September 30, 2004, the payment adjustment under this section is based on a hospital's location, for the purpose of receiving payment, under §412.63(a).

(ii) For discharges occurring on or after October 1, 2004, the payment adjustment under this section is based on the geographic classifications specified under §412.64, except as provided for in paragraph (a)(1)(iii) of this section.

(iii) For purposes of this section, the geographic classifications specified under §412.64 apply, except that, effective for discharges occurring on or after October 1, 2006, and before October 1, 2023, for an urban hospital that is reclassified as rural as set forth in §412.103, the geographic classification is rural.

(2) The hospital meets the criteria in §412.106(c)(2).

(b) *Payment adjustment factor.* (1) If a hospital meets the criteria in paragraph (a)(1) of this section for a disproportionate share hospital for purposes of capital prospective payments, the disproportionate share payment adjustment factor equals [e raised to the power of (.2025 × the hospital's disproportionate patient percentage as determined under §412.106(b)(5)), −1], where e is the natural antilog of 1.

(2) If a hospital meets the criteria in §412.106(c)(2) for purposes of hospital inpatient operating prospective payments, the disproportionate share adjustment factor is the factor that results from deeming the hospital to have the same disproportionate share patient percentage that would yield its operating disproportionate share adjustment.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992, as amended at 58 FR 46339, Sept. 1, 1993; 69 FR 49250, Aug. 11, 2004; 71 FR 48140, Aug. 18, 2006; 88 FR 59334, Aug. 28, 2023]

§412.322 Indirect medical education adjustment factor.

(a) *Basic data.* CMS determines the following for each hospital:

(1) The hospital's number of full-time equivalent residents as determined under §412.105(f).

(2) The hospital's average daily census is determined by dividing the total number of inpatient days in the acute inpatient area of the hospital by the number of days in the cost reporting period.

(3) The measurement of teaching activity is the ratio of the hospital's full-time equivalent residents to average daily census. This ratio cannot exceed 1.5.

(b) *Payment adjustment factor*. The indirect teaching adjustment factor equals [e (raised to the power of .2822 × the ratio of residents to average daily census) − 1].

(c)–(d) [Reserved]

[56 FR 43449, Aug. 30, 1991, as amended at 63 FR 26357, May 12, 1998; 63 FR 41004, July 31, 1998; 72 FR 47412, Aug. 22, 2007; 74 FR 43998, Aug. 27, 2009]

DETERMINATION OF TRANSITION PERIOD PAYMENT RATES FOR CAPITAL-RELATED COSTS

§ 412.324 General description.

(a) *Hospitals under Medicare in FY 1991*. During the ten-year transition period, payments to a hospital with a hospital-specific rate below the Federal rate are based on the fully prospective payment methodology under § 412.340 or for a hospital with a hospital-specific rate above the Federal rate, the hold-harmless payment methodology under § 412.344.

(b) *New hospitals*. (1) A new hospital, as defined under § 412.300(b), is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its cost reporting period ending at least 2 years after the hospital accepts its first patient.

(2) For the third year through the remainder of the transition period, the hospital is paid based on the fully prospective payment methodology or the hold-harmless payment methodology using the base period determined under § 412.328(a)(2).

(3) If the hospital is paid under the hold-harmless methodology described in § 412.344, the hold-harmless payment for old capital costs described in § 412.344(a)(1) is payable for up to and including 8 years and may continue beyond the first cost reporting period beginning on or after October 1, 2000.

(c) *Hospitals with 52–53 week fiscal years ending September 25 through September 29*. For purposes of this subpart, a hospital with a 52–53 week fiscal year period beginning September 26 through September 30, 1992 is deemed to have the same beginning date for all cost reporting periods beginning before October 1, 2000 (unless the hospital later changes its cost reporting period).

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, Jan. 27, 1992]

§ 412.328 Determining and updating the hospital-specific rate.

(a) *Base-year cost reporting period*—(1) *Last 12 month cost reporting period ending on or before December 31, 1990*. For each hospital, the intermediary uses the hospital's latest 12-month or longer cost reporting period ending on or before December 31, 1990 as the base period to determine a hospital's hospital-specific rate.

(2) *New hospitals*. The base-year cost reporting period for a new hospital is its 12-month cost reporting period (or a combination of cost reporting periods covering at least 12 months) that begins at least 1 year after the hospital accepts its first patient.

(3) *Other hospitals*. For other than a new hospital as defined in § 412.300(b), if a hospital does not have a 12-month cost reporting period or does not have adequate Medicare utilization to file a cost report in a period ending on or before December 31, 1990, the hospital-specific rate is based on the hospital's old capital costs (per discharge) in its first 12-month cost reporting period (or combination of cost reporting periods covering at least 12 months) ending after December 31, 1990.

(b) *Base-year costs per discharge*—(1) *Base period allowable inpatient capital costs per discharge*—(i) *Determination*. The intermediary determines the base period allowable inpatient capital costs per discharge for the hospital by dividing the hospital's total allowable Medicare inpatient hospital capital-related cost in the base period by the number of Medicare discharges in the base period.

(ii) *Disposal of assets in the base year*. When a depreciable asset has been disposed of in the base year, only that portion of the gain or loss that is allocated to the base-year cost reporting period is reflected in the hospital-specific rate.

(iii) *Disposal of assets subsequent to the base year*. If an asset for which the

Medicare program had recognized depreciation during the base year is disposed of subsequent to the base year, the hospital-specific rate will not be revised to recognize the portion of the gain or loss allocated to the base year.

(2) *Discharges.* For the purpose of determining a hospital's base period capital costs per discharge, a discharge includes discharges as defined in §412.4(a) and transfers as defined in §412.4(b)(2), adjusted by the transfer adjustment factor that is determined under paragraph (b)(3) of this section.

(3) *Transfer adjustment factor.* (i) For base year cost reporting periods ending on or before December 31, 1990, CMS uses the base year MEDPAR data received as of June 30, 1991 to develop an adjustment to discharges to account for transfers. CMS divides the length of stay for each transfer case by the geometric mean length of stay for the DRG (but in no case using a number greater than 1.0) and assigns each nontransfer case a value of 1.0. To determine the transfer adjustment factor, CMS adds together the adjusted discharges and divides the result by total discharges including transfers.

(ii) For base year cost reporting periods ending after December 31, 1990 but beginning before October 1, 1991, CMS determines a transfer adjustment factor as described in paragraph (b)(3)(i) of this section for a hospital using the applicable base year MEDPAR data on file as of the December 31 or June 30 occurring at least 6 months after the close of the approved base year.

(iii) For base year cost reporting periods beginning on or after October 1, 1991, the intermediary determines the transfer adjustment factor in place of CMS as described in paragraph (b)(3)(i) of this section based on the most recent billing data available as of the date of the final determination of the hospital-specific rate.

(c) *Case-mix adjustment*—(1) *Determining transfer-adjusted case mix value. Step 1:* For base year cost reporting periods ending on or before December 31, 1990, CMS uses the base year MEDPAR data received as of June 30, 1991 to determine the hospital's transfer-adjusted case-mix value. For base year cost reporting periods ending after December 31, 1990 and beginning before October 1, 1991, CMS determines a transfer-adjusted case-mix value for a hospital using the applicable base year MEDPAR data on file as of the December 31 or June 30 occurring at least 6 months after the close of the base year. For base year cost reporting periods beginning on or after October 1, 1991, the intermediary determines the transfer-adjusted case-mix value based on the most recent billing data available as of the date of the final determination of the hospital-specific rate. CMS or the intermediary, as appropriate, multiplies the DRG weight for each case by one of the following factors:

(i) If the case is not a transfer, the factor equals 1.0.

(ii) If the case is a transfer, the factor equals the lesser of 1.0 or the ratio of the length of stay for the case divided by the geometric mean length of stay for the DRG.

Step 2: The products derived for all cases under Step 1 are added together and the result is divided by the adjusted discharges used to calculate the transfer adjustment factor determined under paragraph (b)(3) of this section.

(2) *Adjusting base period capital costs per discharge by the hospital's transfer-adjusted case-mix value.* The intermediary divides the base period capital costs per discharge for each hospital as determined in paragraph (b) of this section by the hospital's transfer-adjusted case mix value for the cost reporting period determined under paragraph (c)(1) of this section.

(d) *Updating to FY 1992.* The intermediary updates the case-mix adjusted base period costs per discharge to FY 1992 based on the national average increase in Medicare inpatient capital costs per discharge as estimated by CMS, excluding the portion of the increase in capital costs per discharge attributable to changes in case mix.

(e) *Hospital-specific rate.* The intermediary determines the hospital-specific rate each year by adjusting the amount determined under paragraph (d) of this section by the following factors:

(1) *Update factor.* After FY 1992, the intermediary updates the hospital-specific rate in accordance with §412.308(c)(1).

(2) *Exceptions payment adjustment factor*. For FY 1992 through FY 2001, the intermediary reduces the updated amount determined in paragraph (d) of this section by an adjustment factor equal to the estimated additional payments for capital-related costs for exceptions under § 412.348, determined as a proportion of the total amount of payments under the hospital-specific rate and Federal rate.

(3) *Budget neutrality adjustment factor*. For FY 1992 through FY 1995, the intermediary adjusts the updated amount determined in paragraph (d) of this section by a budget neutrality adjustment factor determined under § 412.352.

(4) *Payment for transfer cases*. Effective FY 1996, the intermediary reduces the updated amount determined in paragraph (d) of this section by 0.28 percent to account for the effect of the revised policy for payment of transfers under § 412.4(d).

(5) *Reduction of rate: FY 1998*. Effective FY 1998, the unadjusted hospital-specific rate as in effect on September 30, 1997 described in paragraph (e)(1) of this section is reduced by 15.68 percent.

(6) *Reduction of rate: FY 1998 through FY 2002*. For discharges occurring on or after October 1, 1997 through September 30, 2002, the unadjusted hospital-specific rate in effect on September 30, 1997, described in paragraph (e)(1) of this section is further reduced by 2.1 percent.

(f) *Redetermination of hospital-specific rate*—(1) *General*. (i) Upon request by a hospital, the intermediary redetermines the hospital-specific rate to reflect an increase in old capital costs as determined in a cost reporting period subsequent to the base year. An increase in Medicare old capital cost per discharge that is related solely to a decline in utilization is not recognized as an increase in old capital costs for purposes of this section. New capital costs are excluded from the redetermination of the hospital-specific rate.

(ii) The hospital may request redetermination for any cost reporting period beginning subsequent to the base period but no later than the later of the hospital's cost reporting period beginning in FY 1994 or the cost reporting period beginning after obligated capital that is recognized as old capital under § 412.302(b) is put in use.

(iii) The hospital must request a redetermination in writing no later than the date the cost report must be filed with the hospital's intermediary for the first cost reporting period beginning on or after October 1, 1991 or the cost reporting period that will serve as the new base period, whichever is later. The hospital's redetermination request must include the cost report for the new base period and an estimate of the revised hospital-specific rate indicating that the new rate exceeds the hospital's current hospital-specific rate.

(2) *Determination of old capital costs*. The intermediary determines the hospital's old capital costs for the subsequent cost reporting period that will serve as the new base period. The intermediary includes the costs of obligated capital that are recognized as old capital costs under § 412.302(b), excludes the costs of assets disposed of subsequent to the initial base year, and reflects changes in allowable old capital costs occurring subsequent to the initial base period.

(3) *Redetermined hospital-specific rate*. The intermediary redetermines the hospital-specific rate based on the old capital costs that are determined under paragraph (f)(2) of this section for the new base period. The intermediary—

(i) Divides the hospital's old capital costs for the new base period by the number of Medicare discharges in that cost reporting period (consistent with paragraph (b) of this section);

(ii) Divides the old capital costs per discharge by the hospital's transfer adjusted case-mix value for the new base period (consistent with paragraph (c) of this section);

(iii) Applies an update factor, if appropriate, to account for inflation occurring subsequent to the new base year, an exceptions payment adjustment factor, and a budget neutrality adjustment factor (consistent with paragraphs (d) and (e) of this section).

(4) *Denial by intermediary*. If the intermediary determines, after audit, that the revised hospital-specific rate is lower than the current hospital-specific rate, it advises the hospital that

its request is denied and explains the basis for the denial.

(5) *Implementation date.* The redetermined hospital-specific rate applies to discharges occurring on or after the beginning date of the new base period.

(g) *Review and revision of the hospital-specific rate*—(1) *Interim determination.* The intermediary makes an interim determination of the hospital-specific rate based on the best data available and notifies the hospital at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) *Final determination.* (i) The intermediary makes a final determination of the hospital-specific rate based on the final settlement of the base period cost report.

(ii) The final determination of the hospital-specific rate is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991 or, in the case of a redetermination of the hospital-specific rate under §412.328(f), to the beginning of the new base period.

(iii) The final determination of the hospital-specific rate is subject to administrative and judicial review in accordance with subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

(iv) The intermediary adjusts the hospital-specific rate to reflect any revisions that result from administrative or judicial review of the final determination of hospital-specific rate. The revised determination is effective retroactively to the same extent as in paragraph (g)(2)(ii) of this section.

[56 FR 43449, Aug. 30, 1991; 57 FR 3016, 3017, Jan. 27, 1992; 57 FR 39828, Sept. 1, 1992; 60 FR 45849, Sept. 1, 1995; 62 FR 46031, Aug. 29, 1997]

§412.331 Determining hospital-specific rates in cases of hospital merger, consolidation, or dissolution.

(a) *New hospital merger or consolidation.* If, after a new hospital accepts its first patient but before the end of its base year, it merges with one or more existing hospitals, and two or more separately located hospital campuses are maintained, the hospital-specific rate and payment determination for the merged entity are determined as follows—

(1) *Post-merger base year payment methodology.* The new campus is paid based on reasonable costs until the end of its base year. The existing campus remains on its previous payment methodology until the end of the new campus' base year. Effective with the first cost reporting period beginning after the end of the new campus' base year, the intermediary determines a hospital-specific rate applicable to the new campus in accordance with §412.328, and then determines a revised hospital-specific rate for the merged entity in accordance with paragraph (a)(2) of this section.

(2) *Revised hospital-specific rate.* Using each hospital's base period data, the intermediary determines a combined average discharge-weighted hospital-specific rate.

(3) *Post-base year payment determination.* To determine the applicable payment methodology under §412.336 and for payment purposes under §412.340 or §412.344, the discharge-weighted hospital-specific rate determined by the intermediary is compared to the Federal rate. The revised payment methodology is effective on the first day of the cost reporting period beginning after the end of the new campus' base year.

(b) *Hospital merger or consolidation.* If, after the base year, two or more hospitals merge or consolidate into one hospital as provided for under §413.134(k) of this chapter and the provisions of paragraph (a) of this section do not apply, the intermediary determines a revised hospital-specific rate applicable to the combined facility under §412.328, which is effective beginning with the date of merger or consolidation. The following rules apply to the revised hospital-specific rate and payment determination:

(1) *Revised hospital-specific rate.* Using each hospital's base period data, the intermediary determines a combined average discharge weighted hospital-specific rate.

(2) *Payment determination.* The discharge-weighted hospital-specific rate determined by the intermediary is compared to the Federal rate to establish the appropriate payment methodology under §412.336 and for payment

purposes under §§ 412.340 or 412.344. The revised payment methodology is effective as of the date of merger or consolidation.

(3) *Old capital cost determination.* The capital-related costs related to the assets of each merged or consolidated hospital as of December 31, 1990 are recognized as old capital costs during the transition period. If the hospital is paid under the hold-harmless methodology after merger or consolidation, only that original base year old capital is eligible for hold-harmless payments.

(c) *Hospital dissolution.* If a hospital separates into two or more hospitals that are subject to capital payments under this subpart after the base year, the intermediary determines new hospital-specific rates for each separate hospital under the provisions of § 412.328 effective as of the date of the dissolution. The new hospital-specific rates are determined as follows:

(1) *Hospital-specific rate*—(i) *Adequate base year data.* The intermediary determines whether the base year capital-related cost data and necessary statistical records are adequate to reconstruct the cost and other data required under § 412.328 from the former hospital's financial records to determine the hospital-specific rates for each facility. If the data are adequate, the intermediary uses the former hospital's base period to determine the hospital-specific rate for each separate hospital.

(ii) *Inadequate original base year data.* If the intermediary determines that the base period data for the former hospital is inadequate to establish separate hospital-specific rates, the intermediary establishes a new base period for each hospital. The new base period is each hospital's first 12-month or longer cost reporting period (or combination of cost reporting periods covering at least 12 months) immediately following separation of the hospitals. The intermediary determines the hospital-specific rate for each hospital using the new base period under § 412.328.

(2) *Payment determinations.* The intermediary applies the payment methodology provisions of § 412.336. The revised payment determination is effective as of the date of the hospital's dissolution.

(3) *Old capital cost determination.* In determining the old capital costs for each hospital, the amount recognized as old capital is limited to the allowable capital-related costs attributable to assets that were in use for patient care as of December 31, 1990, and the hospitals are subject to all other transition period rules of this subpart.

[57 FR 39828, Sept. 1, 1992, as amended at 63 FR 41004, July 31, 1998]

§ 412.332 Payment based on the hospital-specific rate.

The payment amount for each discharge (as defined in § 412.4(a)) based on the hospital-specific rate determined under § 412.328 (e) or (f) is determined by multiplying the applicable hospital-specific rate by the DRG weighting factor applicable to the discharge under § 412.60 and the applicable hospital-specific rate percentage for the pertinent cost reporting period under § 412.340.

§ 412.336 Transition period payment methodologies.

(a) *General.* For discharges occurring in cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001, a hospital is paid under one of two payment methodologies described in §§ 412.340 and 412.344. Except as provided under paragraph (b) of this section, a hospital is paid under the same methodology throughout the transition period.

(1) *Hospital-specific rate below the Federal rate.* A hospital with a hospital-specific rate below the Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments) is paid under the fully prospective payment methodology as described in § 412.340.

(2) *Hospital-specific rate above the Federal rate.* A hospital with a hospital-specific rate that is above the Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments) is paid under the hold-harmless payment methodology as described in § 412.344.

(b) *Special rule for revised hospital-specific rate.* If a hospital with a hospital-specific rate below the Federal rate requests that its hospital-specific rate be redetermined, the redetermined hospital-specific rate is compared to the

Federal rate that is applicable to the new base period (after taking into account the estimated effect of the payment adjustments and outlier payments). If the redetermined hospital-specific rate is higher than the Federal rate, the hospital is paid under the hold-harmless methodology effective with the beginning of the new base period and continuing throughout the remainder of the transition.

(c) *Interim and final determinations of applicable payment methodology*—(1) *Interim determination.* The intermediary makes an interim determination of the applicable payment methodology based on the best data available and notifies the hospital of its determination at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(2) *Final determination.* (i) The intermediary makes a final determination of the applicable payment methodology based on its final determination of the hospital's hospital-specific rate. The final determination of the applicable payment methodology is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991.

(ii) If the hospital-specific rate is redetermined in accordance with § 412.328(f), the intermediary makes a new determination of the applicable payment methodology. The new determination is effective retroactively to the beginning of the new base period.

(iii) If the hospital-specific rate is revised under § 412.328(g) as a result of administrative or judicial review, the intermediary makes a new determination of the applicable payment methodology. The new determination is effective retroactively to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991 or to the beginning of the new base period.

(d) *Special Rule for Redetermination of Hospital Payment Methodology.* For cost reporting periods beginning on or after October 1, 1993, the intermediary redetermines the hospital payment methodologies to take into account the reduction to the standard Federal rate provided in § 412.308(b)(2):

(1) For a hospital paid under the fully prospective payment methodology in the last hospital cost reporting period beginning before October 1, 1993, the intermediary compares the hospital's FY 1994 hospital-specific rate with the hospital's FY 1994 Federal rate (after taking into account the estimated effect of the payment adjustments and outlier payments).

(i) A hospital with a FY 1994 hospital-specific rate that is above the FY 1994 adjusted Federal rate is paid under the hold-harmless payment methodology described in § 412.344.

(ii) Subject to the provisions of § 412.328(f), a hospital with a FY 1994 hospital-specific rate that is below the FY 1994 adjusted Federal rate continues to be paid under the fully prospective payment methodology as described in § 412.340.

(iii) The intermediary notifies the hospital of the new determination of the hospital's payment methodology within 90 days of the hospital's first cost reporting period beginning on or after October 1, 1993. The new determination is effective to the beginning of the hospital's first cost reporting period beginning on or after October 1, 1993.

(2) A hospital paid under the hold-harmless payment methodology in the last cost reporting period beginning before October 1, 1993, will continue to be paid in accordance with the provisions of § 412.344.

[56 FR 43449, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992, as amended at 58 FR 46340, Sept. 1, 1993]

§ 412.340 Fully prospective payment methodology.

A hospital paid under the fully prospective payment methodology receives a payment per discharge based on a proportion of the hospital-specific rate and the Federal rate as follows:

Cost reporting periods beginning on or after:	Federal rate percentage	Hospital-specific rate percentage
October 1, 1991	10	90
October 1, 1992	20	80
October 1, 1993	30	70
October 1, 1994	40	60
October 1, 1995	50	50
October 1, 1996	60	40
October 1, 1997	70	30
October 1, 1998	80	20
October 1, 1999	90	10

Cost reporting periods beginning on or after:	Federal rate percentage	Hospital-specific rate percentage
October 1, 2000	100	0

§ 412.344 Hold-harmless payment methodology.

(a) *General.* A hospital paid under the hold-harmless payment methodology receives a payment per discharge based on the higher of:

(1) 85 percent of reasonable costs for old capital costs (100 percent for sole community hospitals) plus an amount for new capital costs based on a proportion of the Federal rate. The proportion is equal to the ratio of the hospital's Medicare inpatient costs for new capital to total Medicare inpatient capital costs; or

(2) 100 percent of the Federal rate.

(3) *Exceptions.* (i) A hospital that would receive higher payment under paragraph (a)(1) of this section may elect payment based on 100 percent of the Federal rate under paragraph (a)(2) of this section.

(ii) A hospital that does not maintain records that are adequate to identify its old capital costs is deemed to have elected payment per discharge based on 100 percent of the Federal rate.

(b) *Continued basis of payment.* A hospital paid based on 100 percent of the Federal rate during the later of its cost reporting period beginning in FY 1994 or its first cost reporting period beginning after obligated capital that is recognized as old capital under § 412.302(b) is put in use continues to be paid on that basis in subsequent cost reporting periods during the transition period and does not receive a reasonable cost payment for old capital costs under paragraph (a)(1) of this section.

(c) *Basis of determination.* The determination under paragraph (a) of this section regarding which payment alternative is applicable is made without regard to additional payments under the exceptions process under § 412.348.

(d) *Interim and final payment determinations.* (1) Using the best data available, the intermediary makes an interim payment determination under paragraph (a) of this section concerning the applicable payment alternative, and, in the case of payment under paragraph (a)(1) of this section, the payment amounts for old and new capital. The intermediary notifies the hospital of its determination at least 30 days before the beginning of the hospital's first cost reporting period beginning on or after October 1, 1991. The intermediary may revise its determination based on additional information submitted by the hospital and make appropriate adjustments retroactively.

(2) The final determination of the amount payable under paragraph (a) of this section is based on final settlement of the Medicare cost report for the applicable cost reporting period and is effective retroactively to the beginning of that cost reporting period. This final determination is subject to administrative and judicial review in accordance with subpart R of part 405 of this chapter, governing provider reimbursement determinations and appeals.

[56 FR 43449, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992]

§ 412.348 Exception payments.

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

Annual operating expenses. Annual operating expenses means the sum of net expenses for all reimbursable cost centers for a 12 month cost reporting period. Annual operating expenses are obtained from the Medicare cost report.

Average age of fixed assets. The average age of fixed assets is the ratio of accumulated depreciation for buildings and fixed equipment to current depreciation expense for buildings and fixed equipment. The average age of fixed assets is determined from information on the Medicare cost report.

Fixed assets. Fixed assets mean buildings and fixed equipment.

(b) *Criterion for additional payment during the transition period.* An additional payment is made to a hospital paid under either the fully prospective payment methodology or the hold-harmless payment methodology as determined under paragraph (c) of this section for cost reporting periods beginning on or after October 1, 1991 and before October 1, 2001.

(c) *Minimum payment level by class of hospital.* (1) CMS establishes a minimum payment level by class of hospital. The minimum payment level for

a hospital will equal a fixed percentage of the hospital's capital-related costs. The minimum payment levels may be no greater than the percentages of allowable capital-related costs that follow:

(i) 90 percent for sole community hospitals.

(ii) 80 percent for hospitals located in an urban area for purposes of §412.63(a) with at least 100 beds, as determined under §412.105(b), that have a disproportionate share patient percentage of at least 20.2 percent as determined under §412.106(b), and for hospitals located in an urban area for purposes of §412.63(a) with at least 100 beds that qualify for disproportionate share payments under §412.106(c)(2).

(iii) 70 percent for all other hospitals.

(2) When it is necessary to adjust the minimum payment levels set by class of hospitals specified in paragraphs (c)(1)(i) and (g)(6) of this section, CMS will adjust those levels for each class of hospitals in one percentage point increments as necessary to satisfy the requirement specified in paragraph (h) of this section that total estimated payments under the exception process not exceed 10 percent of the total estimated capital prospective payments (exclusive of hold-harmless payments for old capital) for the same fiscal year.

(d) *Additional payments.* A hospital is entitled to an additional payment if its capital payments for the cost reporting period would otherwise be less than the applicable minimum payment level. The additional payment equals the difference between the applicable minimum payment level and the capital payments that the hospital would otherwise receive minus any offset amount determined under paragraph (e)(2) of this section.

(e) *Determining a hospital's exception payment amount*—(1) *Cumulative comparison.* For each cost reporting period beginning before October 1, 2001, the hospital's exception payment is determined by comparing the cumulative payments made to the hospital under the capital prospective payment system to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the prospective payment system.

(2) *Offsetting amounts.* Any amount by which the hospital's cumulative payments exceed its cumulative minimum payment levels is deducted from the additional payment that would otherwise be payable for a cost reporting period.

(f) *Additional payment exception for extraordinary circumstances.* (1) A hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million (net of proceeds from other payment sources such as insurance, litigation decisions and other State, local or Federal government funding programs) due to extraordinary circumstances beyond the hospital's control. Extraordinary circumstances include, but are not limited to, a flood, fire, or earthquake.

(2) A hospital must apply to its CMS Regional Office by the later of October 1, 1992 or 180 days after the extraordinary circumstance causing the unanticipated expenditures for a determination by CMS of whether the hospital is eligible for an additional payment based on the nature of the circumstances and the amount of financial loss documented by the hospital.

(3) Except for sole community hospitals, the additional payment is based on a minimum payment amount of 85 percent for Medicare's share of allowable capital-related costs attributable to the extraordinary circumstances. For sole community hospitals, the minimum payment amount is 100 percent.

(4) The minimum payment level applicable under paragraph (c)(1) of this section is adjusted to take into account the 85 percent minimum payment level (100 percent for sole community hospitals) under paragraph (f)(3) of this section for the unanticipated capital-related costs. The additional payment for the cost reporting period equals the difference between the adjusted minimum payment level and the capital payments the hospital would otherwise receive less any offset amount determined under paragraph (e)(2) of this section.

(g) *Special exceptions process.* For eligible hospitals that meet a project need requirement, a project size requirement, and, in the case of certain

urban hospitals, meet an excess capacity test, an additional payment may be made for up to 10 years beyond the end of the capital prospective payment system transition period.

(1) *Eligible hospitals.* The following classes of hospitals are eligible to receive exceptions payments under this special exceptions provision:

(i) Sole community hospitals.

(ii) Hospitals located in an urban area under § 412.63(a) with at least 100 beds, as determined under § 412.105(b), that either have a disproportionate share of at least 20.2 percent as determined under § 412.106(b) or qualify for disproportionate share payments under § 412.106(c)(2).

(iii) Hospitals with a combined inpatient Medicare and Medicaid utilization of at least 70 percent.

(2) *Project need requirement.* A hospital must show that it has obtained any required approval from a State or local planning authority. If a hospital is not required to obtain approval from a planning authority, it must satisfy the age of asset test specified in paragraph (g)(3) of this section and, in the case of an urban hospital, the excess capacity test under paragraph (g)(4) of this section.

(3) *Age of assets test.* A hospital must show that its average age of fixed assets is at or above the 75th percentile for the hospital's first cost reporting period beginning on or after October 1, 1991.

(4) *Excess capacity test for urban hospitals.* Urban hospitals that are not required to receive approval from a State or local planning authority must demonstrate that either—

(i) The overall average occupancy rate in its metropolitan statistical area is at least 80 percent; or

(ii) After completion of the project, its capacity is no more than 80 percent of its prior capacity (in terms of bed size).

(5) *Project size requirement.* A hospital must complete, during the period from the beginning of its first cost reporting period beginning on or after October 1, 1991 to the end of its last cost reporting period beginning before October 1, 2001, a project whose costs for replacement and/or renovation of fixed assets related to patient care are at least:

(i) $200 million; or

(ii) 100 percent of its operating cost during the first 12 month cost reporting period beginning on or after October 1, 1991.

(6) *Minimum payment level.* (i) The minimum payment level for qualifying hospitals will be 70 percent.

(ii) CMS will adjust the minimum payment level in one percentage point increments as necessary to satisfy the requirement specified in paragraph (h) of this section that total estimated payments under the exceptions process not exceed 10 percent of the total estimated capital prospective payment system payments for the same fiscal year.

(7) *Limitation on the period for exception payments.* A qualifying hospital may receive an exceptions payment for up to 10 years from the year in which it completes a project for replacement or renovation of capital assets that meets project need and project size requirements (and, if applicable, excess capacity test), provided that it completes the project no later than the end of the hospital's last cost reporting period beginning before October 1, 2001. A project is considered to be completed when the assets are put into use for patient care.

(8) *Determining a hospital's exception payment amount*—(i) *Cumulative comparison.* For each cost reporting period, the hospital's exception payment is determined by comparing the cumulative payments made to the hospital under the capital prospective payment system to the cumulative minimum payment levels applicable to the hospital for each cost reporting period subject to the prospective payment system.

(ii) *Offsetting amounts.* Offsetting amounts are applied in the following order—(A) Any amount by which the hospital's cumulative payments exceed its cumulative minimum payment levels is deducted from the additional payment that would otherwise be payable for a cost reporting period.

(B) Any amount by which the hospital's current year Medicare inpatient operating and capital prospective payment system payments (excluding, if applicable, 75 percent of the hospital's operating prospective payment system

disproportionate share payments) exceed its Medicare inpatient operating and capital costs is deducted from the additional payment that would otherwise be payable for the cost reporting period. For purposes of calculating the offset, the costs and payments for services that are not subject to the hospital inpatient prospective payment system are excluded.

(9) *Notification requirement.* Eligible hospitals must submit documentation to the intermediary indicating the completion date of a project that meets the project need requirement under paragraph (g)(2) of this section, the project size requirement under paragraph (g)(5) of this section, and, in the case of certain urban hospitals, an excess capacity test under paragraph (g)(4) of this section, by the later of October 1, 2001 or within 3 months of the end of the hospital's last cost reporting period beginning before October 1, 2001, during which a qualifying project was completed.

(h) *Limit on exception payments.* Total estimated payments under the exception process may not exceed 10 percent of the total estimated capital prospective payments (exclusive of hold-harmless payments for old capital) for the same fiscal year.

[59 FR 45399, Sept. 1, 1994, as amended at 62 FR 46031, Aug. 29, 1997; 66 FR 39936, Aug. 1, 2001]

§412.352 Budget neutrality adjustment.

For FY 1992 through FY 1995, CMS will determine an adjustment to the hospital-specific rate and the Federal rate proportionately so that the estimated aggregate payments under this subpart for inpatient hospital capital costs each fiscal year will equal 90 percent of what CMS estimates would have been paid for capital-related costs on a reasonable cost basis under §413.130 of this chapter.

SPECIAL RULES FOR PUERTO RICO HOSPITALS

§412.370 General provisions for hospitals located in Puerto Rico.

Except as provided in §412.374, hospitals located in Puerto Rico are subject to the rules in this subpart governing the prospective payment system for inpatient hospital capital-related costs.

§412.374 Payments to hospitals located in Puerto Rico.

(a) *FY 1998 through FY 2004.* Payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 50 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 50 percent of the Federal rate, as determined under §412.308.

(b) *FY 2005 through FY 2016.* For discharges occurring on or after October 1, 2004 and on or before September 30, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

(1) 25 percent of the Puerto Rico capital rate based on data from Puerto Rico hospitals only, which is determined in accordance with procedures for developing the Federal rate; and

(2) 75 percent of the Federal rate, as determined under §412.308.

(c) Effective for fiscal year 1998, the Puerto Rico capital rate described in paragraph (a) of this section in effect on September 30, 1997, is reduced by 15.68 percent.

(d) For discharges occurring on or after October 1, 1997 through September 30, 2002, the Puerto Rico capital rate described in paragraph (a) of this section in effect on September 30, 1997 is further reduced by 2.1 percent.

(e) *FY 2017 and subsequent fiscal years.* For discharges occurring on or after October 1, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are based on 100 percent of the Federal rate, as determined under §412.308.

[62 FR 46032, Aug. 29, 1997, as amended at 69 FR 49250, Aug. 11, 2004; 81 FR 57268, Aug. 22, 2016]

Subpart N—Prospective Payment System for Inpatient Hospital Services of Inpatient Psychiatric Facilities

SOURCE: 69 FR 66977, Nov. 15, 2004, unless otherwise noted.

§ 412.400 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 124 of Public Law 106–113, which provides for the implementation of a per diem-based prospective payment system for inpatient hospital services of inpatient psychiatric facilities.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for the inpatient hospital services of inpatient psychiatric facilities, including the methodology used for the development of the Federal per diem rate, payment adjustments, implementation issues, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2005, payment for the operating and capital-related costs of inpatient hospital services furnished by inpatient psychiatric facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined payment amount applied on a per diem basis.

§ 412.402 Definitions.

As used in this subpart—

Closure of an IPF means closure of a hospital as defined in § 413.79(h)(1)(i) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

Closure of an IPF's residency training program means closure of a hospital residency training program as defined in § 413.79(h)(1)(ii) by an IPF meeting the requirements of § 412.404(b) for the purposes of accounting for indirect teaching costs.

Comorbidity means all specific patient conditions that are secondary to the patient's primary diagnosis and that coexist at the time of admission, develop subsequently, or that affect the treatment received or the length of stay or both. Diagnoses that relate to an earlier episode of care that have no bearing on the current hospital stay are excluded.

Displaced resident means a displaced resident as defined in § 413.79(h)(1)(iii) for the purposes of accounting for indirect teaching costs.

Federal per diem base rate means the payment based on the average routine operating, ancillary, and capital-related cost of 1 day of hospital inpatient services in an inpatient psychiatric facility.

Federal per diem payment amount means the Federal per diem base rate with all applicable adjustments.

Fixed dollar loss threshold amount means a dollar amount which, when added to the Federal payment amount for a case, the estimated costs of a case must exceed in order for the case to qualify for an outlier payment.

Inpatient psychiatric facilities means hospitals that meet the requirements as specified in §§ 412.22, 412.23(a), 482.60, 482.61, and 482.62, and units that meet the requirements as specified in §§ 412.22, 412.25, and 412.27.

Inpatient psychiatric facilities prospective payment system rate year means—

(1) Through June 30, 2011, the 12-month period of July 1 through June 30.

(2) Beginning July 1, 2011, the 15-month period of July 1, 2011 through September 30, 2012.

(3) Beginning October 1, 2012, the 12-month period of October 1 through September 30, referred to as Fiscal Year (FY).

Interrupted stay means a Medicare inpatient is discharged from an inpatient psychiatric facility and is admitted to any inpatient psychiatric facility within 3 consecutive calendar days following discharge. The 3 consecutive calendar days begins with the day of discharge from the inpatient psychiatric facility and ends on midnight of the third day.

New graduate medical education program means a medical education program that receives initial accreditation by the appropriate accrediting body or begins training residents on or after November 15, 2004.

Outlier payment means an additional payment beyond the Federal per diem payment amount for cases with unusually high costs.

Principal diagnosis means the condition established after study to be chiefly responsible for occasioning the admission of the patient to the inpatient psychiatric facility. Principal diagnosis is also referred to as the primary diagnosis.

Qualifying emergency department means an emergency department that is staffed and equipped to furnish a comprehensive array of emergency services and meeting the definitions of a dedicated emergency department as specified in §489.24(b) of this chapter and the definition of ''provider-based status'' as specified in §413.65 of this chapter.

Rural area means for cost reporting periods beginning January 1, 2005, with respect to discharges occurring during the period covered by such cost reports but before July 1, 2006, an area as defined in §412.62(f)(1)(iii). For discharges occurring on or after July 1, 2006, rural area means an area as defined in §412.64(b)(1)(ii)(C).

Urban area means for cost reporting periods beginning on or after January 1, 2005, with respect to discharges occurring during the period covered by such cost reports but before July 1, 2006, an area as defined in §412.62(f)(1)(ii). For discharges occurring on or after July 1, 2006, urban area means an area as defined in §412.64(b)(1)(ii)(A) and §412.64(b)(1)(ii)(B).

[69 FR 66977, Nov. 15, 2004; 70 FR 19728, Apr. 1, 2005, as amended at 71 FR 27086, May 9, 2006; 76 FR 26465, May 6, 2011; 83 FR 38619, Aug. 6, 2018; 86 FR 42678, Aug. 4, 2021]

§412.404 Conditions for payment under the prospective payment system for inpatient hospital services of psychiatric facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2005, an inpatient psychiatric facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient psychiatric facility fails to comply fully with these conditions, CMS may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient psychiatric facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient psychiatric facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment system as specified in §412.1(a)(1).

(b) *Inpatient psychiatric facilities subject to the prospective payment system.* Subject to the special payment provisions of §412.22(c), an inpatient psychiatric facility must meet the general criteria set forth in §412.22. In order to be excluded from the hospital inpatient prospective payment system as specified in §412.1(a)(1), a psychiatric hospital must meet the criteria set forth in §§412.23(a), 482.60, 482.61, and 482.62 and psychiatric units must meet the criteria set forth in §412.25 and §412.27.

(c) *Limitations on charges to beneficiaries*—(1) *Prohibited charges.* Except as permitted in paragraph (c)(2) of this section, an inpatient psychiatric facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's cost of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient psychiatric facility receiving payment under this subpart for a covered hospital stay (that is, a stay that included at least one covered day) may charge the Medicare beneficiary or other person only the applicable deductible and coinsurance amounts under §§409.82, 409.83, and 409.87 of this chapter and for items or services as specified under §489.20(a) of this chapter.

(d) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of §412.422, the applicable payments made under this subpart are payment in full for all inpatient hospital services, as specified in §409.10 of this chapter. Hospital inpatient services do not include the following:

(i) Physicians' services that meet the requirements of §415.102(a) of this chapter for payment on a fee schedule basis.

(ii) Physician assistant services, as specified in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioners and clinical nurse specialist services, as specified in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as specified in section 1861(gg) of the Act.

(v) Qualified psychologist services, as specified in section 1861(ii) of the Act.

(vi) Services of a certified registered nurse anesthetist, as specified in section 1861(bb) of the Act and defined in § 410.69 of this subchapter.

(2) CMS does not pay providers or suppliers other than inpatient psychiatric facilities for services furnished to a Medicare beneficiary who is an inpatient of the inpatient psychiatric facility, except for services described in paragraphs (d)(1)(i) through (d)(1)(vi) of this section

(3) The inpatient psychiatric facility must furnish all necessary covered services to a Medicare beneficiary who is an inpatient of the inpatient psychiatric facility, either directly or under arrangements (as specified in § 409.3 of this chapter).

(e) *Reporting and recordkeeping requirements.* All inpatient psychiatric facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements as specified in §§ 412.27(c), 413.20, 413.24, and 482.61 of this chapter.

[69 FR 66977, Nov. 15, 2004, as amended at 76 FR 26465, May 6, 2011]

§ 412.405 Preadmission services as inpatient operating costs under the inpatient psychiatric facility prospective payment system.

The prospective payment system includes payment for inpatient operating costs of preadmission services if the inpatient operating costs are for—

(a) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary on the date of the beneficiary's inpatient admission, and during the calendar day immediately preceding the date of the beneficiary's inpatient admission, to the inpatient psychiatric facility that meet the following conditions:

(1) The services are furnished by the inpatient psychiatric facility or by an entity wholly owned or wholly operated by the inpatient psychiatric facility. An entity is wholly owned by the inpatient psychiatric facility if the inpatient psychiatric facility is the sole owner of the entity. An entity is wholly operated by an inpatient psychiatric facility if the inpatient psychiatric facility has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the inpatient psychiatric facility also has policymaking authority over the entity.

(2) The services are diagnostic (including clinical diagnostic laboratory tests).

(3) The services are nondiagnostic when furnished on the date of the beneficiary's inpatient admission, the services are nondiagnostic when furnished on the calendar day preceding the date of the beneficiary's inpatient admission and the hospital does not demonstrate that such services are unrelated to the beneficiary's inpatient admission, and are not one of the following:

(i) Ambulance services.

(ii) Maintenance renal dialysis services.

(b) The preadmission services are furnished on or after June 25, 2010.

[75 FR 50415, Aug. 16, 2010]

§ 412.422 Basis of payment.

(a) *Method of Payment.* (1) Under the inpatient psychiatric facility prospective payment system, inpatient psychiatric facilities receive a predetermined Federal per diem base rate for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The Federal per diem payment amount is based on the Federal per diem base rate plus applicable adjustments as specified in § 412.424.

(3) During the transition period, payment is based on a blend of the Federal per diem payment amount as specified in § 412.424, and the facility-specific payment rate as specified in § 412.426.

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable

deductibles and coinsurance as specified in subpart G of part 409 of this chapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient psychiatric facility, but not the cost of an approved medical education program as specified in §413.75 through §413.85 of this chapter.

(2) In addition to the Federal per diem payment amounts, inpatient psychiatric facilities receive payment for bad debts of Medicare beneficiaries, as specified in §413.89 of this chapter.

[69 FR 66977, Nov. 15, 2004; 70 FR 19728, Apr. 1, 2005, as amended at 76 FR 26465, May 6, 2011]

§412.424 Methodology for calculating the Federal per diem payment amount.

(a) *Data sources.* (1) To calculate the Federal per diem base rate (as specified in paragraph (b) of this section for inpatient psychiatric facilities, as specified in paragraph (b) of this section, CMS uses the following data sources:

(2) The best Medicare data available to estimate the average inpatient operating and capital-related costs per day made as specified in part 413 of this chapter.

(i) Patient and facility cost report data capturing routine and ancillary costs.

(ii) An appropriate wage index to adjust for wage differences.

(iii) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by inpatient psychiatric facilities.

(b) *Determining the average per diem cost of inpatient psychiatric facilities for FY 2002.* CMS determines the average inpatient operating, ancillary, and capital-related per diem cost for which payment is made to each inpatient psychiatric facility, using the available data described in paragraph (a) of this section.

(c) *Determining the Federal per diem base rate for cost reporting periods beginning on or after January 1, 2005 through June 30, 2006*—(1) *General.* Payment under the inpatient psychiatric facility prospective payment system is based on a standardized per diem payment referred to as the Federal per diem base rate. The Federal per diem base rate is the adjusted cost for 1 day of inpatient hospital services in an inpatient psychiatric facility in a base year as described in paragraph (b) of this section. The adjusted cost per day is adjusted in accordance with paragraphs (c)(2) through (c)(5) of this section.

(2) *Update of the average per diem cost.* CMS applies the increase factor described in paragraph (a)(2)(iii) of this section to the updated average per diem cost to the midpoint of the January 1, 2005 through June 30, 2006, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act.

(3) *Budget neutrality.* (i) CMS adjusts the updated average per diem cost so that the aggregate payments in the first 18 months (for January 1, 2005 through June 30, 2006) under the inpatient psychiatric facility prospective payment system are estimated to equal the amount that would have been made to the inpatient psychiatric facilities under part 413 of this chapter if the inpatient psychiatric facility prospective payment system described in this subpart were not implemented.

(ii) CMS evaluates the accuracy of the budget-neutrality adjustment within the first 5 years after implementation of the inpatient psychiatric facility prospective payment system. CMS may make a one-time prospective adjustment to the Federal per diem base rate to account for significant differences between the historical data on cost-based TEFRA payments (the basis of the budget-neutrality adjustment at the time of implementation) and estimates of TEFRA payments based on actual data from the first year of the prospective payment system.

(4) *Outlier payments.* CMS determines a reduction factor equal to the estimated proportion of outlier payments described in paragraph (d)(3)(i) of this section.

(5) *Standardization.* CMS determines a reduction factor to reflect estimated increases in the Federal per diem base rate as defined in §412.402 resulting from the facility-level and patient-level adjustments described in paragraph (d) of this section.

(6) *Computation of the Federal per diem base rate.* The Federal per diem base rate is computed as follows:

(i) For cost reporting periods beginning on or after January 1, 2005 and on or before June 30, 2006, the Federal per diem base rate is computed in accordance with paragraph (c) of this section.

(ii) For inpatient psychiatric facilities beginning on or after July 1, 2006, the Federal per diem base rate will be the Federal per diem base rate for the previous year, updated by an increase factor described in paragraph (a)(2)(iii) of this section.

(d) *Determining the Federal per diem payment amount.* The Federal per diem payment amount is the product of the Federal per diem base rate established under paragraph (c) of this section, the facility-level adjustments applicable to the inpatient psychiatric facility, patient-level adjustments and other policy adjustments applicable to the case.

(1) *Facility-level adjustments*— (i) *Adjustment for wages.* CMS adjusts the labor portion of the Federal per diem base rate to account for geographic differences in the area wage levels using an appropriate wage index.

(A) The application of the wage index is made on the basis of the location of the inpatient psychiatric facility in an urban or rural area as defined in § 412.402.

(B) Beginning October 1, 2022, CMS applies a cap on decreases to the wage index, such that the wage index applied to an inpatient psychiatric facility is not less than 95 percent of the wage index applied to that inpatient psychiatric facility in the prior fiscal year.

(ii) *Rural location.* CMS adjusts the Federal per diem base rate for inpatient psychiatric facilities located in a rural area as defined in § 412.402.

(iii) *Teaching adjustment.* CMS adjusts the Federal per diem base rate by a factor to account for indirect teaching costs.

(A) An inpatient psychiatric facility's teaching adjustment is based on the ratio of the number of full-time equivalent residents training in the inpatient psychiatric facility divided by the facility's average daily census.

(B) Residents with less than full-time status and residents rotating through the inpatient psychiatric facility for less than a full year will be counted in proportion to the time they spend in the inpatient psychiatric facility.

(C) Except as described in paragraph (d)(1)(iii)(D) of this section, the actual number of current year full-time equivalent residents used in calculating the teaching adjustment is limited to the number of full-time equivalent residents in the inpatient psychiatric facility's most recently filed cost report filed with its fiscal intermediary before November 15, 2004 (base year).

(D) If the inpatient psychiatric facility first begins training residents in a new approved graduate medical education program after November 15, 2004, the number of full-time equivalent residents determined under paragraph (d)(1)(iii)(C) of this section may be adjusted using the method described in § 413.79(e)(1)(i) and (ii) of this chapter.

(E) The teaching adjustment is made on a claim basis as an interim payment, and the final payment in full for the claim is made during the final settlement of the cost report.

(F) *Closure of an IPF or IPF residency training program—*(*1*) *Closure of an IPF.* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of another IPF's closure if the IPF meets the following criteria:

(*i*) The IPF is training additional displaced residents from an IPF that closed on or after July 1, 2011.

(*ii*) No later than 60 days after the IPF begins to train the displaced residents, the IPF submits a request to its Medicare contractor for a temporary adjustment to its cap, documents that the IPF is eligible for this temporary adjustment by identifying the displaced residents who have come from the closed IPF and have caused the IPF to exceed its cap, and specifies the length of time the adjustment is needed.

(*2*) *Closure of an IPF's residency training program.* If an IPF that closes its residency training program on or after July 1, 2011, agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (d)(1)(iii)(F)(*2*)(*ii*) of this section, another IPF(s) may receive a temporary adjustment to its FTE cap to reflect

displaced residents added because of the closure of the residency training program if the criteria specified in paragraph (d)(1)(iii)(F)(*2*)(*i*) of this section are met.

(*i*) *Receiving IPF(s).* For cost reporting periods beginning on or after July 1, 2011, an IPF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of another IPF's residency training program if the IPF is training additional displaced residents from the residency training program of an IPF that closed a program; and if no later than 60 days after the IPF begins to train the displaced residents, the IPF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the displaced residents who have come from another IPF's closed program and have caused the IPF to exceed its cap, specifies the length of time the adjustment is needed, and submits to its Medicare contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (d)(1)(iii)(F)(*2*)(*ii*) of this section.

(*ii*) *IPF that closed its program.* An IPF that agrees to train displaced residents who have been displaced by the closure of another IPF's program may receive a temporary FTE cap adjustment only if the hospital with the closed program temporarily reduces its FTE cap based on the FTE of displaced residents in each program year training in the program at the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those displaced residents who would have been training in the program during that year had the program not closed. No later than 60 days after the displaced residents who were in the closed program begin training at another hospital, the hospital with the closed program must submit to its Medicare contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IPF training the displaced residents to obtain a temporary adjustment to its cap; identifies the displaced residents who were in training at the time of the program's closure; identifies the IPFs to which the displaced residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(iv) *Inpatient psychiatric facilities located in Alaska and Hawaii.* CMS adjusts the non-labor portion of the Federal per diem base rate to reflect the higher cost of living of inpatient psychiatric facilities located in Alaska and Hawaii.

(v) *Adjustment for IPF with qualifying emergency departments.* (A) CMS adjusts the Federal per diem base rate to account for the costs associated with maintaining a qualifying emergency department. A qualifying emergency department is staffed and equipped to furnish a comprehensive array of emergency services (medical and psychiatric) and meets the requirements of §§489.24(b) and 413.65 of this chapter.

(B) Where the inpatient psychiatric facility is part of an acute care hospital that has a qualifying emergency department as described in paragraph (d)(1)(v)(A) of this section and an individual patient is discharged to the inpatient psychiatric facility from that acute care hospital, CMS would not apply the emergency adjustment.

(vi) *Applicable percentage change for fiscal year 2014 payment determination and for subsequent years.* (A) In the case of an inpatient psychiatric facility that is paid under the prospective payment system in §412.1(a)(2) that does not submit quality data to CMS, in the form and manner and at a time specified by CMS, the applicable annual update to a Federal standard rate is reduced by 2.0 percentage points.

(B) Any reduction in the applicable annual update to a Federal standard rate will apply only to the fiscal year involved and will not be taken into account in computing the annual payment update for a subsequent year.

(2) *Patient-level adjustments.* The inpatient psychiatric facility must identify a principal psychiatric diagnosis as specified in §412.27(a) for each patient. CMS adjusts the Federal per diem base rate by a factor to account for the diagnosis-related group assignment associated with the principal diagnosis, as specified by CMS.

(i) *Age.* CMS adjusts the Federal per diem base rate to account for patient age based on age groupings specified by CMS.

(ii) *Diagnosis-related group assignment.* The inpatient psychiatric facility must identify a principal diagnosis as specified in § 412.27(a) for each patient. CMS adjusts the Federal per diem base rate by a factor to account for the CMS inpatient psychiatric facility prospective payment system recognized diagnosis-related group assignment associated with each patient's principal diagnosis.

(iii) [Reserved]

(iv) *Comorbidities.* CMS adjusts the Federal per diem base rate by a factor to account for certain comorbidities as specified by CMS.

(v) *Variable per diem adjustments.* CMS adjusts the Federal per diem base rate by factors as specified by CMS to account for the cost of each day of inpatient psychiatric care relative to the cost of the median length of stay.

(3) *Other adjustments.* (i) *Outlier payments.* CMS provides an outlier payment if an inpatient psychiatric facility's estimated total cost for a case exceeds a fixed dollar loss threshold amount for an inpatient psychiatric facility as defined in § 412.402 plus the Federal payment amount for the case.

(A) The fixed dollar loss threshold amount is adjusted for the inpatient psychiatric facility's adjustments for wage area, teaching, rural locations, and cost of living adjustment for facilities located in Alaska and Hawaii.

(B) The outlier payment equals a percentage of the difference between the IPF's estimated cost for the case and the adjusted threshold amount specified by CMS for each day of the inpatient stay.

(C) For discharges occurring in cost reporting periods beginning on or after January 1, 2005, outlier payments are subject to the adjustments specified at §§ 412.84(i) and 412.84(m) of this part, except that national urban and rural median cost-to-charge ratios would be used instead of statewide average cost-to-charge ratios.

(ii) *Stop-loss payments.* CMS will provide additional payments during the transition period, specified in § 412.426(a)(1) through (3), to an inpatient psychiatric facility to ensure that aggregate payments under the prospective payment system are at least 70 percent of the amount the inpatient psychiatric facility would have received under reasonable cost reimbursement had the prospective payment system not been implemented.

(iii) *Special payment provision for interrupted stays.* If a patient is discharged from an inpatient psychiatric facility and is admitted to the same or another inpatient psychiatric facility within 3 consecutive calendar days following the discharge, the case is considered to be continuous for the purposes listed below. The 3 consecutive calendar days begins with the day of discharge from the inpatient psychiatric facility and ends on midnight of day 3.

(A) Determining the appropriate variable per diem adjustment, as specified in paragraph (d)(2)(v) of this section, applicable to the case.

(B) Determining whether the total cost for a case meets the criteria for outlier payments, as specified in paragraph (d)(3)(i)(C) of this section.

(iv) Payment for electroconvulsive therapy treatments. CMS provides an additional payment to reflect the cost of electroconvulsive therapy treatments received by a patient during an inpatient psychiatric facility stay in a manner specified by CMS.

[69 FR 66977, Nov. 15, 2004; 70 FR 16729, Apr. 1, 2005, as amended at 71 FR 27086, May 9, 2006; 76 FR 26465, May 6, 2011; 77 FR 53678, Aug. 31, 2012; 86 FR 42678, Aug. 4, 2021; 87 FR 46878, July 29, 2022]

§ 412.426 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* Except as provided in paragraph (c) of this section, for cost reporting periods beginning on or after January 1, 2005 through December 31, 2007, an inpatient psychiatric facility receives a payment comprised of a blend of the estimated Federal per diem payment amount, as specified in § 412.424(d) of this subpart and a facility-specific payment as specified under paragraph (b) of this section.

(1) For cost reporting periods beginning on or after January 1, 2005 and before January 1, 2006, payment is based on 75 percent of the facility-specific

payment and 25 percent is based on the Federal per diem payment amount.

(2) For cost reporting periods beginning on or after January 1, 2006 and before January 1, 2007, payment is based on 50 percent of the facility-specific payment and 50 percent is based on the Federal per diem payment amount.

(3) For cost reporting periods beginning on or after January 1, 2007 and before January 1, 2008, payment is based on 25 percent of the facility-specific payment and 75 percent is based on the Federal per diem payment amount.

(4) For cost reporting periods beginning on or after January 1, 2008, payment is based entirely on the Federal per diem payment amount.

(b) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the estimated payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital costs in accordance with part 413 of this chapter.

(c) *Treatment of new inpatient psychiatric facilities.* New inpatient psychiatric facilities, are facilities that under present or previous ownership or both have their first cost reporting period as an IPF beginning on or after January 1, 2005. New IPFs are paid based on 100 percent of the Federal per diem payment amount.

[69 FR 66977, Nov. 15, 2004; 70 FR 16729, Apr. 1, 2005, as amended at 71 FR 27087, May 9, 2006; 76 FR 26466, May 6, 2011]

§412.428 Publication of changes to the inpatient psychiatric facility prospective payment system.

CMS will issue annually in the FEDERAL REGISTER information pertaining to changes to the inpatient psychiatric facility prospective payment system. This information includes:

(a) A description of the methodology and data used to calculate the federal per diem base payment amount for the subsequent fiscal year.

(b)(1) For discharges occurring on or after January 1, 2005 but before July 1, 2006, the update, described in §412.424(a)(2)(iii), for the federal portion of the inpatient psychiatric facility's payments is based on the 1997-based excluded hospital with capital market basket under the applicable percentage increase methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(2)(i) For discharges occurring on or after July 1, 2006 but before October 1, 2015, the update for the federal portion of the inpatient psychiatric facility's payment is based on the rehabilitation, psychiatric, and long-term care market basket.

(ii) For discharges occurring on or after October 1, 2015, the update of the inpatient psychiatric facility's payment is based on the inpatient psychiatric facility market basket.

(3) For discharges occurring on or after January 1, 2005 but before October 1, 2005, the update, described in §412.424(a)(2)(iii), for the reasonable cost portion of the inpatient psychiatric facility's payment is based on the 1997-based excluded hospital with capital market basket under the updated methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(4) For discharges occurring on or after October 1, 2005 but before July 1, 2008, the update for the reasonable cost portion of the inpatient psychiatric facility's payment is based on the 2002-based excluded hospital market basket.

(c) The best available hospital wage index and information regarding whether an adjustment to the Federal per diem base rate is needed to maintain budget neutrality.

(d) Updates to the fixed dollar loss threshold amount in order to maintain the appropriate outlier percentage.

(e) Describe the ICD–10–CM coding changes and DRG classification changes discussed in the annual update to the hospital inpatient prospective payment system regulations.

(f) Update the electroconvulsive therapy adjustment by a factor specified by CMS.

(g) Update the national urban and rural cost to charge ratio median and ceilings. CMS will apply the national cost to charge ratio to—

(1) New inpatient psychiatric facilities that have not submitted their first Medicare cost report.

(2) Inpatient psychiatric facilities whose operating or capital cost to charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean.

(3) Other inpatient psychiatric facilities for which the fiscal intermediary obtains inaccurate or incomplete data with which to calculate either an operating or capital cost to charge ratio or both.

(h) Update the cost of living adjustment factor if appropriate.

[69 FR 66977, Nov. 15, 2004, as amended at 71 FR 27087, May 9, 2006; 80 FR 46726, Aug. 5, 2015; 83 FR 38619, Aug. 6, 2018]

§ 412.432 Method of payment under the inpatient psychiatric facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient psychiatric facility receives payment under this subpart for inpatient operating cost and capital-related costs for each inpatient stay following submission of a bill.

(b) *Periodic interim payments (PIP).* (1) Criteria for receiving PIP.

(i) An inpatient psychiatric facility receiving payment under this subpart may receive PIP for Part A services under the PIP method subject to the provisions of § 413.64(h) of this chapter.

(ii) To be approved for PIP, the inpatient psychiatric facility must meet the qualifying requirements in § 413.64(h)(3) of this chapter.

(iii) A hospital that is receiving periodic interim payments also receives payment under this subpart for applicable services furnished by its excluded psychiatric unit.

(iv) As provided in § 413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the annual inpatient psychiatric facility's Federal per diem prospective payments, net of estimated beneficiary deductibles and coinsurance, and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient psychiatric facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as specified in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient psychiatric facility receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient psychiatric facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient psychiatric facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient psychiatric facility no longer meets the requirements of § 413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of the biweekly period of service as specified in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient psychiatric facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an

interim basis. Outlier payments are made based on the submission of a discharge bill and represents final payment subject to the cost report settlement specified in §412.84(i) and §412.84(m) of this part.

(e) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to an inpatient psychiatric facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient psychiatric facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient psychiatric facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient psychiatric facility's preparation and submittal of bills to the intermediary beyond the normal billing cycle.

(2) *Approval of accelerated payment.* An inpatient psychiatric facility's request for an accelerated payment must be approved by the intermediary and CMS.

(3) *Amount of accelerated payment.* The amount of the accelerated payment is computed as a percent of the net payment for unbilled or unpaid covered services.

(4) *Recovery of accelerated payment.* Recovery of the accelerated payment is made by recoupment as inpatient psychiatric facility bills are processed or by direct payment by the inpatient psychiatric facility.

[69 FR 66977, Nov. 15, 2004, as amended at 76 FR 26465, May 6, 2011]

§412.433 Procedural requirements under the IPFQR Program.

(a) *Statutory authority.* Section 1886(s)(4) of the Act requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Under section 1886(s)(4) of the Act, for an IPF paid under the IPF PPS that fails to submit data required for the quality measures selected by the Secretary in a form and manner and at a time specified by the Secretary, we reduce the otherwise applicable annual update to the standard Federal rate by 2.0 percentage points with respect to the applicable fiscal year.

(b) *Participation in the IPFQR Program.* To participate in the IPFQR Program, an IPF (as defined under §412.402) that is paid under the IPF PPS must:

(1) Register and maintain an account on the CMS-designated information system before beginning to report data, identification of a security official is necessary to complete such registration; and

(2) Submit a notice of participation (NOP).

(c) *Withdrawal from the IPFQR Program.* An IPF may withdraw from the IPFQR Program by changing the NOP status in the secure portion of the CMS-designated information system. The IPF may withdraw at any time up to and including August 15 before the beginning of each respective payment determination year. A withdrawn IPF is subject to a reduced annual payment update as specified under paragraph (a) of this section and is mandatory to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the IPFQR Program.

(d) *Submission of IPFQR Program data.* In general, except as provided in paragraph (f) of this section, IPFs that participate in the IPFQR Program must submit to CMS data on measures selected under section 1886(s)(4)(D) of the Act and specified non-measure data in a form and manner, and at a time specified by CMS.

(e) *Quality measure updates, retention, and removal*—(1) *General rule for updates to quality measures.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the IPFQR Program

(2) *General rule for the retention of quality measures.* Quality measures adopted for the IPFQR 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 modified as set forth in paragraph (3) of this section.

(3) *Measure removal, suspension, or modification through the rulemaking process.* CMS will use the regular rulemaking process to remove, suspend, or

modify quality measures in the IPFQR Program to allow for public comment.

(i) *Factors for consideration in removal or replacement of quality measures.* CMS will weigh whether to remove or modify measures based on the following factors:

(A) Factor 1: Measure performance among IPFs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made;

(B) Factor 2: Measure does not align with current clinical guidelines or practice;

(C) Factor 3: Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;

(D) Factor 4: Measure performance or improvement does not result in better patient outcomes;

(E) Factor 5: Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;

(F) Factor 6: Measure collection or public reporting leads to negative unintended consequences other than patient harm;

(G) Factor 7: Measure is not feasible to implement as specified; and

(H) Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Retention.* CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (i) of this subsection if the continued collection of data on the quality measure would align with other CMS and HHS policy goals, align with other CMS programs, or support efforts to move IPFs toward reporting electronic measures.

(f) *Extraordinary circumstances exception.* CMS may grant an exception to one or more data submissions deadlines and requirements in the event of extraordinary circumstances beyond the control of the IPF, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS's data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) Upon request by the IPF.

(2) At the discretion of CMS. CMS may grant exceptions to IPFs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

(g) *Public reporting of IPFQR Program data.* Data that an IPF submits to CMS for the IPFQR Program will be made publicly available on a CMS website after providing the IPF an opportunity to review the data to be made public. IPFs will have a period of 30 days to review and submit corrections to errors resulting from CMS calculations prior to the data being made public.

[88 FR 51161, Aug. 2, 2023]

§ 412.434 Reconsideration and appeals procedures of Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program decisions.

(a) An inpatient psychiatric facility may request reconsideration of a decision by CMS that the inpatient psychiatric facility has not met the requirements of the IPFQR Program for a particular fiscal year. An inpatient psychiatric facility must submit a reconsideration request to CMS no later than 30 days from the date identified on the IPFQR Program Annual Payment Update Notification Letter provided to the inpatient psychiatric facility.

(b) A reconsideration request must contain the following information:

(1) The inpatient psychiatric facility's CMS Certification Number (CCN);

(2) The name of the inpatient psychiatric facility;

(3) Contact information for the inpatient psychiatric facility's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address;

(4) A summary of the reason(s), as set forth in the IPFQR Program Annual Payment Update Notification Letter, that CMS concluded the inpatient psychiatric facility did not meet the requirements of the IPFQR Program;

(5) A detailed explanation of why the inpatient psychiatric facility believes that it complied with the requirements of the IPFQR Program for the applicable fiscal year; and

(6) Any evidence that supports the inpatient psychiatric facility's reconsideration request, such as emails and other documents.

(c) An inpatient psychiatric facility 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.

[77 FR 53678, Aug. 31, 2012, as amended at 86 FR 42678, Aug. 4, 2021]

Subpart O—Prospective Payment System for Long-Term Care Hospitals

SOURCE: 67 FR 56049, Aug. 30, 2002, unless otherwise noted.

§ 412.500 Basis and scope of subpart.

(a) *Basis.* This subpart implements the following:

(1) Section 123 of Public Law 106–113, which provides for the implementation of a prospective payment system for long-term care hospitals described in section 1886(d)(1)(B)(iv) of the Act.

(2) Section 307 of Public Law 106–554, which states that the Secretary shall examine and may provide for appropriate adjustments to that system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and disproportionate share adjustments consistent with section 1886(d)(5)(F) of the Act.

(3) Section 114 of Public Law 110–173, which contains several provisions regarding long-term care hospitals, including the—

(i) Amendment of section 1886 of the Act to add a new subsection (m) that references section 123 of Public Law 106–113 and section 307(b) of Public Law 106–554 for the establishment and implementation of a prospective payment system for payments under title XVIII for inpatient hospital services furnished by a long-term care hospital described in section 1886(d)(1)(B)(iv) of the Act; and

(ii) Revision of the standard Federal rate for RY 2008.

(4) Section 4302(a) of Public Law 111–5, which amended sections 114(c) and (d) of Public Law 110–173 relating to several moratoria on the establishment of new long-term care hospitals and satellite facilities and on the increase in the number of beds in existing long-term care hospitals and satellite facilities under the long-term care hospital prospective payment system.

(5) Sections 3106(a) and 10312(a) of Public Law 111–148, which extended certain payment rules and moratoria under the long-term care hospital prospective payment system by further amending sections 114(c) and (d) of Public Law 110–173.

(6) Section 1206 of Public Law 113–67, which further extended certain payment rules and moratoria under the long-term care hospital prospective payment system by amending sections 114(c) and (d) of Public Law 110–173, and which:

(i) Added a new section 1886(m)(6) to the Act to establish a site neutral payment amount for long-term care hospital discharges that fail to meet the applicable criteria in cost reporting periods beginning on or after October 1, 2015; and

(ii) Requires the Secretary's review of the payment rates and regulations governing long-term care hospitals established under section 1886(d)(1)(B)(iv)(II) of the Act and application of payment adjustments based on that review.

(7) Section 411 of Public Law 114–10 which revises the annual update to the LTCH PPS standard Federal payment rate in FY 2018.

(8) Public Law 114–255 which at—

(i) Section 15004 amended the moratorium on increasing beds in existing LTCHs and LTCH satellite facilities and amended high cost outlier payment requirements;

(ii) Section 15006 amended moratoria on certain payment policies;

(iii) Section 15007 amended the average length of stay requirements;

(iv) Section 15009 temporally excepted certain spinal cord specialty hospitals from the site neutral payment rate; and

(v) Section 15010 temporally excepted certain wound care discharges from certain LTCHs from the site neutral payment rate.

(9) Section 51005(a) of Public Law 115–123 which extended the blended payment rate for the site neutral payment rate cases to apply to discharges occurring in cost reporting periods beginning in FYs 2018 and 2019.

(10) Section 51005(b) of Public Law which reduces the IPPS comparable amount for the site neutral payment rate cases by 4.6 percent for FYs 2018 through 2026.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for long-term care hospitals, including the methodology used for the development of payment rates and associated adjustments and related rules. Under this system, for cost reporting periods beginning on or after October 1, 2002, payment for the operating and capital-related costs of inpatient hospital services furnished by long-term care hospitals is made on the basis of prospectively determined rates and applied on a per discharge basis.

[67 FR 56049, Aug. 30, 2002, as amended at 73 FR 24879, May 6, 2008; 79 FR 50355, Aug. 22, 2014; 82 FR 38512, Aug. 14, 2017; 83 FR 41704, Aug. 17, 2018]

§ 412.503 Definitions.

As used in this subpart—

CMS stands for the Centers for Medicare & Medicaid Services.

Discharge. A Medicare patient in a long-term care hospital is considered discharged when—

(1) For purposes of the long-term care hospital qualification calculation, as described in § 412.23(e)(3), the patient is formally released;

(2) For purposes of payment, as described in § 412.521(b), the patient stops receiving Medicare-covered long-term care services; or

(3) The patient dies in the long-term care facility.

Long-term care hospital prospective payment system fiscal year means, beginning October 1, 2010, the 12-month period of October 1 through September 30.

Long-term care hospital prospective payment system payment year means the general term that encompasses both the definition of ''long-term care hospital prospective payment system rate year'' and ''long-term care hospital prospective payment system fiscal year'' specified in this section.

Long-term care hospital prospective payment system rate year means—

(1) From July 1, 2003 and ending on or before June 30, 2008, the 12-month period of July 1 through June 30.

(2) From July 1, 2008 and ending on September 30, 2009, the 15-month period of July 1, 2008 through September 30, 2009.

(3) From October 1, 2009 through September 30, 2010, the 12-month period of October 1 through September 30.

LTC–DRG stands for the diagnosis-related group used to classify patient discharges from a long-term care hospital based on clinical characteristics and average resource use, for prospective payment purposes. Effective October 1, 2007, long-term care hospital patient discharges occurring on or after October 1, 2007, are classified by a severity-adjusted patient classification system, the MS–LTC–DRGs. Any reference to the term ''LTC–DRG'' shall be considered a reference to the term ''MS–LTC–DRG'' when applying the provisions of this subpart for policy descriptions and payment calculations for discharges from a long-term care hospital occurring on or after October 1, 2007.

MSA means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

MSA-dominant area means an MSA in which an MSA-dominant hospital is located.

MSA-dominant hospital means a hospital that has discharged more than 25 percent of the total subsection (d) hospital Medicare discharges in the MSA (not including discharges paid by a Medicare Advantage plan) in which the hospital is located.

MS–LTC–DRG stands for the severity-adjusted diagnosis-related group used to classify patient discharges from a long-term care hospital based on clinical characteristics and average resource use, for prospective payment purposes for discharges from a long-term care hospital occurring on or after October 1, 2007.

Outlier payment means an additional payment beyond the long-term care hospital standard Federal payment rate or the site neutral payment rate (including, when applicable, the blended payment rate), as applicable, for cases with unusually high costs.

QIO (formerly PRO or Peer Review Organization) stands for the Quality Improvement Organization.

Rural area means—(1) For cost reporting periods beginning on or after October 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before July 1, 2005, an area defined in § 412.62(f)(1)(iii);

(2) For discharges occurring on or after July 1, 2005, and before July 1, 2008, an area as defined in § 412.64(b)(1)(ii)(C); and

(3) For discharges occurring on or after July 1, 2008, any area outside an urban area.

Subsection (d) hospital means, for purposes of § 412.522, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

Urban area means—(1) For cost reporting periods beginning on or after October 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before July 1, 2005, an area defined in § 412.62(f)(1)(ii);

(2) For discharges occurring on or after July 1, 2005, and before July 1, 2008, an urban area means an area as defined in § 412.64(b)(1)(ii)(A) and (B); and

(3) For discharges occurring on or after July 1, 2008, a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

[67 FR 56049, Aug. 30, 2002, as amended at 72 FR 47412, Aug. 22, 2007; 73 FR 26838, May 9, 2008; 75 FR 50416, Aug. 16, 2010; 80 FR 49767, Aug. 17, 2015; 81 FR 57268, Aug. 22, 2016]

§ 412.505 Conditions for payment under the prospective payment system for long-term care hospitals.

(a) *Long-term care hospitals subject to the prospective payment system.* To be eligible to receive payment under the prospective payment system specified in this subpart, a long-term care hospital must meet the criteria to be classified as a long-term care hospital set forth in § 412.23(e) for exclusion from the acute care hospital inpatient prospective payment systems specified in § 412.1(a)(1). This condition is subject to the special payment provisions of § 412.22(c), the provisions on change in hospital status of § 412.22(d), the provisions related to hospitals-within-hospitals under § 412.22(e), and the provisions related to satellite facilities under § 412.22(h).

(b) *General requirements.* (1) Effective for cost reporting periods beginning on or after October 1, 2002, a long-term care hospital must meet the conditions for payment of this section, § 412.22(e)(3) and (h)(6), if applicable, and § 412.507 through § 412.511 to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare beneficiaries.

(2) If a long-term care hospital fails to comply fully with these conditions for payment with respect to inpatient hospital services furnished to one or more Medicare beneficiaries, CMS may withhold (in full or in part) or reduce Medicare payment to the hospital.

[67 FR 56049, Aug. 30, 2002, as amended at 71 FR 48140, Aug. 19, 2006]

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system.

(1) If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met.

(2) If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate (including, when applicable, the blended payment rate), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(3) For cost reporting periods beginning on or after October 1, 2016, for Medicare payments to a long-term care hospital described in § 412.23(e)(2)(ii), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(4) If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier is met.

(b) *Permitted charges.* (1) A long-term care hospital that receives a payment at the full LTCH prospective payment system standard Federal payment rate or the site neutral payment rate may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, and for items and services as specified under § 489.20(a) of this chapter.

(2) A long-term care hospital that receives a payment at less than the full LTCH prospective payment system standard Federal payment rate for a short-stay outlier case, in accordance with § 412.529 (which would not include any discharge paid at the site neutral payment rate), may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay that were not the basis for the short-stay adjusted payment.

(3) For cost reporting periods beginning on or after October 1, 2016, a long-term care hospital described in § 412.23(e)(2)(ii) may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay for which benefit days were not available and that were not the basis for adjusted LTCH prospective payment system payment amount under § 412.526.

[80 FR 49767, Aug. 17, 2015, as amended at 81 FR 57268, Aug. 22, 2016]

§ 412.508 Medical review requirements.

(a) *Admission and quality review.* A long-term care hospital must have an agreement with a QIO to have the QIO review, on an ongoing basis, the following:

(1) The medical necessity, reasonableness, and appropriateness of hospital admissions and discharges.

(2) The medical necessity, reasonableness, and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.523(d)(1) and 412.525(a).

(3) The validity of the hospital's diagnostic and procedural information.

(4) The completeness, adequacy, and quality of the services furnished in the hospital.

(5) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Physician acknowledgement.* Payment under the long-term care hospital prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record. The hospital must assure that physicians complete an acknowledgement statement to this effect in accordance with paragraphs (b)(1) and (b)(2) of this section.

(1) *Content of physician acknowledgement statement.* When a claim is submitted, the hospital must have on file a signed and dated acknowledgement from the attending physician that the physician has received the following notice:

NOTICE TO PHYSICIANS: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

(2) *Completion of acknowledgement.* The acknowledgement must be completed by the physician at the time

that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

(c) *Denial of payment as a result of admissions and quality review.* (1) If CMS determines, on the basis of information supplied by a QIO, that a hospital has misrepresented admissions, discharges, or billing information, or has taken an action that results in the unnecessary admission or unnecessary multiple admissions of an individual entitled to benefits under Part A, or other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries, CMS may, as appropriate—

(i) Deny payment (in whole or in part) under Part A with respect to inpatient hospital services provided for an unnecessary admission or subsequent readmission of an individual; or

(ii) Require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(2) When payment with respect to admission of an individual patient is denied by a QIO under paragraph (c)(1) of this section, and liability is not waived in accordance with §§411.400 through 411.402 of this chapter, notice and appeals are provided under procedures established by CMS to implement the provisions of section 1155 of the Act, Right to Hearing and Judicial Review.

(3) A determination under paragraph (c)(1) of this section, if it is related to a pattern of inappropriate admissions and billing practices that has the effect of circumventing the prospective payment system, is referred to the Department's Office of Inspector General for handling in accordance with §1001.201 of this title.

[67 FR 56049, Aug. 30, 2002, as amended at 71 FR 48140, Aug. 19, 2006]

§412.509 Furnishing of inpatient hospital services directly or under arrangement.

(a) Subject to the provisions of §412.521(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in §409.10 of this chapter. Inpatient hospital services do not include the following:

(1) Physicians' services that meet the requirements of §415.102(a) of this subchapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioners and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(6) Services of an anesthetist, as defined in §410.69 of this subchapter.

(b) Medicare does not pay any provider or supplier other than the long-term care hospital for services furnished to a Medicare beneficiary who is an inpatient of the hospital except for services described in paragraphs (a)(1) through (a)(6) of this section.

(c) The long-term care hospital must furnish all necessary covered services to the Medicare beneficiary who is an inpatient of the hospital either directly or under arrangements (as defined in §409.3 of this subchapter).

§412.511 Reporting and recordkeeping requirements.

A long-term care hospital participating in the prospective payment system under this subpart must meet the requirement of §§412.22(e)(3) and 412.22(h)(6) to report co-located status, if applicable, and the recordkeeping and cost reporting requirements of §§413.20 and 413.24 of this subchapter.

[71 FR 48140, Aug. 18, 2006]

§412.513 Patient classification system.

(a) *Classification methodology.* CMS classifies specific inpatient hospital discharges from long-term care hospitals by long-term care diagnosis-related groups (LTC-DRGs) to ensure that each hospital discharge is appropriately assigned based on essential data abstracted from the inpatient bill for that discharge.

(b) *Assignment of discharges to LTC-DRGs.* (1) The classification of a particular discharge is based, as appropriate, on the patient's age, sex, principal diagnosis (that is, the diagnosis established after study to be chiefly responsible for causing the patient's admission to the hospital), secondary diagnoses, procedures performed, and the patient's discharge status.

(2) Each discharge from a long-term care hospital is assigned to only one LTC-DRG (related, except as provided in paragraph (b)(3) of this section, to the patient's principal diagnosis), regardless of the number of conditions treated or services furnished during the patient's stay.

(3) When the discharge data submitted by a hospital show a surgical procedure unrelated to a patient's principal diagnosis, the bill is returned to the hospital for validation and reverification. The LTC-DRG classification system provides a LTC-DRG, and an appropriate weighting factor, for those cases for which none of the surgical procedures performed are related to the principal diagnosis.

(c) *Review of LTC-DRG assignment.* (1) A hospital has 60 days after the date of the notice of the initial assignment of a discharge to a LTC-DRG to request a review of that assignment. The hospital may submit additional information as a part of its request.

(2) The intermediary reviews that hospital's request and any additional information and decides whether a change in the LTC-DRG assignment is appropriate. If the intermediary decides that a different LTC-DRG should be assigned, the case will be reviewed by the appropriate QIO as specified in § 476.71(c)(2) of this chapter.

(3) Following the 60-day period described in paragraph (c)(1) of this section, the hospital may not submit additional information with respect to the DRG assignment or otherwise revise its claim.

§ 412.515 LTC–DRG weighting factors.

(a) For each LTC–DRG, CMS assigns an appropriate weight that reflects the estimated relative cost of hospital resources used within that group compared to discharges classified within other groups.

(b)(1) Beginning FY 2023, each LTC–DRG weight is subject to a maximum 10 percent reduction as compared to the weight for the same LTC–DRG for the prior fiscal year, except as provided in paragraph (b)(2) of this section.

(2) The limitation described in paragraph (b)(1) of this section does not apply to LTC–DRGs with less than 25 applicable LTCH cases in the data used to determine the relative weights for the fiscal year.

[87 FR 49405, Aug. 10, 2022]

§ 412.517 Revision of LTC-DRG group classifications and weighting factors.

(a) CMS adjusts the classifications and weighting factors annually to reflect changes in—

(1) Treatment patterns;

(2) Technology;

(3) Number of discharges; and

(4) Other factors affecting the relative use of hospital resources.

(b) Beginning in FY 2008, the annual changes to the LTC–DRG classifications and recalibration of the weighting factors described in paragraph (a) of this section are made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

(c) Beginning in FY 2016, the annual recalibration of the weighting factors described in paragraph (a) of this section is determined using long-term care hospital discharges described in § 412.522(a)(2) (or that would have been described in such section had the application of the site neutral payment rate been in effect at the time of the discharge).

[67 FR 56049, Aug. 30, 2002, as amended at 72 FR 26991, May 11, 2007; 80 FR 49768, Aug. 17, 2015]

§ 412.521 Basis of payment.

(a) *Method of payment.* (1) Under the prospective payment system, long-term care hospitals receive a predetermined payment amount per discharge for inpatient services furnished to Medicare beneficiaries.

(2) Except as provided for in § 412.526, the amount of payment under the prospective payment system is based on

either the long-term care hospital prospective payment system standard Federal payment rate established in accordance with §412.523, including adjustments described in §412.525, or the site neutral payment rate established in accordance with §412.522(c), or, if applicable during a transition period, the blend of the LTCH PPS standard Federal payment rate and the applicable site neutral payment rate described in §412.522(c)(3).

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance described in subpart G of part 409 of this subchapter) for covered inpatient operating costs as described in §§412.2(c)(1) through (c)(4) of this part and §412.540 and capital-related costs described in subpart G of part 413 of this subchapter associated with furnishing Medicare covered services in long-term care hospitals.

(2) In addition to payment based on prospective payment rates, long-term care hospitals may receive payments separate from payments under the prospective payment system for the following:

(i) The costs of approved medical education programs described in §§413.75 through 413.83, 413.85, and 413.87 of this subchapter.

(ii) Bad debts of Medicare beneficiaries, as provided in §413.89 of this subchapter.

(iii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

(iv) Anesthesia services furnished by hospital employed nonphysician anesthetists or obtained under arrangements, as specified in §412.113(c)(2).

(v) The costs of photocopying and mailing medical records requested by a QIO, in accordance with §476.78(c) of this chapter.

(c) *Payment by workers' compensation, automobile medical, no-fault or liability insurance or an employer group health plan primary to Medicare.* If workers' compensation, automobile medical, no-fault, or liability insurance or an employer group health plan that is primary to Medicare pays in full or in part, payment is determined in accordance with the guidelines specified in §412.120(b).

(d) *Effect of change of ownership on payments under the prospective payment system.* When a hospital's ownership changes, as described in §489.18 of this chapter, the following rules apply:

(1) Payment for the operating and capital-related costs of inpatient hospital services for each patient, including outlier payments as provided in §412.525 and payments for hemophilia clotting factor costs as provided in paragraph (b)(2)(iii) of this section, are made to the entity that is the legal owner on the date of discharge. Payments are not prorated between the buyer and seller.

(i) The owner on the date of discharge is entitled to submit a bill for all inpatient hospital services furnished to a beneficiary regardless of when the beneficiary's coverage began or ended during a stay, or of how long the stay lasted.

(ii) Each bill submitted must include all information necessary for the intermediary to compute the payment amount, whether or not some of that information is attributable to a period during which a different party legally owned the hospital.

(2) Other payments for the direct costs of approved medical education programs, bad debts, anesthesia services furnished by hospital employed nonphysician anesthetists, and costs of photocopying and mailing medical records to the QIO as provided for under paragraphs (b)(2)(i), (ii), (iv), and (v) of this section are made to each owner or operator of the hospital (buyer and seller) in accordance with the principles of reasonable cost reimbursement.

(e) *Special payment provisions for patients in acute care hospitals that change classification status to LTCH status during a patient stay.* (1) If a patient is admitted to an acute care hospital and then the acute care hospital meets the criteria at §412.23(e) to be paid as a LTCH during the course of the patient's hospitalization, Medicare considers all the days of the patient stay in the facility (days prior to and after the designation of LTCH status) to be a single episode of LTCH care. Payment for the entire patient stay (days prior

to and after the designation of LTCH status) will include the day and cost data for that patient at both the acute care hospital and the LTCH in determining the payment to the LTCH under this subpart. The requirements of this paragraph (e)(1) apply only to a patient stay in which a patient is in an acute care hospital and that hospital is designated as a LTCH on or after October 1, 2004.

(2) The days of the patient's stay prior to and after the hospital's designation as a LTCH as specified in paragraph (e)(1) of this section are included for purposes of determining the beneficiary's length of stay.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34162, June 6, 2003; 69 FR 49250, Aug. 11, 2004; 70 FR 47487, Aug. 12, 2005; 75 FR 50416, Aug. 16, 2010; 79 FR 50355, Aug. 22, 2014; 80 FR 49768, Aug. 17, 2015]

§ 412.522 Application of site neutral payment rate.

(a) *General.* For discharges in cost reporting periods beginning on or after October 1, 2015—

(1) Except as provided for in paragraph (b) of this section, all discharges are paid based on the site neutral payment rate as determined under the provisions of paragraph (c) of this section.

(2) Discharges that meet the criteria for exclusion from site neutral payment rate specified in paragraph (b) of this section are paid based on the standard Federal prospective payment rate established under § 412.523.

(b) *Criteria for exclusion from the site neutral payment rate*—(1) *General criteria*—(i) *Basis and scope.* A discharge that meets the following criteria is excluded from the site neutral payment rate specified under this section.

(A) The discharge from the long-term care hospital does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation based on the LTC–DRG assignment of the discharge under § 412.513; and

(B) The admission to the long-term care hospital was immediately preceded by a discharge from a subsection (d) hospital and meets either the intensive care unit criterion specified in paragraph (b)(1)(ii) of this section or the ventilator criterion specified in paragraph (b)(1)(iii) of this section. In order for an admission to a long-term care hospital to be considered immediately preceded for purposes of this section, the patient discharged from the subsection (d) hospital must be directly admitted to the long-term care hospital.

(ii) *Intensive care unit criterion.* In addition to meeting the requirements of paragraph (b)(1)(i) of this section, the discharge from the subsection (d) hospital that immediately preceded the admission to the long-term care hospital includes at least 3 days in an intensive care unit (as defined in § 413.53(d) of this chapter), as evidenced by at least one of the revenue center codes on the claim for the discharge that indicate such services were provided for the requisite number of days during the stay.

(iii) *Ventilator criterion.* In addition to meeting the requirements of paragraph (b)(1)(i) of this section, the discharge from the long-term care hospital is assigned to a LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours, as evidenced by the procedure code on the discharge bill indicating such services were provided during the stay.

(2) *Special criteria*—(i) *Definitions.* For purposes of this paragraph (b)(2) the following definitions are applicable:

Severe wound means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, infected wound, fistula, osteomyelitis or wound with morbid obesity as identified by the applicable code on the claim from the long-term care hospital.

Wound means an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(ii) *Discharges for severe wounds.* A discharge that occurs on or after April 21, 2016 and before January 1, 2017 for a patient that was treated for a severe wound that meets the all of following criteria is excluded from the site neutral payment rate specified under this section:

(A) The severe wound meets the definition specified in paragraph (b)(2)(i) of this section.

(B) The discharge is from a long term care hospital that is—

(*1*) Described in §412.23(e)(2)(i) and meets the criteria of §412.22(f); and

(*2*) Located in a rural area (as defined at §412.503) or reclassified as rural by meeting the requirements set forth in §412.103.

(3) *Temporary exception for certain severe wound discharges.*—(i) *Definitions.* For purposes of this paragraph (b)(3) the following definitions are applicable:

Severe wound means a wound which is a stage 3 wound, stage 4 wound, unstageable wound, non-healing surgical wound, fistula, as identified by the applicable code on the claim from the long-term care hospital.

Wound means an injury, usually involving division of tissue or rupture of the integument or mucous membrane with exposure to the external environment.

(ii) *Discharges for severe wounds.* A discharge that occurs in a cost reporting period beginning during fiscal year 2018 for a patient who was treated for a severe wound that meets all of the following criteria is excluded from the site neutral payment rate specified under this section:

(A) The severe wound meets the definition specified in paragraph (b)(3)(i) of this section.

(B) The discharge is from a long-term care hospital that is described in §412.23(e)(2)(i) and meets the criteria of §412.22(f); and

(C) The discharge is classified under MS–LTC–DRG 539, 540, 602, or 603.

(4) *Temporary exception for certain spinal cord specialty hospitals.* For discharges in cost reporting periods beginning in fiscal years 2018 and 2019, the site neutral payment rate specified under this section does not apply if such discharge is from a long-term care hospital that meets each of the following requirements:

(i) The hospital was a not-for-profit long-term care hospital on June 1, 2014, as determined by cost report data;

(ii) Of the discharges in calendar year 2013 from the long-term care hospital for which payment was made under subpart O, at least 50 percent were classified under MS–LTC–DRGs 28, 29, 52, 57, 551, 573, and 963; and

(iii) The long-term care hospital discharged inpatients (including both individuals entitled to, or enrolled for, benefits under Medicare Part A and individuals not so entitled or enrolled) during fiscal year 2014 who had been admitted from at least 20 of the 50 States determined by the States of residency of such inpatients.

(c) *Site neutral payment rate*—(1) *General.* Subject to the provisions of paragraph (c)(2) of this section, the site neutral payment rate is the lower of—

(i) The inpatient hospital prospective payment system comparable per diem amount determined under §412.529(d)(4), including any applicable outlier payments specified in §412.525(a); or

(ii) 100 percent of the estimated cost of the case determined under the provisions of §412.529(d)(2). The provisions for cost-to-charge ratios at §412.529(f)(4)(i) through (iii) apply to the calculation of the estimated cost of the case under this paragraph.

(iii) For discharges occurring in fiscal years 2018 through 2026, the amount in paragraph (c)(1)(i) of this section is reduced by 4.6 percent.

(2) *Adjustments.* CMS adjusts the payment rate determined under paragraph (c)(1) of this section to account for—

(i) Outlier payments, by applying a reduction factor equal to the estimated proportion of outlier payments under §412.525(a) payable for discharges from a long-term care hospital described in paragraph (a)(1) of this section to total estimated payments under the long-term care hospital prospective payment system to discharges from a long-term care hospital described in paragraph (a)(1) of this section. The adjustment under this paragraph (c)(2)(i) does not include the portion of the blended payment rate described in paragraph (c)(3)(ii) of this section.

(ii) A 3-day or less interruption of a stay and a greater than 3-day interruption of a stay, as provided for in §412.531. For purposes of the application of the provisions of §412.531 to discharges from a long-term care hospital described under paragraph (a)(1) of this section, the long-term care hospital prospective payment system standard Federal payment-related terms, such as ''LTC–DRG payment,'' ''full Federal

LTC–DRG prospective payment,'' and ''Federal prospective payment,'' mean the site neutral payment rate calculated under paragraph (c) of this section.

(iii) The special payment provisions for long-term care hospitals-within-hospitals and satellite facilities of long-term care hospitals specified in § 412.534.

(iv) The special payment provisions for long-term care hospitals and satellite facilities of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite facility of the long-term care hospital, as provided in § 412.536.

(3) *Transition.* For discharges occurring in cost reporting periods beginning on or after October 1, 2015 and on or before September 30, 2019, payment for discharges under paragraph (c)(1) of this section are made using a blended payment rate, which is determined as—

(i) 50 percent of the site neutral payment rate amount for the discharge as determined under paragraph (c)(1) of this section; and

(ii) 50 percent of the standard Federal prospective payment rate amount for the discharge as determined under § 412.523.

(d) *Discharge payment percentage.* (1) For purposes of this section, the discharge payment percentage is a ratio, expressed as a percentage, of Medicare discharges that meet the criteria for exclusion from the site neutral payment rate as described under paragraph (a)(2) of this section to total Medicare discharges paid under this subpart during the cost reporting period.

(2) CMS will inform each long-term care hospital of its discharge payment percentage, as determined under paragraph (d)(1) of this section, for each cost reporting period beginning on or after October 1, 2015.

(3) For cost reporting periods beginning on or after October 1, 2019, if a long-term care hospital's discharge payment percentage for the cost reporting period is not at least 50 percent, discharges in all cost reporting periods beginning after the notification described under paragraph (d)(2) of this section will be paid under the payment adjustment described in paragraph (d)(4) of this section until reinstated under paragraph (d)(5) or (6) of this section.

(4) For cost reporting periods subject to the payment adjustment under paragraph (d)(3) of this section, the payment for all discharges consists of—

(i) An amount equivalent to the hospital inpatient prospective payment system amount as determined under § 412.529(d)(4)(i)(A) and (d)(4)(ii) and (iii); and

(ii) If applicable, an additional payment for high cost outlier cases based on the fixed-loss amount established for the hospital inpatient prospective payment system in effect at the time of the LTCH discharge.

(5) For full reinstatement—

(i) When the discharge payment percentage for a cost reporting period is calculated to be at least 50 percent, any payment adjustment described in paragraph (d)(4) of this section will be discontinued for cost reporting periods beginning on or after the notification described under paragraph (d)(2) of this section.

(ii) A long-term care hospital reinstated under paragraph (d)(5)(i) of this section will be subject to the payment adjustment under paragraph (d)(4) of this section if, after being reinstated, it again meets the criteria in paragraph (d)(3) of this section.

(6) For special probationary reinstatement—

(i) A hospital that would be subject to the payment adjustment under paragraph (d)(4) of this section for a cost reporting period will have application of the payment adjustment delayed for that period if, for the period of at least 5 consecutive months of the 6 months immediately preceding the cost reporting period, the discharge payment percentage is calculated to be at least 50 percent.

(ii) For any cost reporting period to which the payment adjustment under paragraph (d)(4) of this section would have applied but for a delay under paragraph (d)(6)(i) of this section, the payment adjustment under paragraph (d)(4) of this section will be applied to

all discharges in the cost reporting period if the discharge payment percentage for the cost reporting period is not calculated to be at least 50 percent.

[80 FR 49768, Sept. 1, 2015, as amended at 81 FR 23438, Apr. 21, 2016; 81 FR 57269, Aug. 22, 2016; 82 FR 38512, Aug. 14, 2017; 83 FR 41704, Aug. 17, 2018; 84 FR 42614, Aug. 16, 2019]

§ 412.523 Methodology for calculating the Federal prospective payment rates.

(a) *Data used.* To calculate the initial prospective payment rates for inpatient hospital services furnished by long-term care hospitals, CMS uses—

(1) The best Medicare data available; and

(2) A rate of increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient long-term care hospital services.

(b) *Determining the average costs per discharge for FY 2003.* CMS determines the average inpatient operating and capital-related costs per discharge for which payment is made to each inpatient long-term care hospital using the available data under paragraph (a)(1) of this section. The cost per discharge is adjusted to FY 2003 by a rate of increase factor, described in paragraph (a)(2) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year.

(c) *Determining the Federal prospective payment rates*—(1) *General.* The Federal prospective payment rates will be established using a standard payment amount referred to as the standard Federal rate. The standard Federal rate is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors and other adjustments.

(2) *Update the cost per discharge.* CMS applies the increase factor described in paragraph (a)(2) of this section to each hospital's cost per discharge determined under paragraph (b) of this section to compute the cost per discharge for FY 2003. Based on the updated cost per discharge, CMS estimates the payments that would have been made to each hospital for FY 2003 under Part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard Federal rate.* Subject to the provisions of paragraph (c)(4) of this section, the standard Federal rate is computed as follows:

(i) *For FY 2003.* Based on the updated costs per discharge and estimated payments for FY 2003 determined in paragraph (c)(2) of this section, CMS computes a standard Federal rate for FY 2003 that reflects, as appropriate, the adjustments described in paragraph (d) of this section. The FY 2003 standard Federal rate is effective for discharges occurring in cost reporting periods beginning on or after October 1, 2002 through June 30, 2003.

(ii) *For long-term care hospital prospective payment system rate years beginning on or after July 1, 2003 and ending on or before June 30, 2006.* The standard Federal rate for long-term care hospital prospective payment system rate years beginning on or after July 1, 2003 and ending on or before June 30, 2006 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year, updated by the increase factor described in paragraph (a)(2) of this section, and adjusted, as appropriate, as described in paragraph (d) of this section. For the rate year from July 1, 2003 through June 30, 2004, the updated and adjusted standard Federal rate is offset by a budget neutrality factor to account for updating the FY 2003 standard Federal rate on July 1 rather than October 1.

(iii) *For long-term care hospital prospective payment system rate year beginning July 1, 2006 and ending June 30, 2007.* The standard Federal rate for long-term care hospital prospective payment system rate year beginning July 1, 2006 and ending June 30, 2007 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year updated by zero percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(iv) *For long-term care hospital prospective payment system rate year beginning July 1, 2007 and ending June 30, 2008.* (A) The standard Federal rate for long-term care hospital prospective

payment system rate year beginning July 1, 2007 and ending June 30, 2008 is the same as the standard Federal rate for the previous long-term care hospital prospective payment system rate year. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after July 1, 2007 and before April 1, 2008, payments are based on the standard Federal rate in paragraph (c)(3)(iii) of this section updated by 0.71 percent.

(v) *For long-term care hospital prospective payment system rate year beginning July 1, 2008 and ending September 30, 2009.* The standard Federal rate for long-term care hospital prospective payment system rate year beginning July 1, 2008 and ending September 30, 2009 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year updated by 2.7 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(vi) *For long-term care hospital prospective payment system rate year beginning October 1, 2009 and ending September 30, 2010.* (A) The standard Federal rate for long-term care hospital prospective payment system rate year beginning October 1, 2009 and ending September 30, 2010 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year updated by 1.74 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after October 1, 2009 and before April 1, 2010, payments are based on the standard Federal rate in paragraph (c)(3)(v) of this section updated by 2.0 percent.

(vii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2010, and ending September 30, 2011.* The standard Federal rate for the long-term care hospital prospective payment system fiscal year beginning October 1, 2010, and ending September 30, 2011, is the standard Federal rate for the previous long-term care hospital prospective payment system rate year updated by −0.49 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(viii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2011, and ending September 30, 2012.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2011, and ending September 30, 2012, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

(ix) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2012, and ending September 30, 2013.* (A) The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2012, and ending September 30, 2013, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.8 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(B) With respect to discharges occurring on or after October 1, 2012 and before December 29, 2012, payments are based on the standard Federal rate in paragraph (c)(3)(ix)(A) of this section without regard to the adjustment provided for under paragraph (d)(3)(ii) of this section.

(x) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2013, and ending September 30, 2014.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2013, and ending September 30, 2014, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.7 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xi) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2014, and ending September 30, 2015.* The standard Federal rate for the long-term care hospital prospective payment system beginning October 1, 2014, and ending September

30, 2015, is the standard Federal rate for the previous long-term care hospital prospective payment system fiscal year updated by 2.2 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2015, and ending September 30, 2016.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2015, and ending September 30, 2016, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.7 percent, and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xiii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2016, and ending September 30, 2017.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2016, and ending September 30, 2017, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.75 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xiv) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2017, and ending September 30, 2018.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2017, and ending September 30, 2018, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.0 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xv) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2018, and ending September 30, 2019.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2018, and ending September 30, 2019, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.35 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xvi) *For long-term care prospective payment system fiscal year beginning October 1, 2019, and ending September 30, 2020.* The long-term care hospital prospective payment system standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2019 and ending September 30, 2020 is the standard Federal payment rate for the previous long-term care prospective payment system fiscal year updated by 2.5 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

(xvii) *For long-term care prospective payment system fiscal year 2021 and subsequent fiscal years.* The long-term care hospital prospective payment system standard Federal payment rate for a long-term care hospital prospective payment system fiscal year is the standard Federal payment rate for the previous long-term care prospective payment system fiscal year updated by the percentage increase in the market basket index (as determined by CMS) less a multifactor productivity adjustment (as determined by CMS), and further adjusted, as appropriate, as described in paragraph (d) of this section.

(4) *For fiscal year 2014 and subsequent fiscal years—*

(i) In the case of a long-term care hospital that does not submit quality reporting data to CMS in the form and manner and at a time specified by the Secretary, the annual update to the standard Federal rate specified in paragraph (c)(3) of this section is further reduced by 2.0 percentage points.

(ii) Any reduction of the annual update to the standard Federal rate under paragraph (c)(4)(i) of this section will apply only to the fiscal year involved and will not be taken into account in computing the annual update to the standard Federal rate for a subsequent fiscal year.

(5) *Determining the Federal prospective payment rate for each LTC-DRG.* The Federal prospective payment rate for each LTC-DRG is the product of the weighting factors described in §412.515

and the standard Federal rate described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard Federal rate.* The standard Federal rate described in paragraph (c)(3) of this section will be adjusted for—

(1) *Outlier payments.* CMS adjusts the LTCH PPS standard Federal payment rate by a reduction factor of 8 percent, the estimated proportion of outlier payments under § 412.525(a) payable for discharges described in § 412.522(a)(2) (notwithstanding the provisions of § 412.525(a)(2)(ii) for FY 2018 and subsequent years.

(2) *Budget neutrality.* CMS adjusts the Federal prospective payment rates for FY 2003 so that aggregate payments under the prospective payment system are estimated to equal the amount that would have been paid to long-term care hospitals under part 413 of this subchapter without regard to the prospective payment system implemented under this subpart, excluding the effects of section 1886(b)(2)(E) and (b)(3)(J) of the Act.

(3)(i) *General.* The Secretary reviews payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates no earlier than December 29, 2012, so that the effect of any significant difference between the data used in the original computations of budget neutrality for FY 2003 and more recent data to determine budget neutrality for FY 2003 is not perpetuated in the prospective payment rates for future years.

(ii) *Adjustment to the standard Federal rate.* The standard Federal rate determined in paragraph (c)(3) of this section is permanently adjusted by 3.75 percent to account for the estimated difference between projected aggregate payments in FY 2003 made under the prospective payment system implemented under this subpart and the projected aggregate payments that would have been made in FY 2003 under Part 413 of this chapter without regard to the implementation of the prospective payment system implemented under this subpart, excluding the effects of sections 1886(b)(2)(E) and (b)(3)(J) of the Act. This adjustment is transitioned over 3 years beginning in FY 2013.

(iii) *Special rule for certain discharges occurring during FY 2013.* The adjustment applied under paragraph (d)(3)(ii) of this section is not applicable when making payments under this subpart for discharges occurring on or after October 1, 2012, and on or before December 28, 2012.

(4) *Changes to the adjustment for area wage levels.* Beginning in FY 2012, CMS adjusts the standard Federal rate by a factor that accounts for the estimated effect of any adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments.

(5) *Adjustment for changes to the short-stay outlier policy.* The standard Federal rate determined under paragraph (c)(3) of this section is permanently adjusted by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2018 are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the change in the short-stay outlier policy for FY 2018 under § 412.529(c)(4).

(6) *Adjustment for the elimination of the limitation on long-term care hospital admissions from referring hospitals.* The standard Federal payment rate determined in paragraph (c)(3) of this section is adjusted as follows:

(i) For discharges occurring on or after October 1, 2018 and before October 1, 2019, by a one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2019, and the portion of estimated aggregate payments to site neutral cases that are paid based on the LTCH PPS standard Federal rate in FY 2019, are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals. This adjustment only applies to the fiscal year involved and will not be taken into account in computing the standard Federal payment rate for a subsequent fiscal year.

(ii) For discharges occurring on or after October 1, 2019 and before October 1, 2020, by a one-time factor so that estimated aggregate payments to LTCH

PPS standard Federal rate cases in FY 2020, and the portion of estimated aggregate payments to site neutral payment rate cases that are paid based on the LTCH PPS standard Federal rate in FY 2020, are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals. This adjustment only applies to the fiscal year involved and will not be taken into account in computing the standard Federal payment rate for a subsequent fiscal year.

(iii) For discharges occurring on or after October 1, 2020, by a permanent, one-time factor so that estimated aggregate payments to LTCH PPS standard Federal rate cases in FY 2021 are projected to equal estimated aggregate payments that would have been paid for such cases without regard to the elimination of the limitation on long-term care hospital admissions from referring hospitals.

(e) *Calculation of the adjusted Federal prospective payment.* For each discharge, a long-term care hospital's Federal prospective payment is computed on the basis of the Federal prospective payment rate multiplied by the relative weight of the LTC-DRG assigned for that discharge. A hospital's Federal prospective payment rate will be adjusted, as appropriate, to account for outliers and other factors as specified in §412.525.

[67 FR 56049, Aug. 30, 2002]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §412.523, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§412.525 Adjustments to the Federal prospective payment.

(a) *Adjustments for high-cost outliers.* (1) CMS provides for an additional payment to a long-term care hospital if its estimated costs for a patient exceed the applicable long-term care hospital prospective payment system payment plus an applicable fixed-loss amount. For each long-term care hospital prospective payment system payment year, CMS annually establishes a fixed-loss amount that is the maximum loss that a long-term care hospital would incur under the long-term care hospital prospective payment system for a case with unusually high costs before receiving an additional payment.

(2)(i) The fixed loss-amount for discharges from a long-term care hospital described under §412.522(a)(2) is determined for the long-term care hospital prospective payment system payment year, using the LTC–DRG relative weights that are in effect at the start of the applicable long-term care hospital prospective payment system payment year.

(ii) For FY 2018 and subsequent years, the fixed-loss amount for long-term care hospital discharges described under §412.522(a)(2) is determined such that the estimated proportion of outlier payments under paragraph (a) of this section payable for such discharges is projected to be equal to 99.6875 of 8 percent.

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient's care (determined by multiplying the hospital-specific cost-to-charge ratio by the Medicare allowable covered charge) and the sum of the applicable long-term care hospital prospective payment system payment and the applicable fixed-loss amount.

(4)(i) For discharges occurring on or after October 1, 2002 and before August 8, 2003, no reconciliations will be made to outlier payments upon cost report settlement to account for differences between the estimated cost-to-charge ratio and the actual cost-to-charge ratio of the case.

(ii) For discharges occurring on or after August 8, 2003, and before October 1, 2006, high-cost outlier payments are subject to the provisions of §412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(iii) For discharges occurring on or after October 1, 2003, and before October 1, 2006, high-cost outlier payments are subject to the provisions of §412.84(i)(2) for adjustments to cost-to-charge ratios.

(iv) For discharges occurring on or after October 1, 2006, high-cost outlier payments are subject to the following provisions:

(A) CMS may specify an alternative to the cost-to-charge ratio otherwise applicable under paragraph (a)(4)(iv)(B) of this section. A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. A request must be approved by the CMS Regional Office.

(B) The 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 tentatively settled cost report, whichever is from the latest cost reporting period.

(C) The fiscal intermediary may use a statewide average cost-to-charge ratio, which CMS establishes annually, if it is unable to determine an accurate cost-to-charge ratio for a hospital in one of the following circumstances:

(*1*) A new hospital that has not yet submitted its first Medicare cost report. (For this purpose, 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.)

(*2*) A hospital whose cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean cost-to-charge ratio. CMS establishes and publishes this mean annually.

(*3*) Any other hospital for which data to calculate a cost-to-charge ratio are not available.

(D) Any reconciliation of outlier payments is based on the 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 discharge is settled.

(E) At the time of any reconciliation under paragraph (a)(4)(iv)(D) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment is based upon a widely available index to be established in advance by the Secretary, and is applied from the midpoint of the cost reporting period to the date of reconciliation.

(5) For purposes of this paragraph (a)—

(i) *Applicable long-term care hospital prospective payment system payment* means—

(A) The site neutral payment rate established under §412.522(c) for long-term care hospital discharges described under §412.522(a)(1);

(B) The standard Federal prospective payment rates established under §412.523 for long-term care hospital discharges described under §412.522(a)(2); or

(C) The standard Federal prospective payment rates established under §412.523 for discharges occurring on or after October 1, 2015, in a long-term care hospital cost reporting period that begins before October 1, 2015.

(ii) *Applicable fixed-loss amount* means—

(A) For long-term care hospital discharges described under §412.522(a)(1), the fixed-loss amount established for such cases as provided at §412.522(c)(2)(i);

(B) For long-term care hospital discharges described under §412.522(a)(2), the fixed-loss amount established for such cases as provided at §412.523(e); or

(C) For discharges occurring on or after October 1, 2015 in a long-term care hospital cost reporting period that begins before October 1, 2015, the fixed-loss amount payable to discharges described under §412.522(a)(2) as set forth in paragraph (a)(5)(ii)(B) of this section.

(b) *Adjustments for Alaska and Hawaii.* CMS adjusts the Federal prospective payment for the effects of a higher cost of living for hospitals located in Alaska and Hawaii.

(c) *Adjustments for area wage levels.* (1) The labor portion of a long-term care hospital's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index (established by CMS), which reflects the relative level of hospital wages and wage-related costs in the geographic area (that is, urban or rural area as determined in accordance with the definitions set forth in §412.503) of the hospital compared to the national average level of hospital wages and wage-related costs.

(i)(A) The appropriate wage index that is established by CMS is updated annually.

(B) Beginning in fiscal year 2023, if CMS determines that an LTCH's wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(ii) The labor portion of a long-term care hospital's Federal prospective payment is established by CMS and is updated annually.

(2) Beginning in FY 2012, any adjustments or updates to the area wage level adjustment under this paragraph (c) will be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are not affected.

(d) *Special payment provisions.* CMS adjusts the Federal prospective payment to account for—

(1) Short-stay outliers, as provided for in §412.529.

(2) A 3-day or less interruption of a stay and a greater than 3-day interruption of a stay, as provided for in §412.531.

(3) [Reserved]

(4) Long-term care hospitals-within-hospitals and satellites of long-term care hospitals as provided in §412.534.

(5) Long-term care hospitals and satellites of long-term care hospitals that discharged Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital, as provided in §412.536.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34163, June 6, 2003; 68 FR 34515, June 9, 2003; 69 FR 25721, May 7, 2004; 70 FR 24222, May 6, 2005; 71 FR 48140, Aug. 18, 2006; 73 FR 26839, May 9, 2008; 74 FR 43998, Aug. 27, 2009; 75 FR 50416, Aug. 16, 2010; 76 FR 51783, Aug. 18, 2011; 79 FR 50356, Aug. 22, 2014; 80 FR 49769, Aug. 17, 2015; 81 FR 57269, Aug. 22, 2016; 82 FR 38513, Aug. 14, 2017; 83 FR 41705, Aug. 17, 2018; 87 FR 49405, Aug. 10, 2022]

§412.526 Payment provisions for a "subclause (II)" long-term care hospital.

(a) *Definition.* A ''subclause (II)'' long-term care hospital is a hospital that qualifies as an LTCH under section 1886(d)(1)(B)(iv)(II) of the Act.

(b) *Method of payment.* (1) For cost reporting periods beginning on or after October 1, 2003 and before September 30, 2014, payment to a ''subclause (II)'' long-term care hospital is made under the prospective payment system specified in §412.1(a)(4) and Subpart O of this part.

(2) For cost reporting periods beginning on or after October 1, 2014, payment to a ''subclause (II)'' long-term care hospital is made under the prospective payment system specified in §412.1(a)(4) and under Subpart O of this part, as adjusted. The adjusted payment amount is determined based on reasonable cost, as described at §412.526(c).

(c) *Determining the adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules.* Medicare inpatient operating costs are paid based on reasonable cost, subject to a ceiling. The ceiling is the aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that the program will recognize for payment purposes, as determined under paragraph (c)(1) of this section.

(1) *Ceiling.* For each cost reporting period, the ceiling is determined by multiplying the updated target amount, as defined in paragraph (c)(2) of this section, for that period by the number of Medicare discharges paid under this subpart during that period.

(2) *Target amounts.* (i) For cost reporting periods beginning during Federal fiscal year 2015, the target amount equals the hospital's target amount determined under §413.40(c)(4) for its cost reporting period beginning during Federal fiscal year 2000, updated by the applicable annual rate-of-increase percentages specified in §413.40(c)(3) to the subject period.

(ii) For subsequent cost reporting periods, the target amount equals the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in §413.40(c)(3) for the subject cost reporting period.

(3) *Payment for inpatient operating costs.* For cost reporting periods subject to this section, the hospital's Medicare allowable net inpatient operating costs

for that period (as defined at §413.40(a)(3)) are paid on a reasonable cost basis, subject to that hospital's ceiling (as determined under paragraph (c)(1) of this section) for that period.

(4) *Payment for inpatient capital-related costs.* Medicare allowable net inpatient capital costs are paid on a reasonable cost basis, in accordance with the regulations under Part 413 of this chapter.

(5) *Adjustments for extraordinary circumstances*—(i) *General rules.* (A) CMS may adjust the ceiling determined under paragraph (c)(1) of this section for one or more cost reporting periods when unusual inpatient operating costs have resulted in the hospital exceeding its ceiling imposed under this section due to extraordinary circumstances beyond the hospital's control. These circumstances include, but are not limited to, strikes, fire, earthquakes, floods, or similar unusual occurrences with substantial cost effects.

(B) When the hospital requests an adjustment, CMS makes an adjustment only to the extent that the hospital's operating costs are reasonable, attributable to the circumstances specified separately, identified by the hospital, and verified by the Medicare administrative contractor.

(ii) *Process for adjustment requests.* The provisions of §§413.40(e)(1) through (e)(5) of this subchapter are applicable to extraordinary circumstances adjustment requests under this section.

[79 FR 50356, Aug. 22, 2014]

§412.529 Special payment provision for short-stay outliers.

(a) *Short-stay outlier defined.* ''Short-stay outlier'' means a discharge with a covered length of stay in a long-term care hospital that is up to and including five-sixths of the geometric average length of stay for each LTC–DRG.

(b) *Adjustment to payment.* CMS adjusts the hospital's Federal prospective payment to account for any case that is determined to be a short-stay outlier, as defined in paragraph (a) of this section, under the methodology specified in paragraph (c) of this section.

(c) *Method for determining the payment amount*—(1) *Discharges occurring before July 1, 2006.* For discharges from long-term care hospitals described under §412.23(e)(2)(i), occurring before July 1, 2006, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is the least of the following amounts:

(i) One hundred and twenty (120) percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section.

(ii) One hundred and twenty (120) percent of the estimated cost of the case determined under paragraph (d)(2) of this section.

(iii) The Federal prospective payment for the LTC–DRG determined under paragraph (d)(3) of this section.

(2) *Discharges occurring on or after July 1, 2006 and before July 1, 2007 and discharges occurring on or after December 29, 2007 and before December 29, 2012.* For discharges from long-term care hospitals described under §412.23(e)(2)(i) occurring on or after July 1, 2006 and before July 1, 2007 and discharges occurring on or after December 29, 2007 and before December 29, 2012, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is the least of the following amounts:

(i) One hundred and twenty (120) percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section.

(ii) One hundred (100) percent of the estimated cost of the case determined under paragraph (d)(2) of this section.

(iii) The Federal prospective payment for the LTC–DRG as determined under paragraph (d)(3) of this section.

(iv) An amount payable under subpart O computed as a blend of an amount comparable to the hospital inpatient prospective payment system per diem amount determined under paragraph (d)(4)(i) of this section and the 120 percent of the LTC–DRG specific per diem payment amount determined under paragraph (d)(1) of this section.

(A) The blend percentage applicable to the 120 percent of the LTC–DRG specific per diem payment amount determined under paragraph (d)(1) of this section is determined by dividing the covered length-of-stay of the case by the lesser of five-sixths of the geometric average length of stay of the

LTC–DRG or 25 days, not to exceed 100 percent.

(B) The blend percentage of the amount determined under paragraph (d)(4)(i) of this section is determined by subtracting the percentage determined in paragraph (A) from 100 percent.

(3) *Discharges occurring on or after July 1, 2007 and before December 29, 2007 and discharges occurring on or after December 29, 2012 and on or before September 30, 2017.* For discharges from long-term care hospitals described under §412.23(e)(2)(i) occurring on or after July 1, 2007, and on or before December 29, 2007 and discharges occurring on or after December 29, 2012, and on or before September 30, 2017, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is adjusted by either of the following:

(i) If the covered length of stay of the case assigned to a particular LTC–DRG is less than or equal to one standard deviation from the geometric ALOS of the same DRG under the inpatient prospective payment system (the IPPS-comparable threshold), the LTCH prospective payment system adjusted payment amount for such a case is the least of the following amounts:

(A) One hundred and twenty (120) percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section.

(B) One hundred (100) percent of the estimated cost of the case determined under paragraph (d)(2) of this section.

(C) The Federal prospective payment for the LTC–DRG as determined under paragraph (d)(3) of this section.

(D) An amount payable under subpart O of this part comparable to the hospital inpatient prospective payment system per diem amount determined under paragraph (d)(4) of this section.

(ii) If the covered length of stay of the case assigned to a particular LTC–DRG is greater than one standard deviation from the geometric ALOS of the same DRG under the inpatient prospective payment system (the IPPS-comparable threshold), the LTCH prospective payment system adjusted payment amount for such a case is determined under paragraph (c)(2) of this section.

(4) *Discharges occurring on or after October 1, 2017.* For discharges occurring on or after October 1, 2017, short-stay outlier payments are determined according to paragraph (c)(2)(iv) of this section.

(d) *Calculation of alternative payment amounts*—(1) *Determining the LTC–DRG per diem amount.* CMS calculates the LTC–DRG per diem amount for short-stay outliers for each LTC–DRG by dividing the product of the standard Federal payment rate and the LTC–DRG relative weight by the geometric average length of stay of the specific LTC–DRG multiplied by the covered days of the stay.

(2) *Determining the estimated cost of a case.* To determine the estimated cost of a case, CMS multiplies the hospital-specific cost-to-charge ratio by the Medicare allowable charges for the case.

(3) *Determining the Federal prospective payment for the LTC–DRG.* CMS calculates the Federal prospective payment for the LTC–DRG by multiplying the adjusted standard Federal payment rate by the LTC–DRG relative weight.

(4) *Determining the amount comparable to the hospital inpatient prospective payment system per diem amount*—(i) *General.* Under subpart O, CMS calculates—

(A) An amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system based on the sum of the applicable operating inpatient prospective payment system standardized amount and the capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge.

(B) An amount comparable to the hospital inpatient prospective payment system per diem amount for each DRG that is determined by dividing the amount that would otherwise be paid under the hospital inpatient prospective payment system computed under paragraph (A) of this section by the hospital inpatient prospective payment system geometric average length of stay of the specific DRG multiplied by the covered days of the stay.

(C) The payment amount specified under paragraph (d)(4)(i)(B) of this section may not exceed the full amount comparable to what would otherwise be paid under the hospital inpatient prospective payment system determined

under paragraph (d)(4)(i)(A) of this section.

(ii) *Hospital inpatient prospective payment system operating standardized amount.* The hospital inpatient prospective payment system operating standardized amount—

(A) Is adjusted for the applicable hospital inpatient prospective payment system DRG weighting factors.

(B)(*1*) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.503 and the applicable hospital inpatient prospective payment system (IPPS) labor-related share, using the applicable hospital inpatient prospective payment system wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index).

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(*3*) For LTCHs located in Alaska and Hawaii, the amount specified in paragraph (d)(4)(ii) of this section is also adjusted by the applicable hospital inpatient prospective payment system cost of living adjustment factors.

(C) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(iii) *Hospital inpatient prospective payment system capital Federal rate.* The hospital inpatient prospective payment system capital Federal rate—

(A) Is adjusted for the applicable inpatient prospective payment system DRG weighting factors.

(B)(*1*) Is adjusted for the applicable geographic adjustment factors, including local cost variation based on the geographic classifications set forth at § 412.503 and the applicable full hospital inpatient prospective payment system (IPPS) wage index value for nonreclassified hospitals (an LTCH's applicable IPPS wage index) and applicable cost of living adjustment factors for LTCHs in Alaska and Hawaii.

(*2*) Beginning in fiscal year 2023, if CMS determines that an LTCH's applicable IPPS wage index value for a fiscal year would decrease by more than 5 percent as compared to the LTCH's applicable IPPS wage index value for the prior fiscal year, CMS limits the decrease to 5 percent for the fiscal year.

(C) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(e) Short-stay outlier payments to long-term care hospitals described under § 412.23(e)(2)(ii).

(1) For discharges occurring on or after October 1, 2002, through June 30, 2003, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is the least of the following amounts:

(i) 120 percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section;

(ii) 120 percent of the estimated cost of the case determined under paragraph (d)(2) of this section; or

(iii) The Federal prospective payment for the LTC–DRG determined under paragraph (d)(3) of this section.

(2) For discharges occurring on or after July 1, 2003, subject to the provisions of paragraph (e)(2)(v) of this section, the adjusted payment amount for a short-stay outlier is determined under the formulas set forth in paragraphs (e)(1)(i) through (iv) of this section with the following substitutions:

(i) For the first year of the transition period, as specified at § 412.533(a)(1), the 120 percent specified for the LTC–DRG specific per diem amount and the 120 percent of the cost of the case in the formula under paragraphs (e)(1)(i) and (e)(1)(ii) of this section are substituted with 195 percent.

(ii) For the second year of the transition period, as specified at § 412.533(a)(2), the 120 percent specified for the LTC–DRG specific per diem amount and the 120 percent of the cost of the case in the formula under paragraphs (e)(1)(i) and (e)(1)(ii) of this section are substituted with 193 percent.

(iii) For the third year of the transition period, as specified at § 412.533(a)(3), the 120 percent specified for the LTC–DRG specific per diem amount and the 120 percent of the cost

of the case in the formula under paragraphs (e)(1)(i) and (e)(1)(ii) of this section are substituted with 165 percent.

(iv) For the fourth year of the transition period, as specified at §412.533(a)(4), the 120 percent specified for the LTC–DRG specific per diem amount and 120 percent of the cost of the case in the formula under paragraphs (e)(1)(i) and (e)(1)(ii) of this section are substituted with 136 percent.

(v) For discharges occurring in cost reporting periods beginning on or after October 1, 2006 (beginning with the fifth year of the transition period), as specified at §412.533(a)(5), short-stay outlier payments are made based on the least of the following amounts:

(A) 120 percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section;

(B) 120 percent of the estimated cost of the case determined under paragraph (d)(2) of this section; or

(C) The Federal prospective payment for the LTC–DRG determined under paragraph (d)(3) of this section.

(f) *Reconciliation of short-stay payments.* Payments for discharges occurring before October 1, 2017 are reconciled in accordance with one of the following:

(1) *Discharges occurring on or after October 1, 2002, and before August 8, 2003.* For discharges occurring on or after October 1, 2002, and before August 8, 2003, no reconciliations are made to short-stay outlier payments upon cost report settlement to account for differences between cost-to-charge ratio and the actual cost-to-charge ratio of the case.

(2) *Discharges occurring on or after August 8, 2003, and before October 1, 2006.* For discharges occurring on or after August 8, 2003, and before October 1, 2006, short-stay outlier payments are subject to the provisions of §412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(3) *Discharges occurring on or after October 1, 2003, and before October 1, 2006.* For discharges occurring on or after October 1, 2003, and before October 1, 2006, short-stay outlier payments are subject to the provisions of §412.84(i)(2) for adjustments to cost-to-charge ratios.

(4) *Discharges occurring on or after October 1, 2006.* For discharges occurring on or after October 1, 2006, short-stay outlier payments are subject to the following provisions:

(i) CMS may specify an alternative to the cost-to-charge ratio otherwise applicable under paragraph (f)(4)(ii) of this section. A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. This request must be approved by the appropriate CMS Regional Office.

(ii) The 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 tentatively settled cost report, whichever is from the latest cost reporting period.

(iii) The fiscal intermediary may use a statewide average cost-to-charge ratio, which CMS establishes annually, if it is unable to determine an accurate 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 this purpose, 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 cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. CMS establishes and publishes this mean annually.

(C) Any other hospital for which data to calculate a cost-to-charge ratio are not available.

(iv) Any reconciliation of outlier payments is based on the 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 discharge is settled.

(v) At the time of any reconciliation under paragraph (f)(4)(iv) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment is based upon a widely available index to be established in advance by the Secretary, and is applied

from the midpoint of the cost reporting period to the date of reconciliation.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 34163, June 6, 2003; 68 FR 34515, June 9, 2003; 71 FR 27899, May 12, 2006; 71 FR 48141, Aug. 18, 2006; 72 FR 26991, May 11, 2007; 73 FR 24880, May 6, 2008; 73 FR 26839, May 9, 2008; 75 FR 50416, Aug. 16, 2010; 77 FR 53679, Aug. 31, 2012; 82 FR 38513, Aug. 14, 2017; 87 FR 49405, Aug. 10, 2022]

§ 412.531 Special payment provisions when an interruption of a stay occurs in a long-term care hospital.

(a) *Definitions*—(1) *A 3-day or less interruption of stay defined.* ''A 3-day or less interruption of stay'' means a stay at a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, IRF, SNF, or the patient's home and readmitted to the same long-term care hospital within 3 days of the discharge from the long-term care hospital. The 3-day or less period begins with the date of discharge from the long-term care hospital and ends not later than midnight of the third day.

(2) *A greater than 3-day interruption of stay defined.* ''A greater than 3-day or less interruption of stay'' means A stay in a long-term care hospital during which a Medicare inpatient is discharged from the long-term care hospital to an acute care hospital, an IRF, or a SNF for a period of greater than 3 days but within the applicable fixed-day period specified in paragraphs (a)(2)(i) through (a)(2)(iii) of this section before being readmitted to the same long-term care hospital.

(i) For a discharge to an acute care hospital, the applicable fixed day period is between 4 and 9 consecutive days. The counting of the days begins on the date of discharge from the long-term care hospital and ends on the 9th date after the discharge.

(ii) For a discharge to an IRF, the applicable fixed day period is between 4 and 27 consecutive days. The counting of the days begins on the day of discharge from the long-term care hospital and ends on the 27th day after discharge.

(iii) For a discharge to a SNF, the applicable fixed day period is between 4 and 45 consecutive days. The counting of the days begins on the day of discharge from the long-term care hospital and ends on the 45th day after the discharge.

(b) *Methods of determining payments.* (1) For purposes of determining a Federal prospective payment—

(i) *Determining the length of stay.* In determining the length of stay of a patient at a long-term care hospital for payment purposes under this paragraph (b)—

(A) Except as specified in paragraphs (b)(1)(i)(B) and (b)(1)(i)(C) of this section, the number of days that a beneficiary spends away from the long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section is not included in determining the length of stay of the patient at the long-term care hospital when there is no outpatient or inpatient medical treatment or care provided at an acute care hospital or an IRF, or SNF services during the interruption that is considered a covered service delivered to the beneficiary.

(B) The number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section are counted in determining the length of stay of the patient at the long-term care hospital if the beneficiary receives inpatient or outpatient medical care or treatment provided by an acute care hospital or IRF, or SNF services during the interruption. In the case where these services are provided during some, but not all days of a 3-day or less interruption, Medicare will include all days of the interruption in the long-term care hospitals day-count.

(C) Surgical DRG exception to the 3-day or less interruption of stay policy.

(*1*) The number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the beneficiary receives a procedure grouped to a surgical DRG under the hospital inpatient prospective payment system in an acute care hospital during the 2005 and 2006 LTCH prospective payment system rate years are not included in determining the length of stay of the patient at the long-term care hospital.

(*2*) For discharges occurring on or after July 1 2006, the number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the beneficiary receives a procedure grouped to a surgical DRG under the hospital inpatient prospective payment system in an acute care hospital are included in determining the length of stay of the patient at the long-term care hospital.

(D) The number of days that a beneficiary spends away from a LTCH during a greater than 3-day interruption of stay, as defined in paragraph (a)(2) of this section, is not included in determining the length of stay at the LTCH.

(ii) *Determining how payment is made.* (A) Subject to the provisions of paragraphs (b)(1)(ii)(A)(*1*) and (b)(1)(ii)(A)(*2*) of this section, for a 3-day or less interruption of stay under paragraph (a)(1) of this section, the entire stay is paid as a single discharge from the long-term care hospital. CMS makes only one LTC-DRG payment for all portions of a long-term care stay.

(*1*) For a 3-day or less interruption of stay under paragraph (a)(1) of this section in which a long-term care hospital discharges a patient to an acute care hospital and the patient's treatment during the interruption is grouped into a surgical DRG under the acute care inpatient hospital prospective payment system, for the LTCH 2005 and 2006 rate years, CMS also makes a separate payment to the acute care hospital for the surgical DRG discharge in accordance with paragraph (b)(1)(i)(C) of this section.

(*2*) For discharges occurring on or after July 1, 2006, for a 3-day or less interruption of stay under paragraph (a)(1) of this section in which a long-term care hospital discharges a patient to an acute care hospital and the patient's treatment during the interruption is grouped into a surgical DRG under the acute care hospital inpatient prospective payment system, the services must be provided under arrangements in accordance with §412.509(c). CMS does not make a separate payment to the acute care hospital for the surgical treatment. The LTC–DRG payment made to the long-term care hospital is considered payment in full as specified in §412.521(b).

(*3*) For a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the patient receives inpatient or outpatient treatment or services at an acute care hospital or IRF, or SNF services, that are not otherwise excluded under §412.509(a), the services must be provided under arrangements in accordance with §412.509(c). CMS does not make a separate payment to the acute care hospital, IRF, or SNF for these services. The LTC-DRG payment made to the long-term care hospital is considered payment in full as specified in §412.521(b).

(B) For a greater than 3-day interruption of stay under paragraph (a)(2) of this section, CMS will make only one LTC-DRG payment for all portions of a long-term care stay. CMS also separately pays the acute care hospital, the IRF, or the SNF in accordance with their respective payment systems, as specified in paragraph (c) of this section.

(iii) *Basis for the prospective payment.* Payment to the long-term care hospital is based on the patient's LTC-DRG that is determined in accordance with §412.513(b).

(2) If the total number of days of a patient's length of stay in a long-term care hospital prior to and following a 3-day or less interruption of stay under paragraphs (b)(1)(i)(A), (B), or (C) of this section or a greater than 3-day interruption of stay under paragraph (b)(1)(i)(D) of this section is up to and including five-sixths of the geometric average length of stay of the LTC-DRG, CMS will make a Federal prospective payment for a short-stay outlier in accordance with §412.529(c).

(3) If the total number of days of a patient's length of stay in a long-term care hospital prior to and following a 3-day or less interruption of stay under paragraphs (b)(1)(i)(A), (B), or (C) of this section or a greater than 3-day interruption of stay under paragraph (b)(1)(i)(D) of this section exceeds five-sixths of the geometric average length of stay for the LTC-DRG, CMS will

make one full Federal LTC-DRG prospective payment for the case. An additional payment will be made if the patient's stay qualifies as a high-cost outlier, as set forth in § 412.525(a).

(4) Notwithstanding the provisions of paragraph (a) of this section, if a patient who has been discharged from a long-term care hospital to another facility and is readmitted to the long-term care hospital for additional treatment or services in the long-term care hospital following the stay at the other facility, the subsequent admission to the long-term care hospital is considered a new stay, even if the case is determined to fall into the same LTC-DRG, and the long-term care hospital will receive two separate Federal prospective payments if one of the following conditions are met:

(i) The patient has a length of stay in the acute care hospital that exceeds 9 days from the day of discharge from the long-term care hospital;

(ii) The patient has a length of stay in the IRF that exceeds 27 days from the day of discharge from the long-term care hospital; or

(iii) The patient has a length of stay in the SNF that exceeds 45 days from the day of discharge from the long-term care hospital.

(c) *Payments to an acute care hospital, an IRF, or a SNF during an interruption of a stay.* (1) Payment to the acute care hospital for the acute care hospital stay following discharge from the long-term care hospital will be paid in accordance with the acute care hospital inpatient prospective payment systems specified in § 412.1(a)(1).

(2) Payment to an IRF for the IRF stay following a discharge from the long-term care hospital will be paid in accordance with the IRF prospective payment system specified in § 412.624 of subpart P of this part.

(3) Payment to a SNF for the SNF stay following a discharge from the long-term care hospital will be paid in accordance with the SNF prospective payment system specified in subpart J of part 413 of this subchapter.

[67 FR 56049, Aug. 30, 2002, as amended at 69 FR 25721, May 7, 2004; 70 FR 24222, May 6, 2005; 71 FR 27900, May 12, 2006]

§ 412.533 Transition payments.

(a) *Duration of transition periods.* Except for a long-term care hospital that makes an election under paragraph (c) of this section or for a long-term care hospital that is defined as new under § 412.23(e)(4), for cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, a long-term care hospital receives a payment comprised of a blend of the adjusted Federal prospective payment as determined under § 412.523, and the payment determined under the cost-based reimbursement rules under Part 413 of this subchapter.

(1) For cost reporting periods beginning on or after October 1, 2002 and before October 1, 2003, payment is based on 20 percent of the Federal prospective payment rate and 80 percent of the cost-based reimbursement rate.

(2) For cost reporting periods beginning on or after October 1, 2003 and before October 1, 2004, payment is based on 40 percent of the Federal prospective payment rate and 60 percent of the cost-based reimbursement rate.

(3) For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005, payment is based on 60 percent of the Federal prospective payment rate and 40 percent of the cost-based reimbursement rate.

(4) For cost reporting periods beginning on or after October 1, 2005 and before October 1, 2006, payment is based on 80 percent of the Federal prospective payment rate and 20 percent of the cost-based reimbursement rate.

(5) For cost reporting periods beginning on or after October 1, 2006, payment is based entirely on the adjusted Federal prospective payment rate.

(b) *Adjustments based on reconciliation of cost reports.* The cost-based percentage of the provider's total Medicare payment under paragraphs (a)(1) through (a)(4) of this section are subject to adjustments based on reconciliation of cost reports.

(c) *Election not to be paid under the transition period methodology.* A long-term care hospital may elect to be paid based on 100 percent of the Federal prospective rate at the start of any of its cost reporting periods during the 5-year transition periods specified in paragraph (a) of this section. Once a

long-term care hospital elects to be paid based on 100 percent of the Federal prospective payment rate, it may not revert to the transition blend.

(1) *General requirement.* A long-term care hospital must notify its fiscal intermediary of its intent to elect to be paid based on 100 percent of the Federal prospective rate at the start of any of its cost reporting periods during the 5-year transition period specified in paragraph (a) of this section.

(2) *Notification requirement to make election.* (i) The request by the long-term care hospital to make the election under paragraph (c)(1) of this section must be made in writing to the Medicare fiscal intermediary.

(ii) For cost reporting periods that begin on or after October 1, 2002 through November 30, 2002, the fiscal intermediary must receive the notification of the election before November 1, 2002.

(iii) For cost reporting periods that begin on or after December 1, 2002 through September 30, 2006, the fiscal intermediary must receive the notification of the election on or before the 30th day before the applicable cost reporting period begins.

(iv) The fiscal intermediary must receive the notification by the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section will not be accepted. If the date specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section falls on a day that the postal service or other delivery sources are not open for business, the long-term care hospital is responsible for allowing sufficient time for the delivery of the notification before the deadline.

(v) If a long-term care hospital's notification is not received by the dates specified in paragraphs (c)(2)(ii) and (c)(2)(iii) of this section, payment will be based on the transition period rates specified in paragraphs (a)(1) through (a)(5) of this section.

(d) *Payments to new long-term care hospitals.* A new long-term care hospital, as defined in §412.23(e)(4), will be paid based on 100 percent of the standard Federal rate, as described in §412.523, with no transition payments, as described in §412.533(a)(1) through (a)(5).

§412.534 Special payment provisions for long-term care hospitals-within-hospitals and satellites of long-term care hospitals, effective for discharges occurring in cost reporting periods beginning on or before September 30, 2016.

(a) *Scope.* Except as provided in paragraph (h), the policies set forth in this section apply to discharges occurring in cost reporting periods beginning on or after October 1, 2004 from long-term care hospitals as described in §412.23(e)(2)(i) meeting the criteria in §412.22(e)(2), or satellite facilities of long-term care hospitals that meet the criteria in §412.22(h).

(b) *Patients admitted from hospitals not located in the same building or on the same campus as the long-term care hospital or long-term care hospital satellite—* (1) *For cost reporting periods beginning on or after October 1, 2004 and before July 1, 2007.* Payments to the long-term care hospital as described in §412.23(e)(2)(i) meeting the criteria in §412.22(e)(2) for patients admitted to the long-term care hospital or to a long-term care hospital satellite facility as described in §412.23(e)(2)(i) that meets the criteria of §412.22(h) from another hospital that is not the co-located hospital are made under the rules in this subpart with no adjustment under this section.

(2) *For cost reporting periods beginning on or after July 1, 2007.* For cost reporting periods beginning on or after July 1, 2007, payments to one of the following long-term care hospitals or long-term care hospital satellites are subject to the provisions of §412.536 of this subpart:

(i) A long-term care hospital as described in §412.23(e)(2)(i) of this part that meets the criteria of §412.22(e) of this part.

(ii) Except as provided in paragraph (h) of this section, a long-term care hospital as described in §412.23(e)(2)(i) of this part that meets the criteria of §412.22(f) of this part.

(iii) A long-term care hospital satellite facility as described in §412.23(e)(2)(i) of this part that meets

the criteria in § 412.22(h) or § 412.22(h)(3)(i) of this part.

(c) *Patients admitted from the hospital located in the same building or on the same campus as the long-term care hospital or satellite facility.* Except for a long-term care hospital or a long-term care hospital satellite facility that meets the requirements of paragraphs (d) or (e) of this section, payments to the long-term care hospital for patients admitted to it or to its long-term care hospital satellite facility from the co-located hospital are made under either of the following:

(1) *For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2007 and for cost reporting periods beginning on or after October 1, 2016.* (i) Except as provided in paragraphs (c)(3), (g), and (h) of this section, for any cost reporting period beginning on or after October 1, 2004 and before October 1, 2007, and for cost reporting periods beginning on or after October 1, 2016 in which the long-term care hospital or its satellite facility has a discharged Medicare inpatient population of whom no more than 25 percent were admitted to the hospital or its satellite facility from the co-located hospital, payments are made under the rules at §§ 412.500 through 412.541 with no adjustment under this section.

(ii) Except as provided in paragraph (g) or (h) of this section, for any cost reporting period beginning on or after October 1, 2004 and before October 1, 2007 and for cost reporting periods beginning on or after October 1, 2013 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than 25 percent were admitted to the hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 25 percent threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that would be determined under the rules at § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at §§ 412.500 through 412.541 with no adjustment under this section.

(iii) In determining the percentage of patients admitted to the long-term care hospital or its satellite from the co-located hospital under paragraphs (c)(1)(i) and (c)(1)(ii) of this section, patients on whose behalf an outlier payment was made to the co-located hospital are not counted towards the 25 percent threshold.

(2) *For cost reporting periods beginning on or after October 1, 2007 and before October 1, 2016.* (i) Except for a long-term care hospital or a long-term care hospital satellite facility subject to paragraph (g) or (h) of this section, payments are determined using the methodology specified in paragraph (c)(1) of this section.

(ii) Payments for a long-term care hospital or long-term care hospital satellite facility subject to paragraph (g) of this section are determined using the methodology specified in paragraph (c)(1) of this section except that 25 percent is substituted with 50 percent.

(3) For a long-term care hospital satellite facility described in § 412.22(h)(3)(i), for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payments will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 50 percent.

(d) *Special treatment of rural hospitals*—(1) *For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2007 and for cost reporting periods beginning on or after October 1, 2016.* (i) Subject to paragraphs (g) and (h) of this section, in the case of a long-term care hospital or satellite facility that is located in a rural area as defined in § 412.503 and is co-located with another hospital for any cost reporting period beginning on or after October 1, 2004 and before October 1, 2007 and for any cost reporting period beginning on or after October 1, 2016 in which the long-term care hospital or long-term care satellite facility has a discharged Medicare inpatient population of whom more than 50 percent were admitted to

the long-term care hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 50 percent threshold for discharged patients who were admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that were otherwise payable under §412.1(a). Payments for the remainder of the long-term care hospital's or long-term care hospital satellite facility's patients are made under the rules in this subpart at §§412.500 through 412.541 with no adjustment under this section.

(ii) In determining the percentage of patients admitted from the co-located hospital under paragraph (d)(1)(i) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the 50 percent threshold.

(2) *For cost reporting periods beginning on or after October 1, 2007, and before October 1, 2016.* (i) Except for a long-term care hospital or a long-term care hospital satellite facility subject to paragraph (g) or (h) of this section, payments are determined using the methodology specified in paragraph (d)(1) of this section.

(ii) Payments for long-term care hospitals and long-term care hospital satellite facilities subject to paragraph (g) of this section are determined using the methodology specified in paragraph (d)(1) of this section except that 50 percent is substituted with 75 percent.

(3) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payment for a long-term care hospital satellite facility described in §412.22(h)(3)(i) will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(e) *Special treatment of urban single or MSA-dominant hospitals*—(1) *For cost reporting periods beginning on or after October 1, 2004 and before October 1, 2007 and for cost reporting periods beginning on or after October 1, 2016.* (i) Subject to paragraphs (g) and (h) of this section, in the case of a long-term care hospital or a long-term care hospital satellite facility that is co-located with the only other hospital in the MSA or with a MSA-dominant hospital as defined in paragraph (e)(1)(iv) of this section, for any cost reporting period beginning on or after October 1, 2004, and before October 1, 2007 and for any cost reporting periods beginning on or after October 1, 2016, in which the long-term care hospital or long-term care hospital satellite facility has a discharged Medicare inpatient population of whom more than the percentage calculated under paragraph (e)(1)(ii) of this section were admitted to the hospital from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital to exceed the applicable threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that otherwise would be determined under §412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart with no adjustment under this section.

(ii) For purposes of paragraph (e)(1)(i) of this section, the percentage used is the percentage of total Medicare discharges in the Metropolitan Statistical Area in which the hospital is located that are from the co-located hospital for the cost reporting period for which the adjustment was made, but in no case is less than 25 percent or more than 50 percent.

(iii) In determining the percentage of patients admitted from the co-located hospital under paragraph (e)(1)(i) of this section, patients on whose behalf outlier payment was made at the co-located hospital are not counted toward the applicable threshold.

(iv) For purposes of this paragraph, an ''MSA-dominant hospital'' is a hospital that has discharged more than 25 percent of the total hospital Medicare

discharges in the MSA in which the hospital is located.

(2) *For cost reporting periods beginning on or after October 1, 2007 and before October 1, 2016.* (i) Except for a long-term care hospital or a long-term care hospital satellite facility subject to paragraph (g) or (h) of this section, payments are determined using the methodology specified in paragraph (e)(1) of this section.

(ii) Payments for a long-term care hospital or long-term care hospital satellite facilities subject to paragraph (g) of this section are determined using the methodology specified in paragraph (e)(1) of this section except that the percentage of Medicare discharges that may be admitted from the co-located hospital without being subject to the payment adjustment at paragraph (e)(1) of this section is 75 percent.

(3) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, payments for a long-term care hospital satellite facility described in § 412.22(h)(3)(i) will be determined using the methodology specified in paragraph (c)(1) of this section, except that the applicable percentage threshold for Medicare discharges is 75 percent.

(f) *Calculation of rates*—(1) *Calculation of LTCH prospective payment system amount.* CMS calculates an amount payable under subpart O equivalent to an amount that would otherwise be paid under the hospital inpatient prospective payment system based on the sum of the applicable hospital inpatient prospective payment system operating standardized amount and capital Federal rate in effect at the time of the LTCH discharge.

(2) *Operating inpatient prospective payment system standardized amount.* The hospital inpatient prospective payment system operating standardized amount—

(i) Is adjusted for the applicable hospital inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.503 and the applicable hospital inpatient prospective payment system labor-related share, using the applicable hospital inpatient prospective payment system wage index value for non-reclassified hospitals. For LTCHs located in Alaska and Hawaii, this amount is also adjusted by the applicable hospital inpatient prospective payment system cost of living adjustment factors;

(iii) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(3) *Hospital inpatient prospective payment system capital Federal rate.* The hospital inpatient prospective payment system capital Federal rate—

(i) Is adjusted for the applicable hospital inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted by the applicable geographic adjustment factors, including local cost variation based on the applicable geographic classifications set forth at § 412.503 and the applicable full hospital inpatient prospective payment system wage index value for non-reclassified hospitals, applicable large urban location and cost of living adjustment factors for LTCHs for Alaska and Hawaii, if applicable;

(iii) Includes, where applicable, capital inpatient prospective payment system adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(4) *High cost outlier.* An additional payment for high cost outlier cases is based on the fixed loss amount established for the hospital inpatient prospective payment system.

(g) *Transition period for long-term care hospitals and satellite facilities paid under this subpart.* Except as specified in paragraph (h)(2), in the case of a long-term care hospital or a satellite facility that is paid under the provisions of this subpart on October 1, 2004 or of a hospital that is paid under the provisions of this subpart and whose qualifying period under § 412.23(e) began on or before October 1, 2004, the amount paid is calculated as specified below:

(1) For each discharge during the first cost reporting period beginning on or after October 1, 2004, and before October 1, 2005, the amount paid is the amount payable under this subpart with no adjustment under this section

but the hospital may not exceed the percentage of patients admitted from the host during its FY 2004 cost reporting period.

(2) For each discharge during the cost reporting period beginning on or after October 1, 2005, and before October 1, 2006, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from the host during its FY 2004 cost reporting period or 75 percent.

(3) For each discharge during the cost reporting period beginning on or after October 1, 2006, and before October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed the lesser of the percentage of patients admitted from the host during its FY 2004 cost reporting period or 50 percent.

(4) For each discharge during cost reporting periods beginning on or after October 1, 2007, the percentage that may be admitted from the host with no payment adjustment may not exceed 25 percent or the applicable percentage determined under paragraph (d) or (e) of this section.

(h) *Effective date of policies in this section for certain co-located long-term care hospitals and satellite facilities of long-term care hospitals.* Except as specified in paragraph (h)(4) of this section, the policies set forth in this paragraph (h) apply to Medicare patient discharges that were admitted from a hospital located in the same building or on the same campus as a long-term care hospital described in §412.23(e)(2)(i) that meets the criteria in §412.22(f) and a satellite facility of a long-term care hospital as described under §412.22(h)(3)(i) for discharges occurring in cost reporting periods beginning on or after July 1, 2007.

(1) Except as specified in paragraph (h)(4) of this section, in the case of a long-term care hospital or long-term care hospital satellite facility that is described under this paragraph (h), the thresholds applied at paragraphs (c), (d), and (e) of this section are not less than the following percentages:

(i) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2008, the lesser of 75 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or long-term care hospital satellite facility from its co-located hospital during the cost reporting period or the percentage of Medicare discharges that had been admitted to the long-term care hospital or satellite from that co-located hospital during the long-term care hospital's or satellite's RY 2005 cost reporting period.

(ii) For cost reporting periods beginning on or after July 1, 2008 and before July 1, 2009, the lesser of 50 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or the long-term care hospital satellite facility from its co-located hospital or the percentage of Medicare discharges that had been admitted from that co-located hospital during the long-term care hospital's or satellite's RY 2005 cost reporting period.

(iii) For cost reporting periods beginning on or after July 1, 2009, 25 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or satellite from its co-located hospital during the cost reporting period.

(2) In determining the percentage of Medicare discharges admitted from the co-located hospital under this paragraph, patients on whose behalf a Medicare high cost outlier payment was made at the co-located referring hospital are not counted toward this threshold.

(3) Except as specified in paragraph (h)(4) of this section, for cost reporting periods beginning on or after July 1, 2007, payments to long term care hospitals described in §412.23(e)(2)(i) that meet the criteria in §412.22(f) and satellite facilities of long-term care hospitals described at §412.22(h)(3)(i) are subject to the provisions of §412.536 for discharges of Medicare patients who are admitted from a hospital not located in the same building or on the same campus as the LTCH or LTCH satellite facility.

(4) For a long-term care hospital described in §412.23(e)(2)(i) that meets the criteria in §412.22(f), the policies set forth in this paragraph (h) and in

§ 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007.

(5) For a long-term care hospital or a satellite facility that, as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location, the policies set forth in this paragraph (h) and in § 412.536 do not apply for discharges occurring in cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016.

[69 FR 49251, Aug. 11, 2004, as amended at 69 FR 78529, Dec. 30, 2004; 71 FR 27900, May 12, 2006; 72 FR 26992, May 11, 2007; 73 FR 26839, May 9, 2008; 73 FR 29709, May 22, 2008; 74 FR 43998, Aug. 27, 2009; 75 FR 50416, Aug. 16, 2010; 77 FR 53679, Aug. 31, 2012; 77 FR 63752, Oct. 17, 2012; 79 FR 50356, Aug. 22, 2014]

§ 412.535 Publication of the Federal prospective payment rates.

Except as specified in paragraph (b), CMS publishes information pertaining to the long-term care hospital prospective payment system effective for each annual update in the FEDERAL REGISTER.

(a) For the period beginning on or after July 1, 2003 and ending on June 30, 2008, information on the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates are published on or before May 1 prior to the start of each long-term care hospital prospective payment system rate year which begins July 1, unless for good cause it is published after May 1, but before June 1.

(b) For the period beginning on July 1, 2008 and ending on September 30, 2009, information of the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates are published on or before May 1 prior to the start of the long-term care hospital prospective payment system rate year which begins July 1, unless for good cause it is published after May 1, but before June 1.

(c) For the period beginning on or after October 1, 2009, information on the unadjusted Federal payment rates and a description of the methodology and data used to calculate the payment rates are published on or before August 1 prior to the start of the Federal fiscal year which begins October 1, unless for good cause it is published after August 1, but before September 1.

(d) Information on the LTC-DRG classification and associated weighting factors is published on or before August 1 prior to the beginning of each Federal fiscal year.

[68 FR 34163, June 6, 2003, as amended at 73 FR 26839, May 9, 2008]

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharge Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital, effective for discharges occurring on or before September 30, 2016 or in cost reporting periods beginning on or before June 30, 2016.

(a) *Scope.* (1) Except as specified in paragraph (a)(2) of this section, for cost reporting periods beginning on or after July 1, 2007, the policies set forth in this section apply to discharges from the following:

(i) Long-term care hospitals as described in § 412.23(e)(2)(i) that meet the criteria in § 412.22(e).

(ii) Long-term care hospitals as described in § 412.23(e)(2)(i) and that meet the criteria in § 412.22(f).

(iii) [Reserved]

(iv) Long-term care hospitals as described in § 412.23(e)(5).

(2) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2016, the policies set forth in this section are not applicable to discharges from:

(i) A long-term care hospital described in § 412.23(e)(5) of this part; or

(ii) [Reserved]

(iii) A long-term care hospital or satellite facility, that as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Act at the off-campus location.

(b) For cost reporting periods beginning on or after July 1, 2007, payments for discharges of Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or long-term care hospital satellite facility will be made under either paragraph (b)(1) or paragraph (b)(2) of this section.

(1) Except as provided in paragraphs (c), (d) and subject to paragraph (f) of this section, for any cost reporting period beginning on or after July 1, 2007 in which a long-term care hospital or a long-term care hospital satellite facility has a discharged Medicare inpatient population of whom no more than 25 percent were admitted to the long-term care hospital or the satellite facility from any individual hospital not co-located with the long-term care hospital or with the satellite of a long-term care hospital, payments for the Medicare discharges admitted from that hospital are made under the rules at §412.500 through §412.541 in this subpart with no adjustment under this section.

(2) Except as provided in paragraph (c) and (d) and subject to paragraph (f) of this section, for any cost reporting period beginning on or after July 1, 2007 in which a long-term care hospital or long-term care hospital satellite facility has a discharged Medicare inpatient population of whom more than 25 percent were admitted to the long-term care hospital or satellite facility from any individual hospital not co-located with the long-term care hospital or with the satellite of a long-term care hospital, payment for the Medicare discharges who cause the long-term care hospital or satellite facility to exceed the 25 percent threshold for discharged patients who have been admitted from that referring hospital is the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (e) of this section, to the amount that would be determined under the rules at subpart A, §412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients admitted from that referring hospital are made under the rules in this subpart at §§412.500 through 412.541 with no adjustment under this section.

(3) In determining the percentage of Medicare discharges admitted to the long-term care hospital or long-term care hospital satellite facility from any referring hospital not co-located with the long-term care hospital or with the satellite of a long-term care hospital, under paragraphs (b)(1) and (b)(2) of this section, patients on whose behalf a Medicare high cost outlier payment was made to the referring hospital are not counted towards the 25 percent threshold from that referring hospital.

(c) *Special treatment of rural hospitals.* (1) Subject to paragraph (f) of this section, in the case of a long-term care hospital or long-term care hospital satellite facility that is located in a rural area as defined in §412.503 that has a discharged Medicare inpatient population of whom more than 50 percent were admitted to the long-term care hospital or long-term care hospital satellite facility from a hospital not co-located with the long-term care hospital or with the satellite of a long-term care hospital, payment for the Medicare discharges who are admitted from that hospital and who cause the long-term care hospital or satellite facility to exceed the 50 percent threshold for Medicare discharges is determined at the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (e) of this section, to the amount that is otherwise payable under subpart A, §412.1(a). Payments for the remainder of the long-term care hospital's or long-term care hospital satellite facility's Medicare discharges admitted from that referring hospital are made under the rules in this subpart at §§412.500 through 412.541 with no adjustment under this section.

(2) In determining the percentage of Medicare discharges admitted from the referring hospital under paragraph (c)(1) of this section, patients on whose behalf a Medicare high cost outlier payment was made at the referring hospital are not counted toward the 50 percent threshold.

(d) *Special treatment of urban single or MSA dominant hospitals.* (1) Subject to

paragraph (f) of this section, in the case of a long-term care hospital or long-term care hospital satellite facility that admits Medicare patients from the only other hospital in the MSA or from a referring MSA dominant hospital as defined in paragraph (d)(4) of this section, that are not co-located with the long-term care hospital or with the satellite of a long-term care hospital for any cost reporting period beginning on or after July 1, 2007, in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than the percentage calculated under paragraph (d)(2) of this section were admitted to the hospital from the single or MSA-dominant referring hospital, payment for the Medicare discharges who are admitted from the referring hospital and who cause the long-term care hospital or long-term care hospital satellite facility to exceed the applicable threshold for Medicare discharges who have been admitted from the referring hospital is the lesser of the amount otherwise payable under this subpart or the amount under this subpart that is equivalent, as set forth in paragraph (e) of this section, to the amount that otherwise would be determined under subpart A, §412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's Medicare discharges admitted from that referring hospital are made under the rules in this subpart at §§412.500 through 412.541 with no adjustment under this section.

(2) For purposes of paragraph (d)(1) of this section, the percentage threshold is equal to the percentage of total Medicare discharges in the Metropolitan Statistical Area (MSA) in which the hospital is located that are from the referring hospital, but in no case is less than 25 percent or more than 50 percent.

(3) In determining the percentage of patients admitted from the referring hospital under paragraph (d)(1) of this section, patients on whose behalf a Medicare outlier payment was made at the referring hospital are not counted toward the applicable threshold.

(4) For purposes of this paragraph, an ''MSA-dominant hospital'' is a hospital that has discharged more than 25 percent of the total hospital Medicare discharges in the MSA in which the hospital is located.

(e) *Calculation of adjusted payment*—(1) *Calculation of adjusted long-term care hospital prospective payment system amount.* CMS calculates an amount payable under subpart O equivalent to an amount that would otherwise be paid under the hospital inpatient prospective payment system at subpart A, §412.1(a). The amount is based on the sum of the applicable hospital inpatient prospective payment system operating standardized amount and capital Federal rate in effect at the time of the long-term care hospital discharge.

(2) *Operating inpatient prospective payment system standardized amount.* The hospital inpatient prospective payment system operating standardized amount—

(i) Is adjusted for the applicable hospital inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted for different area wage levels based on the geographic classifications defined at §412.503 and the applicable hospital inpatient prospective payment system labor-related share, using the applicable hospital inpatient prospective payment system wage index value for nonreclassified hospitals. For long-term care hospitals located in Alaska and Hawaii, this amount is also adjusted by the applicable hospital inpatient prospective payment system cost of living adjustment factors;

(iii) Includes, where applicable, adjustments for indirect medical education costs and for the costs of serving a disproportionate share of low-income patients.

(3) *Hospital inpatient prospective payment system capital Federal rate.* The hospital inpatient prospective payment system capital Federal rate—

(i) Is adjusted for the applicable hospital inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted by the applicable geographic adjustment factors, including local cost variation based on the applicable geographic classifications set forth at §412.503 and the applicable full hospital inpatient prospective payment

system wage index value for non-reclassified hospitals, applicable large urban location and cost of living adjustment factors for long-term care hospitals for Alaska and Hawaii, if applicable;

(iii) Includes, where applicable, capital inpatient prospective payment system adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(4) *High cost outlier.* An additional payment for high cost outlier cases is based on the applicable fixed loss amount established for the hospital inpatient prospective payment system.

(f) *Transition period for long-term care hospitals and satellites paid under this section.* In the case of a long-term care hospital or satellite of a long-term care hospital that is paid under the provisions of this section, the thresholds applied under paragraphs (b), (c) and (d) of this section will not be less than the percentages specified below:

(1) For cost reporting periods beginning on or after July 1, 2007 and before July 1, 2008, the lesser of 75 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or satellite facility of a long-term care hospital from all referring hospitals not co-located with the long-term care hospital or with the satellite facility of a long-term care hospital during the cost reporting period or the percentage of Medicare discharges that had been admitted to the long-term care hospital or satellite of a long-term care hospital from that referring hospital during the long-term care hospital's or satellite's RY 2005 cost reporting period.

(2) For cost reporting periods beginning on or after July 1, 2008 and before July 1, 2009, the lesser of 50 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or to the satellite facility of a long-term care hospital from all referring hospitals not co-located with the long-term care hospital or with the satellite facility of a long-term care hospital during the cost reporting period or the percentage of Medicare discharges that had been admitted from that referring hospital during the long-term care hospital's or satellite's RY 2005 cost reporting period.

(3) For cost reporting periods beginning on or after July 1, 2009, 25 percent of the total number of Medicare discharges that were admitted to the long-term care hospital or to the satellite facility of a long-term care hospital from all referring hospitals not co-located with the long-term care hospital or with the satellite facility of a long-term care hospital to the long-term care hospital during the cost reporting period.

(4) In determining the percentage of Medicare discharges admitted from the referring hospital under this paragraph, patients on whose behalf a Medicare high cost outlier payment was made at the referring hospital are not counted toward this threshold.

[72 FR 26993, May 11, 2007, as amended at 73 FR 26840, May 9, 2008; 73 FR 29711, May 22, 2008; 74 FR 44000, Aug. 27, 2009; 75 FR 50416, Aug. 16, 2010; 77 FR 53680, Aug. 31, 2012; 77 FR 63752, Oct. 17, 2012; 79 FR 50357, Aug. 22, 2014]

§ 412.538 [Reserved]

§ 412.540 Method of payment for preadmission services under the long-term care hospital prospective payment system.

The prospective payment system includes payment for inpatient operating costs of preadmission services that are—

(a) Otherwise payable under Medicare Part B;

(b) Furnished to a beneficiary on the date of the beneficiary's inpatient admission, and during the calendar day immediately preceding the date of the beneficiary's inpatient admission, to the long-term care hospital, or to an entity wholly owned or wholly operated by the long-term care hospital; and

(1) An entity is wholly owned by the long-term care hospital if the long-term care hospital is the sole owner of the entity.

(2) An entity is wholly operated by a long-term care hospital if the long-term care hospital has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the long-term care hospital also has policymaking authority over the entity.

(c) Related to the inpatient stay. A preadmission service is related if—

(1) It is diagnostic (including clinical diagnostic laboratory tests); or

(2) It is nondiagnostic when furnished on the date of the beneficiary's inpatient admission; or

(3) On or after June 25, 2010, it is nondiagnostic when furnished on the calendar day preceding the date of the beneficiary's inpatient admission and the hospital does not attest that such service is unrelated to the beneficiary's inpatient admission.

(d) Not one of the following—

(1) Ambulance services.

(2) Maintenance renal dialysis services.

[75 FR 50416, Aug. 16, 2010]

§ 412.541 Method of payment under the long-term care hospital prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, long-term care hospitals receive payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments*—(1) *Criteria for receiving periodic interim payments.* (i) A long-term care hospital receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of § 413.64(h) of this subchapter.

(ii) To be approved for PIP, the long-term care hospital must meet the qualifying requirements in § 413.64(h)(3) of this subchapter.

(iii) As provided in § 413.64(h)(5) of this subchapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of the PIP resulting in an overpayment to the provider.

(2) *Frequency of payment.* (i) For long-term care hospitals approved for PIP and paid solely under Federal prospective payment system rates under §§ 412.533(a)(5) and 412.533(c), the intermediary estimates the long-term care hospital's Federal prospective payments net after estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year.

(ii) For long-term care hospitals approved for PIP and paid using the blended payment schedule specified in § 412.533(a) for cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, the intermediary estimates the hospital's portion of the Federal prospective payments net and the hospital's portion of the reasonable cost-based reimbursement payments net, after beneficiary deductibles and coinsurance, in accordance with the blended transition percentages specified in § 412.533(a), and makes biweekly payments equal to 1/26 of the total estimated amount of both portions of payments for the year.

(iii) If the long-term care hospital has payment experience under the long-term care hospital prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year.

(iv) Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this subchapter.

(v) The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a hospital receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the hospital.* Subject to paragraph (b)(1)(iii) of this section, a long-term care hospital receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the long-term care hospital no longer meets the requirements of § 413.64(h) of this subchapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for the costs of an approved education program, blood clotting factors, anesthesia services furnished by hospital-employed nonphysician anesthetists or obtained

under arrangement, and photocopying and mailing medical records to a QIO, which are costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of the biweekly period of service as described in § 413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if a long-term care hospital receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Special interim payment for unusually long lengths of stay*—(1) *First interim payment.* A hospital that is not receiving periodic interim payments under paragraph (b) of this section may request an interim payment 60 days after a Medicare beneficiary has been admitted to the hospital. Payment for the interim bill is determined as if the bill were a final discharge bill and includes any outlier payment determined as of the last day for which services have been billed.

(2) *Additional interim payments.* A hospital may request additional interim payments at intervals of at least 60 days after the date of the first interim bill submitted under paragraph (d)(1) of this section. Payment for these additional interim bills, as well as the final bill, is determined as if the bill were the final bill with appropriate adjustments made to the payment amount to reflect any previous interim payment made under the provisions of this paragraph.

(e) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(f) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to a long-term care hospital that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the hospital is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the long-term care hospital.

(ii) Due to an exceptional situation, there is a temporary delay in the hospital's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* A request by a long-term care hospital for an accelerated payment must be approved by the intermediary and by CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as long-term care hospital bills are processed or by direct payment by the long-term care hospital.

[67 FR 56049, Aug. 30, 2002, as amended at 68 FR 10988, Mar. 7, 2003; 71 FR 48141, Aug. 18, 2006]

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

(a) *Participation in the LTCH QRP.* A long-term-care hospital must begin submitting data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1), and 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act, under the LTCH QRP by no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter.

(b) *Data submission requirements and payment impact.* (1) Except as provided in paragraph (c) of this section, a long-term care hospital must submit to CMS data on measures specified under sections 1886(m)(5)(D), 1899B(c)(1) and 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. Such data must be submitted in a form and manner, and at a time, specified by CMS.

(2) A long-term care hospital that does not submit data in accordance

with sections 1886(m)(5)(C) and 1886(m)(5)(F) of the Act with respect to a given fiscal year will have its annual update to the standard Federal rate for discharges for the long-term care hospital during the fiscal year reduced by 2 percentage points.

(3) CMS may remove a quality measure from the LTCH QRP based on one or more of the following factors:

(i) Measure performance among long-term care hospitals 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) *Exception and extension request requirements.* Upon request by a long-term care hospital, CMS may grant an exception or extension with respect to the measures data and standardized patient assessment data reporting requirements, for one or more quarters, in the event of certain extraordinary circumstances beyond the control of the long-term care hospital, subject to the following:

(1) A long-term care hospital that wishes to request an exception or extension with respect to measures data and standardized patient assessment data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

(2) A long-term care hospital must submit its request for an exception or extension to CMS via email. Email is the only form that may be used to submit to CMS a request for an exception or an extension.

(3) The email request for an exception or extension must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address. (The mailing address may not be a post office box.)

(v) A statement of the reason for the request for the exception or extension.

(vi) Evidence of the impact of the extraordinary circumstances, including, but not limited to, photographs, newspaper articles, and other media.

(vii) The date on which the long-term care hospital will be able to again submit measures data and standardized patient assessment data under the LTCH QRP and a justification for the proposed date.

(4) CMS may grant an exception or extension to a long-term care hospital that has not been requested by the long-term care hospital if CMS determines that—

(i) An extraordinary circumstance affects an entire region or locale; or

(ii) A systemic problem with one of CMS' data collection systems directly affected the ability of the long-term care hospital to submit measures data and standardized patient assessment data.

(d) *Reconsiderations of noncompliance decisions*— (1) *Written letter of non-compliance decision.* Long-term care hospitals that do not meet the requirement in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC.

(2) *Request for reconsideration of non-compliance decision.* A long-term care hospital may request a reconsideration

of CMS' decision of noncompliance no later than 30 calendar days from the date of the written notification of noncompliance. The reconsideration request by the long-term care hospital must be submitted to CMS via email and must contain the following information:

(i) The CCN for the long-term care hospital.

(ii) The business name of the long-term care hospital.

(iii) The business address of the long-term care hospital.

(iv) Contact information for the long-term care hospital's chief executive officer or designated personnel, including each individual's name, title, email address, telephone number, and physical mailing address. (The physical address may not be a post office box.)

(v) CMS's identified reason(s) for the noncompliance decision from the written notification of noncompliance.

(vi) The reason for requesting reconsideration of CMS' noncompliance decision.

(vii) Accompanying documentation that demonstrates compliance of the long-term care hospital with the LTCH QRP requirements. This documentation must be submitted electronically at the same time as the reconsideration request as an attachment to the email.

(3) *CMS decision on reconsideration request.* CMS will notify long-term care hospitals, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the MAC.

(e) *Appeals of reconsideration requests.* A long-term care 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.

(f) *Data completion thresholds.* (1) Long-term care hospitals must meet or exceed the following data completeness thresholds with respect to a fiscal year:

(i)(A) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) on at least 80 percent of the assessments LTCHs submit through the CMS designated data submission system for the FY 2014 through the FY 2025 LTCH QRP.

(B) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the LCDS on at least 85 percent of the assessments LTCHs submit through the CMS designated data submission system beginning with the FY 2026 LTCH QRP.

(ii) The threshold set at 100 percent for measures data collected and submitted using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for FY 2014 and all subsequent payment updates.

(2) The thresholds in paragraph (f)(1) of this section apply to all data that must be submitted under paragraph (b) of this section.

(3) A long-term care hospital must meet or exceed both thresholds in paragraph (f)(1) of this section to avoid receiving a 2 percentage point reduction to its annual payment update for a given fiscal year, beginning with the FY 2019 LTCH QRP.

[80 FR 49769, Aug. 17, 2015, as amended at 81 FR 57270, Aug. 22, 2016; 82 FR 38513, Aug. 14, 2017; 83 FR 41705, Aug. 17, 2018; 84 FR 42615, Aug. 16, 2019; 88 FR 59334, Aug. 28, 2023]

Subpart P—Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units

SOURCE: 66 FR 41388, Aug. 7, 2001, unless otherwise noted.

§ 412.600 Basis and scope of subpart.

(a) *Basis.* This subpart implements section 1886(j) of the Act, which provides for the implementation of a prospective payment system for inpatient rehabilitation hospitals and rehabilitation units (in this subpart referred to as ''inpatient rehabilitation facilities'').

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for inpatient rehabilitation facilities, including the methodology

used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules. Under this system, for cost reporting periods beginning on or after January 1, 2002, payment for the operating and capital costs of inpatient hospital services furnished by inpatient rehabilitation facilities to Medicare Part A fee-for-service beneficiaries is made on the basis of prospectively determined rates and applied on a per discharge basis.

§ 412.602 Definitions.

As used in this subpart—

Assessment reference date means the specific calendar day in the patient assessment process that sets the designated endpoint of the common patient observation period, with most patient assessment items usually referring back in time from this endpoint.

Closure of an IRF has the same meaning as ''closure of a hospital'' as defined in § 413.79(h)(1)(i) as applied to an IRF meeting the requirements of § 412.604(b) for the purposes of accounting for indirect teaching costs.

Closure of an IRF's residency training program has the same meaning as ''closure of a hospital residency training program'' as defined in § 413.79(h)(1)(ii) as applied to an IRF meeting the requirements of § 412.604(b) for the purposes of accounting for indirect teaching costs.

CMS stands for the Centers for Medicare & Medicaid Services.

Comorbidity means a specific patient condition that is secondary to the patient's principal diagnosis that is the primary reason for the inpatient rehabilitation stay.

Discharge. A Medicare patient in an inpatient rehabilitation facility is considered discharged when—

(1) The patient is formally released from the inpatient rehabilitation facility; or

(2) The patient dies in the inpatient rehabilitation facility.

Displaced resident has the same meaning as a ''displaced resident'' as defined in § 413.79(h)(1)(iii) as applied to an IRF, for purposes of accounting for indirect teaching costs.

Encode means entering data items into the fields of the computerized patient assessment software program.

Functional-related groups refers to the distinct groups under which inpatients are classified using proxy measurements of inpatient rehabilitation relative resource usage.

Interrupted stay means a stay at an inpatient rehabilitation facility during which a Medicare inpatient is discharged from the inpatient rehabilitation facility and returns to the same inpatient rehabilitation facility within 3 consecutive calendar days. The duration of the interruption of the stay of 3 consecutive calendar days begins with the day of discharge from the inpatient rehabilitation facility and ends on midnight of the third day.

Outlier payment means an additional payment beyond the standard Federal prospective payment for cases with unusually high costs.

Patient assessment instrument refers to a document that contains clinical, demographic, and other information on a patient.

Rural area means: For cost-reporting periods beginning on or after January 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before October 1, 2005, an area as defined in § 412.62(f)(1)(iii). For discharges occurring on or after October 1, 2005, rural area means an area as defined in § 412.64(b)(1)(ii)(C).

Transfer means the release of a Medicare inpatient from an inpatient rehabilitation facility to another inpatient rehabilitation facility, a short-term, acute-care prospective payment hospital, a long-term care hospital as described in § 412.23(e), or a nursing home that qualifies to receive Medicare or Medicaid payments.

Urban area means: For cost-reporting periods beginning on or after January 1, 2002, with respect to discharges occurring during the period covered by such cost reports but before October 1, 2005, an area as defined in § 412.62(f)(1)(ii). For discharges occurring on or after October 1, 2005, urban area means an area as defined in

§§412.64(b)(1)(ii)(A) and 412.64(b)(1)(ii)(B).

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003; 70 FR 47952, Aug. 15, 2005; 87 FR 47090, Aug. 1, 2022]

§412.604 Conditions for payment under the prospective payment system for inpatient rehabilitation facilities.

(a) *General requirements.* (1) Effective for cost reporting periods beginning on or after January 1, 2002, an inpatient rehabilitation facility must meet the conditions of this section to receive payment under the prospective payment system described in this subpart for inpatient hospital services furnished to Medicare Part A fee-for-service beneficiaries.

(2) If an inpatient rehabilitation facility fails to comply fully with these conditions with respect to inpatient hospital services furnished to one or more Medicare Part A fee-for-service beneficiaries, CMS or its Medicare fiscal intermediary may, as appropriate—

(i) Withhold (in full or in part) or reduce Medicare payment to the inpatient rehabilitation facility until the facility provides adequate assurances of compliance; or

(ii) Classify the inpatient rehabilitation facility as an inpatient hospital that is subject to the conditions of subpart C of this part and is paid under the prospective payment systems specified in §412.1(a)(1).

(b) *Inpatient rehabilitation facilities subject to the prospective payment system.* Subject to the special payment provisions of §412.22(c), an inpatient rehabilitation facility must meet the general criteria set forth in §412.22 and the criteria to be classified as a rehabilitation hospital or rehabilitation unit set forth in §§412.23(b), 412.25, and 412.29 for exclusion from the inpatient hospital prospective payment systems specified in §412.1(a)(1).

(c) *Completion of patient assessment instrument.* For each Medicare part A fee-for-service patient admitted to or discharged from an IRF on or after January 1, 2002, the inpatient rehabilitation facility must complete a patient assessment instrument in accordance with §412.606. IRFs must also complete a patient assessment instrument in accordance with §412.606 for each Medicare Part C (Medicare Advantage) patient admitted to or discharged from an IRF on or after October 1, 2009. In addition, IRFs must complete a patient assessment instrument in accordance with §412.606 for all other patients, regardless of payer, admitted to or discharged from an IRF on or after October 1, 2024.

(d) *Limitation on charges to beneficiaries*—(1) *Prohibited charges.* Except as provided in paragraph (d)(2) of this section, an inpatient rehabilitation facility may not charge a beneficiary for any services for which payment is made by Medicare, even if the facility's costs of furnishing services to that beneficiary are greater than the amount the facility is paid under the prospective payment system.

(2) *Permitted charges.* An inpatient rehabilitation facility receiving payment under this subpart for a covered hospital stay (that is, a stay that includes at least one covered day) may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts under §§409.82, 409.83, and 409.87 of this subchapter and for items or services as specified under §489.20(a) of this chapter.

(e) *Furnishing of inpatient hospital services directly or under arrangement.* (1) Subject to the provisions of §412.622(b), the applicable payments made under this subpart are payment in full for all inpatient hospital services, as defined in §409.10 of this subchapter. Inpatient hospital services do not include the following:

(i) Physicians' services that meet the requirements of §415.102(a) of this subchapter for payment on a fee schedule basis.

(ii) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(iii) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(iv) Certified nurse midwife services, as defined in section 1861(gg) of the Act.

(v) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(vi) Services of an anesthetist, as defined in § 410.69 of this chapter.

(2) Medicare does not pay any provider or supplier other than the inpatient rehabilitation facility for services furnished to a Medicare beneficiary who is an inpatient of the inpatient rehabilitation facility, except for services described in paragraphs (e)(1)(i) through (e)(1)(vi) of this section.

(3) The inpatient rehabilitation facility must furnish all necessary covered services to the Medicare beneficiary either directly or under arrangements (as defined in § 409.3 of this subchapter).

(f) The prospective payment system includes payment for inpatient operating costs of preadmission services that are—

(1) Otherwise payable under Medicare Part B;

(2) Furnished to a beneficiary on the date of the beneficiary's inpatient admission, and during the calendar day immediately preceding the date of the beneficiary's inpatient admission, to the inpatient rehabilitation facility, or to an entity wholly owned or wholly operated by the inpatient rehabilitation facility; and

(i) An entity is wholly owned by the inpatient rehabilitation facility if the inpatient rehabilitation facility is the sole owner of the entity.

(ii) An entity is wholly operated by an inpatient rehabilitation facility if the inpatient rehabilitation facility has exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether the inpatient rehabilitation facility also has policymaking authority over the entity.

(3) Related to the inpatient stay. A preadmission service is related if—

(i) It is diagnostic (including clinical diagnostic laboratory tests); or

(ii) It is nondiagnostic when furnished on the date of the beneficiary's inpatient admission; or

(iii) On or after June 25,, 2010, it is nondiagnostic when furnished on the calendar day preceding the date of the beneficiary's inpatient admission and the hospital does not attest that such service is unrelated to the beneficiary's inpatient admission.

(4) Not one of the following—

(i) Ambulance services.

(ii) Maintenance renal dialysis services.

(g) *Reporting and recordkeeping requirements.* All inpatient rehabilitation facilities participating in the prospective payment system under this subpart must meet the recordkeeping and cost reporting requirements of §§ 413.20 and 413.24 of this subchapter.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003; 74 FR 39810, Aug. 7, 2009; 75 FR 50417, Aug. 16, 2010; 87 FR 47090, Aug. 1, 2022]

§ 412.606 Patient assessments.

(a) *Patient assessment instrument.* An inpatient rehabilitation facility must use the CMS inpatient rehabilitation facility patient assessment instrument to assess Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) inpatients who are admitted on or after January 1, 2002, or were admitted before January 1, 2002, and are still inpatients as of January 1, 2002.

(1) Starting on October 1, 2024, inpatient rehabilitation facilities must use the CMS inpatient rehabilitation facility patient assessment instrument to assess all inpatients, regardless of payer, who are admitted on or after October 1, 2024, or who were admitted before October 1, 2024 and are still inpatients as of October 1, 2024.

(2) [Reserved]

(b) *Comprehensive assessments.* (1) A clinician of the inpatient rehabilitation facility must perform a comprehensive, accurate, standardized, and reproducible assessment of each Medicare Part A fee-for-service inpatient using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of this section as part of his or her patient assessment in accordance with the schedule described in § 412.610. IRFs must also complete a patient assessment instrument in accordance with § 412.606 for each Medicare Part C (Medicare Advantage) patient admitted to or discharged from an IRF on or after October 1, 2009. In addition, IRFs must complete a patient assessment instrument in accordance with § 412.606 for all other patients, regardless of payer, admitted to or discharged from an IRF on or after October 1, 2024.

(2) A clinician employed or contracted by an inpatient rehabilitation facility who is trained on how to perform a patient assessment using the inpatient rehabilitation facility patient assessment instrument specified in paragraph (b) of the section must record appropriate and applicable data accurately and completely for each item on the patient assessment instrument.

(3) The assessment process must include—

(i) Direct patient observation and communication with the patient; and

(ii) When appropriate and to the extent feasible, patient data from the patient's physician(s), family, someone personally knowledgeable about the patient's clinical condition or capabilities, the patient's clinical record, and other sources.

[66 FR 41388, Aug. 7, 2001, as amended at 74 FR 39810, Aug. 7, 2009; 83 FR 38573, Aug. 6, 2018; 87 FR 47090, Aug. 1, 2022]

§412.608 Patients' rights regarding the collection of patient assessment data.

(a) Before performing an assessment using the inpatient rehabilitation facility patient assessment instrument, a clinician of the inpatient rehabilitation facility must give a Medicare inpatient—

(1) The form entitled ''Privacy Act Statement—Health Care Records''; and

(2) The simplified plain language description of the Privacy Act Statement—Health Care Records which is a form entitled ''Data Collection Information Summary for Patients in Inpatient Rehabilitation Facilities.''

(b) The inpatient rehabilitation facility must document in the Medicare inpatient's clinical record that the Medicare inpatient has been given the documents specified in paragraph (a) of this section.

(c) By giving the Medicare inpatient the forms specified in paragraph (a) of this section the inpatient rehabilitation facility will inform the Medicare patient of—

(1) Their privacy rights under the Privacy Act of 1974 and 45 CFR 5b.4(a)(3); and

(2) The following rights:

(i) The right to be informed of the purpose of the collection of the patient assessment data;

(ii) The right to have the patient assessment information collected be kept confidential and secure;

(iii) The right to be informed that the patient assessment information will not be disclosed to others, except for legitimate purposes allowed by the Federal Privacy Act and Federal and State regulations;

(iv) The right to refuse to answer patient assessment questions; and

(v) The right to see, review, and request changes on his or her patient assessment.

(d) The patient rights specified in this section are in addition to the patient rights specified in §82.13 of this chapter.

[68 FR 45699, Aug. 1, 2003]

§412.610 Assessment schedule.

(a) *General.* For each inpatient, an inpatient rehabilitation facility must complete a patient assessment instrument as specified in §412.606 that covers a time period that is in accordance with the assessment schedule specified in paragraph (c) of this section.

(b) *Starting the assessment schedule day count.* The first day that the inpatient is furnished services during his or her current inpatient rehabilitation facility hospital stay is counted as day one of the patient assessment schedule.

(c) *Assessment schedules and references dates.* The inpatient rehabilitation facility must complete a patient assessment instrument upon the patient's admission and discharge as specified in paragraphs (c)(1) and (2) of this section.

(1) *Admission assessment*—(i) *General rule.* The admission assessment—

(A) *General.* Time period is a span of time that covers calendar days 1 through 3 of the patient's current hospitalization.

(B) Has an admission assessment reference date that is the third calendar day of the span of time specified in paragraph (c)(1)(i)(A) of this section; and

(C) Must be completed by the calendar day that follows the admission assessment reference day.

(ii) *Exception to the general rule.* We may specify in the patient assessment

instrument item-by-item guide and in other issued instructions, items that have a different admission assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(2) *Discharge assessment*—(i) *General rule.* The discharge assessment—

(A) Time period is a span of time that covers 3 calendar days, and is the discharge assessment reference date itself specified in paragraph (c)(2)(ii) of this section and the 2 calendar days prior to the discharge assessment reference date; and

(B) Must be completed on the 5th calendar day that follows the discharge assessment reference date specified in paragraph (c)(2)(ii) of this section with the discharge assessment reference date itself being counted as the first day of the 5 calendar day time span.

(ii) *Discharge assessment reference date.* The discharge assessment reference date is the actual day that the first of either of the following two events occurs:

(A) The patient is discharged from the inpatient rehabilitation facility; or

(B) The patient stops being furnished inpatient rehabilitation services.

(iii) *Exception to the general rule.* We may specify in the patient assessment instrument item-by-item guide and in other issued instructions, items that have a different discharge assessment time period to most appropriately capture patient information for payment and quality of care monitoring objectives.

(d) *Encoding dates.* The admission and discharge patient assessments must be encoded by the 7th calendar day from the completion dates specified in paragraph (c) of this section.

(e) *Accuracy of the patient assessment data.* The encoded patient assessment data must accurately reflect the patient's clinical status at the time of the patient assessment.

(f) *Patient assessment instrument record retention.* An inpatient rehabilitation facility must maintain all patient assessment data sets completed on all Medicare Part A fee-for-service patients within the previous 5 years, on Medicare Part C (Medicare Advantage) patients within the previous 10 years, and all other patients within the previous 5 years either in a paper format in the patient's clinical record or in an electronic computer file format that the inpatient rehabilitation facility can easily obtain and produce upon request to CMS or its contractors.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45699, Aug. 1, 2003; 74 FR 39810, Aug. 7, 2009; 87 FR 47090, Aug. 1, 2022]

§ 412.612 Coordination of the collection of patient assessment data.

(a) *Responsibilities of the clinician.* A clinician of an inpatient rehabilitation facility who has participated in performing the patient assessment must have responsibility for—

(1) The accuracy and thoroughness of the specific data recorded by that clinician on the patient's assessment instrument; and

(2) The accuracy of the assessment reference date inserted on the patient assessment instrument completed under § 412.610(c).

(b) *Penalty for falsification.* (1) Under Medicare, an individual who knowingly and willfully—

(i) Completes a material and false statement in a patient assessment is subject to a civil money penalty of not more than $1,000 as adjusted annually under 45 CFR part 102 for each assessment; or

(ii) Causes another individual to complete a material and false statement in a patient assessment is subject to a civil money penalty of not more than $5,000 as adjusted annually under 45 CFR part 102 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

[66 FR 41388, Aug. 7, 2001, as amended at 81 FR 61562, Sept. 6, 2016]

§ 412.614 Transmission of patient assessment data.

(a) *Data format—General rule.* The inpatient rehabilitation facility must encode and transmit data for each inpatient—

(1) Using the computerized version of the patient assessment instrument available from us; or

(2) Using a computer program(s) that conforms to our standard electronic

record layout, data specifications, and data dictionary, includes the required patient assessment instrument data set, and meets our other specifications.

(b) *How to transmit data.* The inpatient rehabilitation facility must—

(1) Electronically transmit complete, accurate, and encoded data from the patient assessment instrument for each inpatient to our patient data system in accordance with the data format specified in paragraph (a) of this section; and

(2) Transmit data using electronic communications software that provides a direct telephone connection from the inpatient rehabilitation facility to the our patient data system.

(c) *Transmission dates.* The inpatient rehabilitation facility must transmit both the admission patient assessment and the discharge patient assessments at the same time to the our patient data system by the 7th calendar day in the period beginning with the applicable patient assessment instrument encoding date specified in §412.610(d).

(d) *Failure to submit complete and timely IRF–PAI data, as required under paragraph (c) of this section*—(1) *Medicare Part-A fee-for-service.* (i) A given Medicare Part-A fee-for-service IRF claim will not be accepted and processed for payment until a corresponding IRF–PAI has been received and accepted by CMS.

(ii) [Reserved]

(2) *Medicare Part C (Medicare Advantage) data.* Failure of the inpatient rehabilitation facility to transmit all of the required patient assessment instrument data for its Medicare Part C (Medicare Advantage) patients to our patient data system in accordance with the transmission timeline in paragraph (c) of this section will result in a forfeiture of the facility's ability to have any of its Medicare Part C (Medicare Advantage) data used in the calculations for determining the facility's compliance with the regulations in §412.29(b)(1).

(3) *All other payer data.* Failure of the inpatient rehabilitation facility to transmit all of the required patient assessment instrument data for all other patients, regardless of payer, to our patient data system in accordance with the transmission timeline in paragraph (c) of this section will result in a forfeiture of the facility's ability to have any of its other payer data used in the calculations for determining the facility's compliance with the regulations in §412.29(b)(1).

(e) *Exemption to the consequences for transmitting the IRF–PAI data late for Medicare Part C (Medicare Advantage) patients and all other patients, regardless of payer.* CMS may waive the consequences of failure to submit complete and timely IRF–PAI data specified in paragraph (d) of this section when, due to an extraordinary situation that is beyond the control of an inpatient rehabilitation facility, the inpatient rehabilitation facility is unable to transmit the patient assessment data in accordance with paragraph (c) of this section. Only CMS can determine if a situation encountered by an inpatient rehabilitation facility is extraordinary and qualifies as a situation for waiver of the forfeiture specified in paragraphs (d)(2) or (3) of this section. An extraordinary situation may be due to, but is not limited to, fires, floods, earthquakes, or similar unusual events that inflect extensive damage to an inpatient facility. An extraordinary situation may be one that produces a data transmission problem that is beyond the control of the inpatient rehabilitation facility, as well as other situations determined by CMS to be beyond the control of the inpatient rehabilitation facility. An extraordinary situation must be fully documented by the inpatient rehabilitation facility.

[66 FR 41388, Aug. 7, 2001, as amended at 68 FR 45699, Aug. 1, 2003; 74 FR 39811, Aug. 7, 2009; 82 FR 36304, Aug. 3, 2017; 87 FR 47091, Aug. 1, 2022]

§412.616 Release of information collected using the patient assessment instrument.

(a) *General.* An inpatient rehabilitation facility may release information from the patient assessment instrument only as specified in §482.24(b)(3) of this chapter.

(b) *Release to the inpatient rehabilitation facility's agent.* An inpatient rehabilitation facility may release information that is patient-identifiable to an

agent only in accordance with a written contract under which the agent agrees not to use or disclose the information except for the purposes specified in the contract and only to the extent the facility itself is permitted to do so under paragraph (a) of this section.

§ 412.618 Assessment process for interrupted stays.

For purposes of the patient assessment process, if any patient has an interrupted stay, as defined under § 412.602, the following applies:

(a) *Assessment requirements.* (1) The initial case-mix group classification from the admission assessment remains in effect (that is, no new admission assessment is performed).

(2) When the patient has completed his or her entire rehabilitation episode stay, a discharge assessment must be performed.

(b) *Recording and encoding of data.* The clinician must record the interruption of the stay on the patient assessment instrument.

(c) If the interruption in the stay occurs during the admission assessment time period, the assessment reference date, completion date, and encoding date for the admission assessment are advanced by the same number of calendar days as the length of the patient's interruption in the stay.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 74 FR 39811, Aug. 7, 2009; 87 FR 47091, Aug. 1, 2022]

§ 412.620 Patient classification system.

(a) *Classification methodology.* (1) A patient classification system is used to classify patients in inpatient rehabilitation facilities into mutually exclusive case-mix groups.

(2) For purposes of this subpart, case-mix groups are classes of Medicare patient discharges by functional-related groups that are based on a patient's impairment, age, comorbidities, functional capabilities, and other factors that may improve the ability of the functional-related groups to estimate variations in resource use.

(3) Data from admission assessments under § 412.610(c)(1) are used to classify a Medicare patient into an appropriate case-mix group.

(4) Data from the discharge assessment under § 412.610(c)(2) are used to determine the weighting factors under paragraph (b)(4) of this section.

(b) *Weighting factors*—(1) *General.* An appropriate weight is assigned to each case-mix group that measures the relative difference in facility resource intensity among the various case-mix groups.

(2) *Short-stay outliers.* We will determine a weighting factor or factors for patients that are discharged and not transferred (as defined in § 412.602) within a number of days from admission as specified by us.

(3) *Patients who expire.* We will determine a weighting factor or factors for patients who expire within a number of days from admission as specified by us.

(4) *Comorbidities.* We will determine a weighting factor or factors to account for the presence of a comorbidity, as defined in § 412.602, that is relevant to resource use in the classification system.

(c) *Revision of case-mix group classifications and weighting factors.* We may periodically adjust the case-mix groups and weighting factors to reflect changes in—

(1) Treatment patterns;

(2) Technology;

(3) Number of discharges; and

(4) Other factors affecting the relative use of resources.

§ 412.622 Basis of payment.

(a) *Method of payment.* (1) Under the prospective payment system, inpatient rehabilitation facilities receive a predetermined amount per discharge for inpatient services furnished to Medicare Part A fee-for-service beneficiaries.

(2) The amount of payment under the prospective payment system is based on the Federal payment rate, including adjustments described in § 412.624 and, if applicable, during a transition period, on a blend of the Federal payment rate and the facility-specific payment rate described in § 412.626.

(3) *IRF coverage criteria.* In order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, there must be a

reasonable expectation that the patient meets all of the following requirements at the time of the patient's admission to the IRF—

(i) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the Public Health Emergency, as defined in §400.200 of this chapter, requires the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy), one of which must be physical or occupational therapy.

(ii) Except during the emergency period described in section 1135(g)(1)(B) of the Act, generally requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy per week. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

(iii) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the Public Health Emergency, as defined in §400.200 of this chapter, is sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation therapy program that is described in paragraph (a)(3)(ii) of this section.

(iv) Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the Public Health Emergency, as defined in §400.200 of this chapter, requires physician supervision by a rehabilitation physician. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, except that during a Public Health Emergency, as defined in §400.200 of this chapter, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). Beginning with the second week of admission to the IRF, a non-physician practitioner who is determined by the IRF to have specialized training and experience in inpatient rehabilitation may conduct 1 of the 3 required face-to-face visits with the patient per week, provided that such duties are within the non-physician practitioner's scope of practice under applicable state law.

(4) *Documentation.* Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the Public Health Emergency, as defined in §400.200 of this chapter, to document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements in paragraph (a)(3) of this section at the time of admission, the patient's medical record at the IRF must contain the following documentation—

(i) A comprehensive preadmission screening that meets all of the following requirements—

(A) It is conducted by a licensed or certified clinician(s) designated by a rehabilitation physician within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as

long as an update is conducted in person or by telephone to update the patient's medical and functional status within the 48 hours immediately preceding the IRF admission and is documented in the patient's medical record.

(B) It includes a detailed and comprehensive review of each patient's condition and medical history, including the patient's level of function prior to the event or condition that led to the patient's need for intensive rehabilitation therapy, expected level of improvement, and the expected length of time necessary to achieve that level of improvement; an evaluation of the patient's risk for clinical complications; the conditions that caused the need for rehabilitation; the treatments needed (that is, physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics); and anticipated discharge destination.

(C) It serves as the basis for the initial determination of whether or not the patient meets the requirements for an IRF admission to be considered reasonable and necessary in paragraph (a)(3) of this section.

(D) It is used to inform a rehabilitation physician who reviews and documents his or her concurrence with the findings and results of the preadmission screening prior to the IRF admission.

(E) It is retained in the patient's medical record at the IRF.

(ii) An individualized overall plan of care for the patient that meets all of the following requirements—

(A) It is developed by a rehabilitation physician with input from the interdisciplinary team within 4 days of the patient's admission to the IRF.

(B) It is retained in the patient's medical record at the IRF.

(5) *Interdisciplinary team approach to care.* Except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the Public Health Emergency, as defined in §400.200 of this chapter, in order for an IRF claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, the patient must require an interdisciplinary team approach to care, as evidenced by documentation in the patients' medical record of weekly interdisciplinary team meetings that meet all of the following requirements—

(i) The team meetings are led by a rehabilitation physician and further consist of a registered nurse with specialized training or experience in rehabilitation; a social worker or case manager (or both); and a licensed or certified therapist from each therapy discipline involved in treating the patient. All team members must have current knowledge of the patient's medical and functional status. The rehabilitation physician may lead the interdisciplinary team meeting remotely via a mode of communication such as video or telephone conferencing.

(ii) The team meetings occur at least once per week throughout the duration of the patient's stay to implement appropriate treatment services; review the patient's progress toward stated rehabilitation goals; identify any problems that could impede progress towards those goals; and, where necessary, reassess previously established goals in light of impediments, revise the treatment plan in light of new goals, and monitor continued progress toward those goals.

(iii) The results and findings of the team meetings, and the concurrence by the rehabilitation physician with those results and findings, are retained in the patient's medical record.

(b) *Payment in full.* (1) The payment made under this subpart represents payment in full (subject to applicable deductibles and coinsurance as described in subpart G of part 409 of this subchapter) for inpatient operating and capital-related costs associated with furnishing Medicare covered services in an inpatient rehabilitation facility, but not for the cost of an approved medical education program described in §§413.75 and 413.85 of this chapter.

(2) In addition to payments based on prospective payment rates, inpatient rehabilitation facilities receive payments for the following:

(i) Bad debts of Medicare beneficiaries, as provided in §413.89 of this chapter; and

(ii) A payment amount per unit for blood clotting factor provided to Medicare inpatients who have hemophilia.

(c) *Definitions.* As used in this section—

Rehabilitation physician means a licensed physician who is determined by the IRF to have specialized training and experience in inpatient rehabilitation.

State (or region, as applicable) that is experiencing a surge means a state (or region, as applicable) that is in phase 1 of the President's Guidelines for Opening Up America Again (*https://www.whitehouse.gov/openingamerica/*), specifically, a state (or region, as applicable) that satisfies all of the following, as determined by applicable state and local officials:

(i) All vulnerable individuals continue to shelter in place.

(ii) Individuals continue social distancing.

(iii) Individuals avoid socializing in groups of more than 10.

(iv) Non-essential travel is minimized.

(v) Visits to senior living facilities and hospitals are prohibited.

(vi) Schools and organized youth activities remain closed.

Week means a period of 7 consecutive calendar days beginning with the date of admission to the IRF.

[66 FR 41388, Aug. 7, 2001, as amended at 70 FR 47952, Aug. 15, 2005; 74 FR 39811, Aug. 7, 2009; 83 FR 38573,Aug. 6, 2018; 84 FR 39172, Aug. 8, 2019; 85 FR 19287, Apr. 6, 2020; 85 FR 27622, May 8, 2020; 85 FR 48462, Aug. 10, 2020; 85 FR 59023, Sept. 18, 2020]

§ 412.624 Methodology for calculating the Federal prospective payment rates.

(a) *Data used.* To calculate the prospective payment rates for inpatient hospital services furnished by inpatient rehabilitation facilities, we use—

(1) The most recent Medicare data available, as of the date of establishing the inpatient rehabilitation facility prospective payment system, to estimate payments for inpatient operating and capital-related costs made under part 413 of this subchapter;

(2) An appropriate wage index to adjust for area wage differences;

(3) An increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient rehabilitation services; and

(4) Patient assessment data described in § 412.606 and other data that account for the relative resource utilization of different patient types.

(b) *Determining the average costs per discharge for fiscal year 2001.* We determine the average inpatient operating and capital costs per discharge for which payment is made to each inpatient rehabilitation facility using the available data specified under paragraph (a)(1) of this section. The cost per discharge is adjusted to fiscal year 2001 by an increase factor, described in paragraph (a)(3) of this section, under the update methodology described in section 1886(b)(3)(B)(ii) of the Act for each year through the midpoint of fiscal year 2001.

(c) *Determining the Federal prospective payment rates*—(1) *General.* The Federal prospective payment rates will be established using a standard payment amount referred to as the standard payment conversion factor. The standard payment conversion factor is a standardized payment amount based on average costs from a base year that reflects the combined aggregate effects of the weighting factors, various facility and case level adjustments, and other adjustments.

(2) *Update the cost per discharge.* CMS applies the increase factor described in paragraph (a)(3) of this section to the facility's cost per discharge determined under paragraph (b) of this section to compute the cost per discharge for fiscal year 2002. Based on the updated cost per discharge, CMS estimates the payments that would have been made to the facility for fiscal year 2002 under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Computation of the standard payment conversion factor.* The standard payment conversion factor is computed as follows:

(i) *For fiscal year 2002.* Based on the updated costs per discharge and estimated payments for fiscal year 2002 determined in paragraph (c)(2) of this section, CMS computes a standard payment conversion factor for fiscal year 2002, as specified by CMS, that reflects,

as appropriate, the adjustments described in paragraph (d) of this section.

(ii) *For fiscal years after 2002.* The standard payment conversion factor for fiscal years after 2002 will be the standardized payments for the previous fiscal year updated by the increase factor described in paragraph (a)(3) of this section, including adjustments described in paragraph (d) of this section as appropriate.

(4) Applicable increase factor for FY 2014 and for subsequent FY. Subject to the provisions of paragraphs (c)(4)(i) and (c)(4)(ii) of this section, the applicable increase factor for FY 2014 and for subsequent years for updating the standard payment conversion factor is the increase factor described in paragraph (a)(3) of this section, including adjustments described in paragraph (d) of this section as appropriate.

(i) In the case of an IRF that is paid under the prospective payment system specified in § 412.1(a)(3) that does not submit quality data to CMS in accordance with § 412.634, the applicable increase factor specified in paragraph (a)(3) of this section, after application of subparagraphs (C)(iii) and (D) of section 1886(j)(3) of the Act, is reduced by 2 percentage points.

(ii) Any reduction of the increase factor will apply only to the fiscal year involved and will not be taken into account in computing the applicable increase factor for a subsequent fiscal year.

(iii) The 2 percentage point reduction described in paragraph (c)(4)(i) of this section may result in the applicable increase factor specified in paragraph (a)(3) of this section being less than 0.0 for a fiscal year, and may result in payment rates under the prospective payment system specified in § 412.1(a)(3) for a fiscal year being less than such payment rates for the preceding fiscal year.

(5) *Determining the Federal prospective payment rate for each case-mix group.* The Federal prospective payment rates for each case-mix group is the product of the weighting factors described in § 412.620(b) and the standard payment conversion factor described in paragraph (c)(3) of this section.

(d) *Adjustments to the standard payment conversion factor.* The standard payment conversion factor described in paragraph (c)(3) of this section will be adjusted for the following:

(1) *Outlier payments.* CMS determines a reduction factor equal to the estimated proportion of additional outlier payments described in paragraph (e)(5) of this section.

(2) *Budget neutrality.* CMS adjusts the Federal prospective payment rates for fiscal year 2002 so that aggregate payments under the prospective payment system, excluding any additional payments associated with elections not to be paid under the transition period methodology under § 412.626(b), are estimated to equal the amount that would have been made to inpatient rehabilitation facilities under part 413 of this chapter without regard to the prospective payment system implemented under this subpart.

(3) *Coding and classification changes.* CMS adjusts the standard payment conversion factor for a given year if CMS determines that revisions in case-mix classifications or weighting factors for a previous fiscal year (or estimates that those revisions for a future fiscal year) did result in (or would otherwise result in) a change in aggregate payments that are a result of changes in the coding or classification of patients that do not reflect real changes in case-mix.

(4) *Payment adjustment for Federal fiscal year 2006 and applicable Federal fiscal years.* CMS adjusts the standard payment conversion factor based on any updates to the adjustments specified in paragraph (e)(2), (3), (4) and (6), of this section, and to any revision specified in § 412.620(c) by a factor as specified by the Secretary.

(e) *Calculation of the adjusted Federal prospective payment.* For each discharge, an inpatient rehabilitation facility's Federal prospective payment is computed on the basis of the Federal prospective payment rate that is in effect for its cost reporting period that begins in a Federal fiscal year specified under paragraph (c) of this section. A facility's Federal prospective payment rate will be adjusted, as appropriate, to account for area wage levels, payments for outliers and transfers, and for other factors as follows:

(1) *Adjustment for area wage levels.* The labor portion of a facility's Federal prospective payment is adjusted to account for geographical differences in the area wage levels using an appropriate wage index.

(i) The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in §412.602.

(ii) Starting on October 1, 2022, CMS applies a cap on decreases to the wage index such that the wage index applied to an IRF is not less than 95 percent of the wage index applied to that IRF in the prior FY.

(iii) Adjustments or updates to the wage data used to adjust a facility's Federal prospective payment rate under paragraph (e)(1) of this section will be made in a budget neutral manner. CMS determines a budget neutral wage adjustment factor, based on any adjustment or update to the wage data, to apply to the standard payment conversion factor.

(2) *Adjustments for low-income patients.* We adjust the Federal prospective payment, on a facility basis, for the proportion of low-income patients that receive inpatient rehabilitation services as determined by us.

(3) *Adjustments for rural areas.* We adjust the Federal prospective payment by a factor, as specified by us for facilities located in rural areas, as defined in §412.602.

(4) *Adjustments for teaching hospitals.* (i) *General.* For discharges on or after October 1, 2005, CMS adjusts the Federal prospective payment on a facility basis by a factor as specified by CMS for facilities that are teaching institutions or units of teaching institutions.

(A) An IRF's teaching adjustment is based on the ratio of the number of full-time equivalent residents training in the IRF divided by the facility's average daily census.

(B) As described in §412.105(f)(1)(iii)(A), residents with less than full-time status are counted as partial full time equivalent based on the proportion of time assigned to the inpatient rehabilitation facility compared to the total time necessary to fill a residency slot. Residents rotating to more than one hospital or non-hospital setting will be counted in proportion to the time they are assigned to inpatient rehabilitation facility compared to the total time worked in all locations. An inpatient rehabilitation facility cannot claim time spent by the resident at another inpatient rehabilitation facility or hospital.

(C) Except as described in paragraph (e)(4)(i)(D) of this section, the actual number of current year full-time equivalent residents used in calculating the teaching adjustment is limited to the number of full-time equivalent residents in the IRF's final settled cost report for the most recent cost reporting period ending on or before November 15, 2004 (base year).

(D) If the inpatient rehabilitation facility first begins training residents in a new approved graduate medical education program after November 15, 2004, the number of full-time equivalent residents determined under paragraph (e)(4)(i)(C) of this section may be adjusted using the method described in §413.79(e)(1)(i).

(E) The teaching adjustment is made on a claim basis as an interim payment, and the final payment in full for the claim is made during the final settlement of the cost report.

(ii) *Closure of an IRF or IRF residency training program.* (A) *Closure of an IRF.* For cost reporting periods beginning on or after October 1, 2011, an IRF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of another IRFs closure if the IRF meets the following criteria:

(*1*) The IRF is training additional displaced residents from an IRF that closed on or after October 1, 2011.

(*2*) No later than 60 days after the IRF begins to train the displaced residents, the IRF submits a request to its Medicare contractor for a temporary adjustment by identifying the displaced residents who have come from the closed IRF and have caused the IRF to exceed its cap, and specifies the length of time the adjustment is needed.

(B) *Closure of an IRF's residency training program.* If an IRF that closes its residency training program on or after October 1, 2011, agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (e)(4)(ii)(A)(*2*) of this section, another

IRF(s) may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of the residency training program if the criteria specified in paragraph (e)(4)(ii)(A)(*1*) of this section are met.

(*1*) *Receiving IRF(s).* For cost reporting periods beginning on or after October 1, 2011, an IRF may receive a temporary adjustment to its FTE cap to reflect displaced residents added because of the closure of another IRF's residency training program if the IRF is training additional displaced residents from the residency training program of an IRF that closed a program; and if no later than 60 days after the IRF begins to train the displaced residents the IRF submits to its Medicare Contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the displaced residents who have come from another IRF's closed program and have caused the IRF to exceed its cap, specifies the length of time the adjustment is needed, and submits to its Medicare Contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (e)(4)(ii)(A)(*2*) of this section.

(*2*) *IRF that closed its program.* An IRF that agrees to train displaced residents who have been displaced by the closure of another IRF's program may receive a temporary FTE cap adjustment only if the hospital with the closed program temporarily reduces its FTE cap based on the FTE of displaced residents in each program year training in the program at the time of the programs closure. This yearly reduction in the FTE cap will be determined based on the number of those displaced residents who would have been training in the program during that year had the program not closed. No later than 60 days after the displaced residents who were in the hospital that closed its program(s) begin training at another hospital must submit to its Medicare Contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the IRF training the displaced residents to obtain a temporary adjustment to its cap; identifies the displaced residents who were in the training at the time of the program's closure; identifies the IRFs to which the displaced residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(5) *Adjustment for high-cost outliers.* CMS provides for an additional payment to an inpatient rehabilitation facility if its estimated costs for a patient exceed a fixed dollar amount (adjusted for area wage levels and factors to account for treating low-income patients, for rural location, and for teaching programs) as specified by CMS. The additional payment equals 80 percent of the difference between the estimated cost of the patient and the sum of the adjusted Federal prospective payment computed under this section and the adjusted fixed dollar amount. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will be subject to the adjustments at §412.84(i), except that CMS calculates a single overall (combined operating and capital) cost-to-charge ratio and national averages that will be used instead of statewide averages. Effective for discharges occurring on or after October 1, 2003, additional payments made under this section will also be subject to adjustments at §412.84(m), except that CMS calculates a single overall (combined operating and capital) cost-to-charge ratio.

(6) *Adjustments for certain facilities geographically redesignated in FY 2006—*(i) *General.* For a facility defined as an urban facility under §412.602 in FY 2006 that was previously defined as a rural facility in FY 2005 as the term rural was defined in FY 2005 under §412.602 and whose payment, after applying the adjustment under this paragraph, will be lower only because of being defined as an urban facility in FY 2006 and it no longer qualified for the rural adjustment under §412.624(e)(3) in FY 2006, CMS will adjust the facility's payment using the following method:

(A) For discharges occurring on or after October 1, 2005, and on or before September 30, 2006, the facility's payment will be increased by an adjustment of two thirds of its prior FY 2005 19.14 percent rural adjustment.

(B) For discharges occurring on or after October 1, 2006, and on or before September 30, 2007, the facility's payment will be increased by an adjustment of one third of its FY 2005 19.14 percent rural adjustment.

(ii) *Exception.* For discharges occurring on or after October 1, 2005 and on or before September 30, 2007, facilities whose payments, after applying the adjustment under this paragraph (e)(7)(i) of this section, will be higher because of being defined as an urban facility in FY 2006 and no longer being qualified for the rural adjustment under §412.624(e)(3) in FY 2006, CMS will adjust the facility's payment by a portion of the applicable additional adjustment described in paragraph (e)(6)(i)(A) and (B) of this section as determined by us.

(f) *Special payment provision for patients that are transferred.* (1) A facility's Federal prospective payment will be adjusted to account for a discharge of a patient who—

(i) Is transferred from the inpatient rehabilitation facility to another site of care, as defined in §412.602; and

(ii) Stays in the facility for a number of days that is less than the average length of stay for nontransfer cases in the case-mix group to which the patient is classified.

(2) We calculate the adjusted Federal prospective payment for patients who are transferred in the following manner:

(i) By dividing the Federal prospective payment by the average length of stay for nontransfer cases in the case-mix group to which the patient is classified to equal the payment per day.

(ii) By multiplying the payment per day under paragraph (f)(2)(i) of this section by the number of days the patient stayed in the facility prior to being discharged to equal the per day payment amount.

(iii) By multiplying the payment per day under paragraph (f)(2)(i) by 0.5 to equal an additional one half day payment for the first day of the stay before the discharge.

(iv) By adding the per day payment amount under paragraph (f)(2)(ii) and the additional one-half day payment under paragraph (f)(2)(iii) to equal the unadjusted payment amount.

(v) By applying the adjustment described in paragraphs (e)(1), (2), (3), (4), and (6) of this section to the unadjusted payment amount determined in paragraph (f)(2)(iv) of this section to equal the adjusted transfer payment amount and making a payment in accordance with paragraph (e)(5) of this section, if applicable.

(g) *Special payment provision for interrupted stays.* When a patient in an inpatient rehabilitation facility has one or more interruptions in the stay, as defined in §412.602 and as indicated on the patient assessment instrument in accordance with §412.618(b), we will make payments in the following manner:

(1) *Patient is discharged and returns on the same day.* Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will be the adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in §412.618(a)(1). Payment for a patient who is discharged and returns to the same inpatient rehabilitation facility on the same day will only be made to the inpatient rehabilitation facility.

(2) *Patient is discharged and does not return by the end of the same day.* Payment for a patient who is discharged and does not return on the same day but does return to the same inpatient rehabilitation facility by or on midnight of the third day, defined as an interrupted stay under §412.602, will be—

(i) The adjusted Federal prospective payment under paragraph (e) of this section that is based on the patient assessment data specified in §412.618(a)(1) made to the inpatient rehabilitation facility; and

(ii) If the reason for the interrupted patient stay is to receive inpatient acute care hospital services, an amount based on the prospective payment systems described in §412.1(a)(1) made to the acute care hospital.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002; 68 FR 45700, Aug. 1, 2003; 70 FR 47952, Aug. 15, 2005; 71 FR 48408, Aug. 18, 2006; 72 FR 44312, Aug. 7, 2007; 76 FR 47892, Aug. 5, 2011; 82 FR 36305, Aug. 3, 2017; 83 FR 38573, Aug. 6, 2018; 87 FR 47091, Aug. 1, 2022]

§ 412.626 Transition period.

(a) *Duration of transition period and proportion of the blended transition rate.* (1) Except for a facility that makes an election under paragraph (b) of this section, for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, an inpatient rehabilitation facility receives a payment comprised of a blend of the adjusted Federal prospective payment, as determined under §412.624(e) or §412.624(f) and a facility-specific payment as determined under paragraph (a)(2) of this section.

(i) For cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002, payment is based on 33⅓ percent of the facility-specific payment and 66⅔ percent of the adjusted FY 2002 Federal prospective payment.

(ii) For cost reporting periods beginning on or after October 1, 2002, payment is based entirely on the adjusted Federal prospective payment.

(2) *Calculation of the facility-specific payment.* The facility-specific payment is equal to the payment for each cost reporting period in the transition period that would have been made without regard to this subpart. The facility's Medicare fiscal intermediary calculates the facility-specific payment for inpatient operating costs and capital-related costs in accordance with part 413 of this chapter.

(b) *Election not to be paid under the transition period methodology.* An inpatient rehabilitation facility may elect a payment that is based entirely on the adjusted Federal prospective payment for cost reporting periods beginning before fiscal year 2003 without regard to the transition period percentages specified in paragraph (a)(1)(i) of this section.

(1) *General requirement.* An inpatient rehabilitation facility will be required to request the election under this paragraph (b) within 30 days of its first cost reporting period for which payment is based on the inpatient rehabilitation facility prospective payment system for cost reporting periods beginning on or after January 1, 2002 and before October 1, 2002.

(2) *Notification requirement to make election.* The request by the inpatient rehabilitation facility to make the election under this paragraph (b) must be made in writing to the Medicare fiscal intermediary. The intermediary must receive the request on or before the 30th day before the applicable cost reporting period begins, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the 30th day before the cost reporting period begins will not be approved. If the 30th day before the cost reporting period begins falls on a day that the postal service or other delivery sources are not open for business, the inpatient rehabilitation facility is responsible for allowing sufficient time for the delivery of the request before the deadline. If an inpatient rehabilitation facility's request is not received timely or is otherwise not approved, payment will be based on the transition period rate specified in paragraph (a)(1)(i) of this section.

[66 FR 41388, Aug. 7, 2001, as amended at 67 FR 44077, July 1, 2002]

§ 412.628 Publication of the Federal prospective payment rates.

We publish information pertaining to the inpatient rehabilitation facility prospective payment system effective for each fiscal year in the FEDERAL REGISTER. This information includes the unadjusted Federal payment rates, the patient classification system and associated weighting factors, and a description of the methodology and data used to calculate the payment rates. This information is published on or before August 1 prior to the beginning of each fiscal year.

§ 412.630 Limitation on review.

Administrative or judicial review under sections 1869 or 1878 of the Act, or otherwise, is prohibited with regard to the establishment of the methodology to classify a patient into the case-mix groups and the associated weighting factors, the Federal per discharge payment rates, additional payments for outliers and special payments, and the area wage index.

[78 FR 47934, Aug. 6, 2013]

§ 412.632 Method of payment under the inpatient rehabilitation facility prospective payment system.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, an inpatient rehabilitation facility receives payment under this subpart for inpatient operating costs and capital-related costs for each discharge only following submission of a discharge bill.

(b) *Periodic interim payments*—(1) *Criteria for receiving periodic interim payments.* (i) An inpatient rehabilitation facility receiving payment under this subpart may receive periodic interim payments (PIP) for Part A services under the PIP method subject to the provisions of § 413.64(h) of this subchapter.

(ii) To be approved for PIP, the inpatient rehabilitation facility must meet the qualifying requirements in § 413.64(h)(3) of this subchapter.

(iii) Payments to a rehabilitation unit are made under the same method of payment as the hospital of which it is a part as described in § 412.116.

(iv) As provided in § 413.64(h)(5) of this chapter, intermediary approval is conditioned upon the intermediary's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* For facilities approved for PIP, the intermediary estimates the inpatient rehabilitation facility's Federal prospective payments net of estimated beneficiary deductibles and coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If the inpatient rehabilitation facility has payment experience under the prospective payment system, the intermediary estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this subchapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP.* (i) *Request by the inpatient rehabilitation facility.* Subject to the provisions of paragraph (b)(1)(iii) of this section, an inpatient rehabilitation facility receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the intermediary.* An intermediary terminates PIP if the inpatient rehabilitation facility no longer meets the requirements of § 413.64(h) of this chapter.

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the intermediary determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6) of this chapter. The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an inpatient rehabilitation facility receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Outlier payments.* Additional payments for outliers are not made on an interim basis. The outlier payments are made based on the submission of a discharge bill and represent final payment.

(e) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to an inpatient rehabilitation facility that is receiving payment under this subpart and is not receiving PIP under paragraph (b) of this section if the inpatient rehabilitation facility is experiencing financial difficulties because of the following:

(i) There is a delay by the intermediary in making payment to the inpatient rehabilitation facility.

(ii) Due to an exceptional situation, there is a temporary delay in the inpatient rehabilitation facility's preparation and submittal of bills to the intermediary beyond its normal billing cycle.

(2) *Approval of payment.* An inpatient rehabilitation facility's request for an accelerated payment must be approved by the intermediary and us.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as inpatient rehabilitation facility bills are processed or by direct payment by the inpatient rehabilitation facility.

§ 412.634 Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP).

(a) *Participation.*(1) For the FY 2018 payment determination and subsequent years, an IRF must begin reporting data under the IRF QRP requirements no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the IRF as operating in the CMS designated data submission system.

(2) [Reserved]

(b) *Submission requirements.* (1) IRFs must submit to CMS data on measures specified under sections 1886(j)(7)(D), 1899B(c)(1), 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act, as applicable. Such data must be submitted in the form and manner, and at a time, specified by CMS.

(2) CMS may remove a quality measure from the IRF QRP based on one or more of the following factors:

(i) Measure performance among IRFs 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) The 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) *Exception and Extension Requirements.* (1) An IRF may request and CMS may grant exceptions or extensions to the measures data or standardized patient assessment data reporting requirements, for one or more quarters, when there are certain extraordinary circumstances beyond the control of the IRF.

(2) An IRF must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred.

(3) Exception and extension requests must be submitted to CMS from the IRF by sending an email to *IRFQRPReconsiderations@cms.hhs.gov* containing all of the following information:

(i) IRF CMS Certification Number (CCN).

(ii) IRF Business Name.

(iii) IRF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) IRF's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the IRF believes it will be able to again submit IRF QRP data and a justification for the proposed date.

(4) CMS may grant exceptions or extensions to IRFs without a request if it is determined that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of an IRF to submit data.

(5) Email is the only form of submission that will be accepted. Any reconsideration requests received through another channel will not be considered as a valid exception or extension request.

(d) *Reconsideration.* (1) IRFs that do not meet the requirement in paragraph (b) of this section for a program year will receive a written notification of non-compliance through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

(2) Reconsideration requests must be submitted to CMS by sending an email to *IRFQRPReconsiderations@cms.hhs.gov* containing all of the following information:

(i) IRF CCN.

(ii) IRF Business Name.

(iii) IRF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration.

(3) The request for reconsideration must be accompanied by supporting documentation demonstrating compliance. This documentation must be submitted electronically as an attachment to the reconsideration request email. Any request for reconsideration that does not contain sufficient evidence of compliance with the IRF QRP requirements will be denied.

(4) Email is the only form of submission that will be accepted. Any reconsideration requests received through another channel will not be considered as a valid exception or extension request.

(5) CMS will notify IRFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

(e) *Appeals.* (1) An IRF may appeal the decision made by CMS on its reconsideration request by filing with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(2) [Reserved]

(f) *Data Completion Thresholds.* (1) IRFs must meet or exceed two separate data completeness thresholds: One threshold set at 95 percent for completion of required quality measures data and standardized patient assessment data collected using the IRF–PAI submitted through the CMS designated data submission system; and a second threshold set at 100 percent for measures data collected and submitted using the CDC NHSN.

(2) These thresholds (95 percent for completion of required quality measures data and standardized patient assessment data on the IRF–PAI; 100 percent for CDC NHSN data) will apply to all measures and standardized patient assessment data requirements adopted into the IRF QRP.

(3) An IRF must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates.

[80 FR 47138, Aug. 6, 2015, as amended at 81 FR 52140, Aug. 5, 2016; 82 FR 36305, Aug. 3, 2017; 83 FR 38573, Aug. 6, 2018; 84 FR 39172, Aug. 8, 2019]

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

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Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

AUTHORITY: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

SOURCE: 51 FR 34793, Sept. 30, 1986, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 413 appear at 76 FR 50537, August 22, 2014.

Subpart A—Introduction and General Rules

§ 413.1 Introduction.

(a) *Basis, scope, and applicability*—(1) *Statutory basis*—(i) *Basic provisions.* (A) Section 1815 of the Act requires that the Secretary make interim payments to providers and periodically determine the amount that should be paid under Part A of Medicare to each provider for the services it furnishes.

(B) Section 1814(b) of the Act (for Part A) and section 1833(a) (for Part B) provide for payment on the basis of the lesser of a provider's reasonable costs or customary charges.

(C) Section 1861(v) of the Act defines ''reasonable cost''.

(ii) *Additional provisions.* (A) Section 1138(b) of the Act specifies the conditions for Medicare payment for organ procurement costs.

(B) Section 1814(j) of the Act provides for exceptions to the ''lower of costs or charges'' provisions.

(C) Sections 1815(a) and 1833(e) of the Act provide the Secretary with authority to request information from providers to determine the amount of Medicare payment due providers.

(D) Section 1833(a)(4) and (i)(3) of the Act provide for payment of a blended amount for certain surgical services furnished in a hospital's outpatient department.

(E) Section 1833(n) of the Act provides for payment of a blended amount for outpatient hospital diagnostic procedures such as radiology.

(F) Section 1834(c)(1)(C) of the Act establishes the method for determining Medicare payment for screening mammograms performed by hospitals.

(G) Section 1834(g) of the Act provides that payment for critical access hospital (CAH) outpatient services is the reasonable costs of the CAH in providing these services, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter.

(H) Section 1881 of the Act authorizes payment for services furnished to ESRD patients.

(I) Section 1883 of the Act provides for payment for post-hospital SNF care furnished by a rural hospital that has swing-bed approval.

(J) Sections 1886(a) and (b) of the Act impose a ceiling on the rate of increase in hospital inpatient costs.

(K) Section 1886(h) of the Act provides for payment to a hospital for the services of interns and residents in approved teaching programs on the basis of a ''per resident'' amount.

(L) Section 1834(x) of the Act authorizes payment for services furnished by rural emergency hospitals (REHs) and establishes the payment methodology.

(2) *Scope.* This part sets forth regulations governing Medicare payment for services furnished to beneficiaries by—

(i) Hospitals, critical access hospitals (CAHs), and rural emergency hospitals (REHs);

(ii) Skilled nursing facilities (SNFs);

(iii) Home health agencies (HHAs);

(iv) End-stage renal disease (ESRD) facilities;

(v) Organ procurement organizations (OPOs) and histocompatibility laboratories.

(3) *Applicability.* The payment principles and related policies set forth in this part are binding on CMS and its fiscal contractors, on the Provider Reimbursement Review Board, and on the entities listed in paragraph (a)(2) of this section.

(b) *Reasonable cost reimbursement.* Except as provided under paragraphs (c) through (h) of this section, Medicare is generally required, under section 1814(b) of the Act (for services covered under Part A) and under section 1833(a)(2) of the Act (for services covered under Part B) to pay for services furnished by providers on the basis of reasonable costs as defined in section 1861(v) of the Act, or the provider's customary charges for those services, if lower. Regulations implementing section 1861(v) are found generally in this part beginning at §413.5.

(c) *Outpatient maintenance dialysis and related services.* Section 1881 of the Act authorizes special rules for the coverage of and payment for services furnished to ESRD patients. Sections 413.170 and 413.174 implement various provisions of section 1881. In particular, §413.170 establishes a prospective payment method for outpatient maintenance dialysis services that applies both to hospital-based and independent ESRD facilities, and under which Medicare pays for both home and infacility dialysis services furnished on or after August 1, 1983.

(d) *Payment for inpatient hospital services.* (1) For cost reporting periods beginning before October 1, 1983, the amount paid for inpatient hospital services is determined on a reasonable cost basis.

(2) Payment to short-term general hospitals located in the 50 States and the District of Columbia for the operating costs of hospital inpatient services for cost reporting periods beginning on or after October 1, 1983, and for the capital-related costs of inpatient services for cost reporting periods beginning on or after October 1, 1991, are determined prospectively on a per discharge basis under part 412 of this chapter except as follows:

(i) Payment for the following is described in §412.113 of this chapter:

(A) Capital related costs for cost reporting periods beginning before October 1991.

(B) Medical education costs.

(C) Organ acquisition costs as specified in part 413, subpart L.

(D) The costs of certain anesthesia services.

(ii) Payment to children's hospitals that are excluded from the prospective payment systems under subpart B of part 412 of this chapter, and hospitals outside the 50 States and the District of Columbia is on a reasonable cost basis, subject to the provisions of §413.40.

(iii) Payment to hospitals subject to a State reimbursement control system is described in paragraph (e) of this section.

(iv) For cost reporting periods beginning before January 1, 2005, payment to psychiatric hospitals (as well as separate psychiatric units (distinct parts) of short-term general hospitals) that are excluded under subpart B of part 412 of this chapter from the prospective payment system is on a reasonable cost basis, subject to the provisions of §413.40.

(v) For cost reporting periods beginning on or after January 1, 2005, payment to inpatient psychiatric facilities that meet the conditions of §412.404 of this chapter, is made under the prospective payment system described in subpart N of part 412 of this chapter.

(vi) For cost reporting periods beginning before January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals), that are excluded under subpart B of part 412 of this subchapter from the prospective payment systems is made on a reasonable cost basis, subject to the provisions of §413.40.

(vii) For cost reporting periods beginning on or after January 1, 2002, payment to rehabilitation hospitals (as well as separate rehabilitation units (distinct parts) of short-term general hospitals) that meet the conditions of §412.604 of this chapter is based on prospectively determined rates under subpart P of part 412 of this subchapter.

(viii) For cost reporting periods beginning before October 1, 2002, payment to long-term care hospitals that are excluded under subpart B of Part 412 of this subchapter from the prospective payment systems is on a reasonable cost basis, subject to the provisions of § 413.40.

(ix) For cost reporting periods beginning on or after October 1, 2002, payment to the long-term hospitals that meet the condition for payment of §§ 412.505 through 412.511 of this subchapter is based on prospectively determined rates under subpart O of Part 412 of this subchapter.

(e) *State reimbursement control systems.* Beginning October 1, 1983, Medicare reimbursement for inpatient hospital services may be made in accordance with a State reimbursement control system rather than under the Medicare reimbursement principles set forth in this part, if the State system is approved by CMS. Regulations implementing this alternative reimbursement authority are set forth in subpart C of part 403 of this chapter.

(f) *Services of qualified nonphysician anesthetists.* For cost reporting periods, or any part of a cost reporting period, beginning on or after January 1, 1989, costs incurred for the services of qualified nonphysician anesthetists are not paid on a reasonable cost basis unless the provisions of § 412.113(c)(2) of this chapter apply. These services are paid under the special rules set forth in § 405.553 of this chapter.

(g) *Payment for services furnished in SNFs.* (1) Except as specified in paragraph (g)(2)(ii) of this section, the amount paid for services furnished in cost reporting periods beginning before July 1, 1998, is determined on a reasonable cost basis or, where applicable, in accordance with the prospectively determined payment rates for low-volume SNFs established under section 1888(d) of the Act, as set forth in subpart I of this part.

(2) The amount paid for services (other than those described in § 411.15(p)(2) of this chapter)—

(i) That are furnished in cost reporting periods beginning on or after July 1, 1998, to a resident who is in a covered Part A stay, is determined in accordance with the prospectively determined payment rates for SNFs established under section 1888(e) of the Act, as set forth in subpart J of this part.

(ii) That are furnished on or after July 1, 1998, to a resident who is not in a covered Part A stay, is determined in accordance with any applicable Part B fee schedule or, for a particular item or service to which no fee schedule applies, by using the existing payment methodology utilized under Part B for such item or service.

(h) *Payment for services furnished by HHAs.* The amount paid for home health services as defined in section 1861(m) of the Act (except durable medical equipment and the covered osteoporosis drug as provided for in that section) that are furnished beginning on or after October 1, 2000 to an eligible beneficiary under a home health plan of care is determined according to the prospectively determined payment rates for HHAs set forth in part 484, subpart E of this chapter.

[51 FR 34793, Sept. 30, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.1, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 413.5 Cost reimbursement: General.

(a) In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution. However, payments to providers of services for services furnished Medicare beneficiaries

are subject to the provisions of §§413.13 and 413.30.

(b) Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.

(5) That the principles should result in the equitable treatment of both nonprofit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

(c) As formulated herein, the principles given recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and an allowance for a reasonable return on equity capital (in the case of certain proprietary providers). With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) [Reserved]

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although ''fringe benefit'' allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

(9) Reasonable cost of physicians' direct medical and surgical services (including supervision of interns and residents in the care of individual patients) furnished in a teaching hospital may be reimbursed as a provider cost (as described in §415.162 of this chapter) if elected as provided for in §415.160 of this chapter.

(d) In developing these principles of reimbursement for the Medicare program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for Medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. Although funding of depreciation is not required,

there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

(e) A return on the equity capital of proprietary facilities, as described in § 413.157, is an allowance in addition to the reasonable cost of covered services furnished to beneficiaries.

(f) Renal dialysis items and services furnished under the ESRD provision are reimbursed and reported under §§ 413.170 and 413.174 respectively. For special rules concerning health maintenance organizations (HMOs), and providers of services and other health care facilities that are owned or operated by an HMO, or related to an HMO by common ownership or control, see §§ 417.242(b)(14) and 417.250(c) of this chapter.

[51 FR 34793, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 57 FR 39829, Sept. 1, 1992; 60 FR 63189, Dec. 8, 1995; 61 FR 63748, Dec. 2, 1996]

§ 413.9 Cost related to patient care.

(a) *Principle.* All payments to providers of services must be based on the reasonable cost of services covered under Medicare and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in furnishing the services, subject to principles relating to specific items of revenue and cost. However, for cost reporting periods beginning after December 31, 1973, payments to providers of services are based on the lesser of the reasonable cost of services covered under Medicare and furnished to program beneficiaries or the customary charges to the general public for such services, as provided for in § 413.13.

(b) *Definitions*—(1) *Reasonable cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this part take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both Medicare and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services furnished to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs that are common and accepted occurrences in the field of the provider's activity.

(c) *Application.* (1) It is the intent of Medicare that payments to providers of services should be fair to the providers, to the contributors to the Medicare trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in Medicare for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation if a particular institution's costs are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of Medicare beneficiaries. Reasonable cost includes all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, if the provider's operating costs include amounts not related to patient care, specifically not reimbursable under the program, or flowing from the provision

of luxury items or services (that is, those items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services), such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

[51 FR 34795, Sept. 30, 1986; 51 FR 37398, Oct. 22, 1986]

§ 413.13 Amount of payment if customary charges for services furnished are less than reasonable costs.

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

Customary charges means the regular rates that providers charge both beneficiaries and other paying patients for the services furnished to them.

Fair compensation means the reasonable cost of covered services.

Nominal charge means a charge equal to 60 percent or less of the reasonable cost of a service.

Public provider means a provider operated by a Federal, State, county, city, or other local government agency or instrumentality.

Reasonable cost means cost actually incurred, to the extent that cost is necessary for the efficient delivery of the service, and subject to the exclusions specified in paragraph (d) of this section.

(b) *Application of the lesser of costs or charges (LCC) principle*—(1) *General rule.* Except as provided in paragraph (c) of this section, CMS pays providers the lesser of the reasonable cost or the customary charges for services furnished to Medicare beneficiaries. Reasonable cost and customary charges are compared separately for Part A services and Part B services.

(2) *Example.* (i) A provider's reasonable cost for covered services furnished to Medicare beneficiaries during a cost reporting period is $125,000.

(ii) The provider's customary charges for those services is $110,000.

(iii) CMS pays the provider $110,000 less the deductible and coinsurance amounts for which the beneficiaries are responsible.

(c) *Exceptions to the LCC principle*—(1) *Providers not subject to the LCC principle.* CMS pays the following providers the fair compensation for the services they furnish:

(i) CORFs.

(ii) Public providers that furnish services free of charge or at a nominal charge.

(iii) Any provider that requests payment of fair compensation and can demonstrate to its contractor that a significant portion of its patients are low income and that its charges are less than costs because its customary practice is to charge patients on the basis of their ability to pay.

(2) *Services not subject to the LCC principle.* The following services are not subject to the LCC principle:

(i) *Part A inpatient hospital services.* Inpatient hospital services are not subject to the LCC principle if they are subject to either of the following:

(A) The prospective payment system under part 412 of this chapter.

(B) The rate of increase limits set forth in § 413.40.

(ii) *Facility services related to ambulatory surgical procedures performed in outpatient hospital departments.* Facility services related to ambulatory surgical procedures performed in hospital outpatient departments are subject to the payment methodology set forth in § 413.118.

(iii) *Services furnished by a critical access hospital (CAH).* Inpatient and outpatient services furnished by a CAH are subject to the payment methodology set forth in § 413.70.

(iv) *Hospital outpatient radiology services.* Hospital outpatient radiology services are subject to the payment methodology set forth in § 413.122.

(v) *Other diagnostic procedures performed by a hospital on an outpatient basis.* Other outpatient diagnostic procedures are subject to the payment methodology set forth in § 413.122.

(vi) *Skilled nursing facility services.* Skilled nursing facility services subject to the payment methodology set forth in §§ 413.330 et seq.

(vii) Services furnished by a rural emergency hospital (REH). Services furnished by a rural emergency hospital are subject to the payment methodology set forth in part 419, subpart J, of this chapter.

(d) *Exclusions from reasonable cost.* For purposes of comparison with customary charges under this section, reasonable cost does not include the following:

(1) Payments made to a provider as reimbursement for bad debts arising from noncollection of Medicare deductible and coinsurance amounts, as provided in § 413.89.

(2) Amounts that represent the recovery of excess depreciation resulting from termination from the Medicare program or a decrease in Medicare utilization applicable to prior cost reporting periods, as provided in § 413.134.

(3) Amounts that result from disposition of depreciable assets, applicable to prior cost reporting periods, as provided in § 413.134.

(4) Payments to funds for the donated services of teaching physicians, as provided in § 413.85.

(5) Except as provided in paragraph (f)(2)(iii) of this section for making nominal charge determinations in special situations, graduate medical education costs.

(e) *Reductions in customary charges.* Customary charges are reduced in proportion to the ratio of the aggregate amount actually collected from charge-paying non-Medicare patients to the amount that would have been realized had customary charges been paid, if the provider—

(1) Did not actually impose charges on most of the patients liable for payment for its services on a charge basis; or

(2) Failed to make a reasonable effort to collect those charges.

(f) *Nominal charge determinations.* In determining whether a provider's customary charges equal 60 percent or less of its reasonable costs, the following rules apply:

(1) *General rule.* The determination is based on charges actually billed to charge-paying, non-Medicare patients, and (except for clinical diagnostic laboratory tests that are paid under section 1833(h) of the Act) is made separately for Part A services and Part B services.

(2) *Determination in special situations.* (i) *Charges based on ability to pay.* For providers that have a sliding scale or discounted charges based on patients' ability to pay, the determination—

(A) Is based on charges billed to all charge-paying patients;

(B) Uses the ratio of the sliding scale charges to the provider's full customary charges; and

(C) Applies the ratio to the discounted charges to equate those charges to customary charges.

(ii) *HHA services.* In determining nominal charges for HHAs, all Part A and Part B services, with the exception of DME, are considered together.

(iii) *Graduate medical education.* When making the nominal charge determination, graduate medical education payments (or the provider's reasonable costs for that education, if supported by appropriate data) are included in reasonable costs.

[65 FR 8661, Feb. 22, 2000, as amended at 70 FR 47487, Aug. 12, 2005; 87 FR 72287, Nov. 23, 2022]

§ 413.17 Cost to related organizations.

(a) *Principle.* Except as provided in paragraph (d) of this section, costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

(b) *Definitions*—(1) *Related to the provider.* Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) *Common ownership.* Common ownership exists if an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) *Control.* Control exists if an individual or an organization has the

power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

(c) *Application.* (1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

(d) *Exception.* (1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the contractor, that—

(i) The supplying organization is a bona fide separate organization;

(ii) A substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization;

(iii) The services, facilities, or supplies are those that commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and

(iv) The charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies.

(2) In such cases, the charge by the supplier to the provider for such services, facilities, or supplies is allowable as cost.

[51 FR 34793, Sept. 30, 1986, as amended at 81 FR 57270, Aug. 22, 2016]

Subpart B—Accounting Records and Reports

§ 413.20 Financial data and reports.

(a) *General.* The principles of cost reimbursement require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under Medicare involve making use of data available from the institution's basis accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

(b) *Frequency of cost reports.* Cost reports are required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal contractors will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

(c) *Recordkeeping requirements for new providers.* A newly participating provider of services (as defined in § 400.202 of this chapter) must make available to its selected contractor for examination

its fiscal and other records for the purpose of determining such provider's ongoing recordkeeping capability and inform the contractor of the date its initial Medicare cost reporting period ends. This examination is intended to assure that—

(1) The provider has an adequate ongoing system for furnishing the records needed to provide accurate cost data and other information capable of verification by qualified auditors and adequate for cost reporting purposes under section 1815 of the Act; and

(2) No financial arrangements exist that will thwart the commitment of the Medicare program to reimburse providers the reasonable cost of services furnished beneficiaries. The data and information to be examined include cost, revenue, statistical, and other information pertinent to reimbursement including, but not limited to, that described in paragraph (d) of this section and in § 413.24.

(d) *Continuing provider recordkeeping requirements.* (1) The provider must furnish such information to the contractor as may be necessary to—

(i) Assure proper payment by the program, including the extent to which there is any common ownership or control (as described in § 413.17(b)(2) and (3)) between providers or other organizations, and as may be needed to identify the parties responsible for submitting program cost reports;

(ii) Receive program payments; and

(iii) Satisfy program overpayment determinations.

(2) The provider must permit the contractor to examine such records and documents as are necessary to ascertain information pertinent to the determination of the proper amount of program payments due. These records include, but are not limited to, matters pertaining to—

(i) Provider ownership, organization, and operation;

(ii) Fiscal, medical, and other recordkeeping systems;

(iii) Federal income tax status;

(iv) Asset acquisition, lease, sale, or other action;

(v) Franchise or management arrangements;

(vi) Patient service charge schedules;

(vii) Costs of operation;

(viii) Amounts of income received by source and purpose; and

(ix) Flow of funds and working capital.

(3)(i) The provider must furnish the contractor, upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

(e) *Suspension of program payments to a provider.* If an contractor determines that a provider does not maintain or no longer maintains adequate records for the determination of reasonable cost under the Medicare program, payments to such provider will be suspended until the contractor is assured that adequate records are maintained. Before suspending payments to a provider, the contractor will, in accordance with the provisions in § 405.372(a) of this chapter, send written notice to such provider of its intent to suspend payments. The notice will explain the basis for the contractor's determination with respect to the provider's records and will identify the provider's recordkeeping deficiencies. The provider must be given the opportunity, in accordance with § 405.372(b) of this chapter, to submit a statement (including any pertinent evidence) as to why the suspension must not be put into effect.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63749, Dec. 2, 1996; 85 FR 59023, Sept. 18, 2020; 86 FR 45521, Aug. 13, 2021]

§ 413.24 Adequate cost data and cost finding.

(a) *Principle.* Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting, except for—

(1) Governmental institutions which operate on a cash basis method of accounting. Cost data based on such basis

of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

(2) Costs of qualified defined benefit pension plans shall be reported on a cash basis method of accounting, as described at § 413.100(c)(2)(vii)(D) for cost reporting periods beginning on or after October 1, 2011.

(b) *Definitions*—(1) *Cost finding.* Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services furnished. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) *Accrual basis of accounting.* As used in this part, the term *accrual basis of accounting* means that revenue is reported in the period in which it is earned, regardless of when it is collected; and an expense is reported in the period in which it is incurred, regardless of when it is paid. (See § 413.100 regarding limitations on allowable accrued costs in situations in which the related liabilities are not liquidated timely.)

(c) *Adequacy of cost information.* Adequate cost information must be obtained from the provider's records to support payments made for services furnished to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures if there is reason to effect such change.

(d) *Cost finding methods.* After the close of the accounting period, providers must use one of the following methods of cost finding to determine the actual costs of services furnished during that period. (These provisions do not apply to SNFs that elect and qualify for prospectively determined payment rates under subpart I of this part for cost reporting periods beginning on or after October 1, 1986. For the special rules that are applicable to those SNFs, see § 413.321.) For cost reporting periods beginning after December 31, 1971, providers using the departmental method of cost apportionment must use the step-down method described in paragraph (d)(1) of this section or an ''other method'' described in paragraph (d)(2) of this section. For cost reporting periods beginning after December 31, 1971, providers using the combination method of cost apportionment must use the modified cost finding method described in paragraph (d)(3) of this section. Effective for cost reporting periods beginning on or after October 1, 1980, HHAs not based in hospitals or SNFs must use the step-down method described in paragraph (d)(1) of this section. (HHAs based in hospitals or SNFs must use the method applicable to the parent institution.) However, an HHA not based in a hospital or SNF that received less than $35,000 in Medicare payment for the immediately preceding cost reporting period, and for whom this payment represented less than 50 percent of the total operating cost of the agency, may use a simplified version of the step-down method, as specified in instructions for the cost report issued by CMS.

(1) *Step-down method.* This method recognizes that services furnished by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers that they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered ''closed'' and no further costs are apportioned to that center. This applies even though it may have

received some service from a center whose cost is apportioned later. Generally, if two centers furnish services to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) *Other methods*—(i) *The double-apportionment method.* The double-apportionment method may be used by a provider upon approval of the contractor. This method also recognizes that the nonrevenue-producing departments or centers furnish services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of non-revenue-producing centers is made. These centers or departments are not ''closed'' after this preliminary allocation. Instead, they remain ''open,'' accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) *More sophisticated methods.* A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the contractor. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the contractor. Written request for the approval must be made on a prospective basis and must be submitted before the end of the fourth month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) *Modified cost finding for providers using the Combination Method for reporting periods beginning after December 31, 1971.* This method differs from the step-down method in that services furnished by nonrevenue-producing departments or centers are allocated directly to revenue-producing departments or centers even though these services may be utilized by other nonrevenue-producing departments or centers. In the application of this method the cost of nonrevenue-producing centers having a common basis of allocation are combined and the total distributed to revenue-producing centers. All nonrevenue-producing centers having significant percentages of cost in relation to total costs will be allocated this way. The combined total costs of remaining nonrevenue-producing costs centers will be allocated to revenue-producing cost centers in the proportion that each bears to total costs, direct and indirect, already allocated. The bases which are to be used and the centers which are to be combined for allocation are not optional but are identified and incorporated in the cost report forms developed for this method. Providers using this method must use the program cost report forms devised for it. Alternative forms may not be used without prior approval by CMS based upon a written request by the provider submitted through the contractor.

(4) *Temporary method for initial period.* If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the contractor for permission to use some other acceptable method that would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

(5) *Simplified optional reimbursement method for small, rural hospitals with distinct parts for cost reporting periods beginning on or after July 20, 1982.* (i) A rural hospital with a Medicare-certified distinct part SNF may elect to be reimbursed for services furnished in its hospital general routine service area and distinct part SNF using the reimbursement method specified in § 413.53 for swing-bed hospitals, if it meets the following conditions:

(A) The institution is located in a rural area as defined in § 482.58 of this chapter.

(B) On the first day of the cost reporting period, the hospital and distinct part SNF have fewer than 50 beds in total (with the exception of beds for newborns and beds in intensive care type inpatient units).

(ii) In applying the optional reimbursement method, only those beds located in the hospital general routine service area and in the distinct part SNF certified by Medicare are combined into a single cost center for purposes of cost finding.

(iii) The reasonable cost of the routine extended care services is determined in accordance with § 413.114(c). The reasonable cost of the hospital general routine services is determined in accordance with § 413.53(a)(2).

(iv) The hospital must make its election to use the optional swing-bed reimbursement method in writing to the contractor before the beginning of the hospital's cost reporting year. The hospital must make any request to revoke the election in writing before the beginning of the affected cost reporting period.

(v) The contractor must approve requests to terminate use of the optional swing-bed reimbursement method. If a hospital terminates use of this optional method, no further elections may be made by the facility to use the optional method.

(6) *Provider-based entities and departments: Preventing duplication of cost.* In some situations, the main provider in a provider-based complex may purchase services for a provider-based entity or for a department of the provider through a contract for services (for example, a management contract), directly assigning the costs to the provider-based entity or department and reporting the costs directly in the cost center for that entity or department. In any situation in which costs are directly assigned to a cost center, there is a risk of excess cost in that cost center resulting from the directly assigned costs plus a share of overhead improperly allocated to the cost center which duplicates the directly assigned costs. This duplication could result in improper Medicare payment to the provider. Where a provider has purchased services for a provider-based entity or for a provider department, like general service costs of the provider (for example, like costs in the administrative and general cost center) must be separately identified to ensure that they are not improperly allocated to the entity or the department. If the like costs of the main provider cannot be separately identified, the costs of the services purchased through a contract must be reclassified to the main provider and allocated among the main provider's benefiting cost centers.

Example: A provider-based complex is composed of a hospital and a hospital-based rural health clinic (RHC). The hospital furnishes the entirety of its own administrative and general costs internally. The RHC, however, is managed by an independent contractor through a management contract. The management contract provides a full array of administrative and general services, with the exception of patient billing. The hospital directly assigns the costs of the RHC's management contract to the RHC cost center (for example, Form CMS 2552–96, Worksheet A, Line 71). A full allocation of the hospital's administrative and general costs to the RHC cost center would duplicate most of the RHC's administrative and general costs. However, an allocation of the hospital's cost (included in hospital administrative and general costs) of its patient billing function to the RHC would be appropriate. Therefore, the hospital must include the costs of the patient billing function in a separate cost center to be allocated to the benefiting cost centers, including the RHC cost center. The remaining hospital administrative and general costs would be allocated to all cost centers, excluding the RHC cost center. If the hospital is unable to isolate the costs of the patient billing function, the costs of the RHC's management contract must be reclassified to the hospital administrative and general cost center to be allocated among all cost centers, as appropriate.

(7) *Costs of services furnished to free-standing entities.* The costs that a provider incurs to furnish services to free-standing entities with which it is associated are not allowable costs of that provider. Any costs of services furnished to a free-standing entity must be identified and eliminated from the allowable costs of the servicing provider, to prevent Medicare payment to that provider for those costs. This may be done by including the free-standing entity on the cost report as a nonreimbursable cost center for the purpose of allocating overhead costs to that entity. If this method would not result in

an accurate allocation of costs to the entity, the provider must develop detailed work papers showing how the cost of services furnished by the provider to the entity were determined. These costs are removed from the applicable cost centers of the servicing provider.

(e) *Accounting basis.* The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

(f) *Cost reports.* For cost reporting purposes, the Medicare program requires each provider of services to submit periodic reports of its operations that generally cover a consecutive 12-month period of the provider's operations. Amended cost reports to revise cost report information that has been previously submitted by a provider may be permitted or required as determined by CMS.

(1) *Cost reports—Terminated providers and changes of ownership.* A provider that voluntarily or involuntarily ceases to participate in the Medicare program or experiences a change of ownership must file a cost report for that period under the program beginning with the first day not included in a previous cost reporting period and ending with the effective date of termination of its provider agreement or change of ownership.

(2) *Due dates for cost reports.* (i) Cost reports are due on or before the last day of the fifth month following the close of the period covered by the report. For cost reports ending on a day other than the last day of the month, cost reports are due 150 days after the last day of the cost reporting period.

(ii) Extensions of the due date for filing a cost report may be granted by the contractor only when a provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as flood or fire.

(3) *Changes in cost reporting periods.* A provider may change its cost reporting period if a change in ownership is experienced or if the—

(i) Provider requests the change in writing from its contractor;

(ii) Contractor receives the request at least 120 days before the close of the new reporting period requested by the provider; and

(iii) Contractor determines that good cause for the change exists. Good cause would not be found to exist if the effect is to change the initial date that a hospital would be affected by the rate of increase ceiling (see § 413.40), or be paid under the prospective payment systems (see part 412 of this chapter).

(4) *Electronic submission of cost reports.*

(i) As used in this paragraph (f)(4), ''provider'' means a hospital, rural emergency hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989, for hospitals; cost reporting periods ending on or after February 1, 1997, for skilled nursing facilities and home health agencies; cost reporting periods ending on or after December 31, 2004, for hospices, and end-stage renal disease facilities; cost reporting periods ending on or after March 31, 2005, for organ procurement organizations, histocompatibility laboratories, rural health clinics, federally qualified health centers, and community mental health centers; and cost reporting periods beginning on or after January 1, 2023, for rural emergency hospitals, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

(iii) The contractor stores the provider's as-filed electronic cost report and may not alter that file for any reason. The contractor makes a ''working

copy'' of the as-filed electronic cost report to be used, as necessary, throughout the settlement process (that is, desk review, processing audit adjustments, and final settlement). The provider's electronic program must be able to disclose if any changes have been made to the as-filed electronic cost report after acceptance by the contractor. If the as-filed electronic cost report does not pass all specified edits, the contractor must return it to the provider for correction. For purposes of the requirements in paragraph (f)(2) of this section concerning due dates, an electronic cost report is not considered to be filed until it is accepted by the contractor.

(iv)(A) Effective as specified in paragraphs (f)(4)(iv)(A)(1) through (5) of this section and except as provided in paragraph (f)(4)(iv)(C) of this section, a provider must submit a hard copy of a settlement summary, if applicable, which is a statement of certain worksheet totals found within the electronic file, and the certification statement described in paragraph (f)(4)(iv)(B) of this section signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report.

(*1*) For hospitals, effective for cost reporting periods ending on or after September 30, 1994;

(*2*) For skilled nursing facilities and home health agencies, effective for cost reporting periods ending on or after February 1, 1997;

(*3*) For hospices and end-stage renal disease facilities, effective for cost reporting periods ending on or after December 31, 2004;

(*4*) For organ procurement organizations, histocompatibility laboratories, rural health clinics, federally qualified health centers, and community mental health centers, effective for cost reporting periods ending on or after March 31, 2005; and

(*5*) For rural emergency hospitals, effective for cost reporting periods beginning on or after January 1, 2023.

(B) The following certification statement must immediately precede the dated original signature, or electronic signature as set forth in paragraph (f)(4)(iv)(C)(*1*) of this section, of the provider's administrator or chief financial officer:

MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by ____ (Provider Name(s) and Number(s)) for the cost reporting period beginning ___ and ending ___ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(C) Effective for cost reporting periods ending on or after December 31, 2017—(*1*) A provider that is required to file an electronic cost report may elect to electronically submit the settlement summary, if applicable, and the certification statement with an electronic signature of the provider's administrator or chief financial officer. The following checkbox for electronic signature and submission will immediately follow the certification statement as set forth in paragraph (f)(4)(iv)(B) of this section and must be checked if electronic signature and submission is elected.

☐ I have read and agree with the above certification statement. I certify that I intend my electronic signature on this certification statement to be

the legally binding equivalent of my original signature.

(*2*) A provider that is required to file an electronic cost report but does not elect to electronically submit the certification statement with an electronic signature, must submit a hard copy of the settlement summary, if applicable, and a certification statement with an original signature of the provider's administrator or chief financial officer as set forth in paragraphs (f)(4)(iv)(A) and (B) of this section.

(v) A provider may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship or if the provider qualifies as a low or no Medicare utilization provider. The provider must submit a written request for delay or waiver with necessary supporting documentation to its contractor no later than 30 days after the end of its cost reporting period. The contractor reviews the request and forwards it, with a recommendation for approval or denial, to CMS central office within 30 days of receipt of the request. CMS central office either approves or denies the request and notifies the contractor within 60 days of receipt of the request.

(5) An acceptable cost report submission is defined as follows:

(i) The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. For providers claiming costs on their cost reports that are allocated from a home office or chain organization, the Home Office Cost statement must be submitted by the home office or chain organization as set forth in paragraph (f)(5)(i)(E) of this section. A cost report is rejected for lack of supporting documentation if it does not include the following, except as provided in paragraphs (f)(5)(i)(A)(*2*)(*ii*) and (f)(5)(i)(E) of this section:

(A) *Teaching hospitals.* For teaching hospitals, the Intern and Resident Information System (IRIS) data.

(*1*) *Data format.* For cost reporting periods beginning on or after October 1, 2021, the IRIS data must be in the new XML IRIS format.

(*2*) *Resident counts.* (*i*) Effective for cost reporting periods beginning on or after October 1, 2021, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

(*ii*) For cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022, the cost report is not rejected if the requirement in paragraph (f)(5)(i)(A)(*2*)(*i*) of this section is not met.

(B) *Bad debt*—Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, a detailed bad debt listing that corresponds to the amount of bad debt claimed in the provider's cost report.

(C) *DSH eligible hospitals*—Effective for cost reporting periods beginning on or after October 1, 2018, for hospitals claiming a disproportionate share hospital payment adjustment, a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. If the hospital submits an amended cost report that changes its Medicaid eligible days, the hospital must submit an amended listing or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report.

(D) *Charity care and uninsured discounts*—Effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a detailed listing of charity care and/or uninsured discounts that corresponds to the amounts claimed in the DSH eligible hospital's cost report.

(E) *Home office cost allocation.* (*1*) *Same fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with the same fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to the amounts allocated

from the home office or chain organization to the provider's cost report.

(*2*) *Differing fiscal year end.* Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming costs on their cost report that are allocated from a home office or chain organization with a different fiscal year end, a Home Office Cost Statement completed and submitted by the home office or chain organization to its chain provider's servicing contractor that corresponds to some portion of the amounts allocated from the home office or chain organization to the provider's cost report.

(ii) For providers that are required to file electronic cost reports—In addition to the requirements of paragraphs (f)(4) and (f)(5)(i) of this section, the provider must submit its cost reports in an electronic cost report format in conformance with the requirements contained in the Electronic Cost Report (ECR) Specifications Manual (unless the provider has received an exemption from CMS).

(iii) The contractor makes a determination of acceptability within 30 days of receipt of the provider's cost report. If the cost report is considered unacceptable, the contractor returns the cost report with a letter explaining the reasons for the rejection. When the cost report is rejected, it is deemed an unacceptable submission and treated as if a report had never been filed.

(g) *Exception from full cost reporting for lack of program utilization.* If a provider does not furnish any covered services to Medicare beneficiaries during a cost reporting period, it is not required to submit a full cost report. It must, however, submit an abbreviated cost report, as prescribed by CMS.

(h) *Waiver of full or simplified cost reporting for low program utilization.* (1) If the provider has had low utilization of covered services by Medicare beneficiaries (as determined by the contractor) and has received correspondingly low interim payments for the cost reporting period, the contractor may waive a full cost report or the simplified cost report described in § 413.321 if it decides that it can determine, without a full or simplified report, the reasonable cost of covered services provided during that period.

(2) If a full or simplified cost report is waived, the provider must submit within the same time period required for full or simplified cost reports:

(i) The cost reporting forms prescribed by CMS for this situation; and

(ii) Any other financial and statistical data the contractor requires.

(i) [Reserved]

(j) *Substantive reimbursement requirement of an appropriate cost report claim—* (1) *General requirement.* In order for a provider to receive or potentially qualify for reimbursement for a specific item for its cost reporting period, the provider's cost report, whether determined on an as submitted, as amended, or as adjusted basis (as prescribed in paragraph (j)(3) of this section), must include an appropriate claim for the specific item, by either—

(i) Claiming full reimbursement in the provider's cost report for the specific item in accordance with Medicare policy, if the provider seeks payment for the item that it believes comports with program policy; or

(ii) Self-disallowing the specific item in the provider's cost report, if the provider seeks payment that it believes may not be allowable or may not comport with Medicare policy (for example, if the provider believes the contractor lacks the authority or discretion to award the reimbursement the provider seeks for the item), by following the procedures (set forth in paragraph (j)(2) of this section) for properly self-disallowing the specific item in the provider's cost report as a protested amount.

(2) *Self-disallowance procedures.* In order to properly self-disallow a specific item, the provider must—

(i) Include an estimated reimbursement amount for each specific self-disallowed item in the protested amount line (or lines) of the provider's cost report; and

(ii) Attach a separate work sheet to the provider's cost report for each specific self-disallowed item, explaining why the provider self-disallowed each specific item (instead of claiming full reimbursement in its cost report for the specific item) and describing how the provider calculated the estimated reimbursement amount for each specific self-disallowed item.

(3) *Procedures for determining whether there is an appropriate cost report claim.* Whether the provider's cost report for its cost reporting period includes an appropriate claim for a specific item (as prescribed in paragraph (j)(1) of this section) must be determined by reference to the cost report that the provider submits originally to, and was accepted by, the contractor for such period, provided that none of the following exceptions applies:

(i) If the provider submits an amended cost report for its cost reporting period and such amended cost report is accepted by the contractor, then whether there is an appropriate cost report claim for the specific item must be determined by reference to such amended cost report, provided that neither of the exceptions set forth in paragraphs (j)(3)(ii) and (iii) of this section applies;

(ii) If the contractor adjusts the provider's cost report, as submitted originally by the provider and accepted by the contractor or as amended by the provider and accepted by the contractor, whichever is applicable, with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the final contractor determination (as defined in § 405.1801(a) of this chapter) for the provider's cost reporting period, provided that the exception set forth in paragraph (j)(3)(iii) of this section does not apply;

(iii) If the contractor reopens either the final contractor determination for the provider's cost reporting period (pursuant to § 405.1885 of this chapter) or a revised final contractor determination for such period (issued pursuant to § 405.1889 of this chapter) and the contractor adjusts the provider's cost report with respect to the specific item, then whether there is an appropriate cost report claim for the specific item must be determined by reference to the provider's cost report, as such cost report claim is adjusted for the specific item in the most recent revised final contractor determination for such period.

(4) *Reimbursement effects of contractor's determination of whether there is an appropriate cost report claim.* If the contractor determines that the provider's cost report included an appropriate claim for a specific item (as specified in paragraphs (j)(1), (2), and (3) of this section) and that all the other substantive reimbursement requirements for the specific item are also satisfied, the final contractor determination (as defined in § 405.1801(a) of this chapter) must include reimbursement for the specific item to the extent permitted by Medicare policy. If the contractor determines that the provider made an appropriate cost report claim for a specific item but the contractor disagrees with material aspects of the provider's claim for the specific item, the contractor must make appropriate adjustments to the provider's cost report and include reimbursement for the specific item in the final contractor determination in accordance with such cost report adjustments and to the extent permitted by program policy. If the contractor determines that the provider did not make an appropriate cost report claim for a specific item, the final contractor determination must not include any reimbursement for the specific item, regardless of whether the other substantive reimbursement requirements for the specific item are or are not satisfied.

(5) *Administrative review of whether there is an appropriate cost report claim.* If the provider files an administrative appeal (pursuant to Part 405, Subpart R of this chapter) seeking reimbursement for a specific item and any party to such appeal questions whether the provider's cost report included an appropriate claim for the specific item under appeal (as specified in paragraphs (j)(1), (2), (3), and (4) of this section), the reviewing entity (as defined in § 405.1801(a) of this chapter) must follow the procedures prescribed in § 405.1873 of this chapter (if the appeal was filed originally with the Board), or the procedures set forth in § 405.1832 of this chapter (if the appeal was filed initially with the contractor), for review of whether the substantive reimbursement requirement of an appropriate cost report claim for the specific item under appeal is satisfied. The reviewing

entity must follow the procedures set forth in paragraph (j)(3) of this section in determining whether the provider's cost report included an appropriate claim for the specific item under appeal. The reviewing entity may permit reimbursement for the specific item under appeal solely to the extent authorized by § 405.1873(f) of this chapter (if the appeal was filed originally with the Board) or by § 405.1832(f) of this chapter (if the appeal was filed initially with the contractor).

[51 FR 34793, Sept. 30, 1986]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.24, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

Subpart C—Limits on Cost Reimbursement

§ 413.30 Limitations on payable costs.

(a) *Introduction*—(1) *Scope.* This section implements section 1861(v)(1)(A) of the Act by setting forth the general rules under which CMS may establish limits on SNF and HHA costs recognized as reasonable in determining Medicare program payments. It also sets forth rules governing exemptions and exceptions to limits established under this section that CMS may make as appropriate in considering special needs or situations of particular providers.

(2) *General principle.* Reimbursable provider costs may not exceed the costs CMS estimates to be necessary for the efficient delivery of needed health care services. CMS may establish estimated cost limits for direct or indirect overall costs or for costs of specific services or groups of services. CMS imposes these limits prospectively and may calculate them on a per admission, per discharge, per diem, per visit, or other basis.

(b) *Procedure for establishing limits.* (1) In establishing limits under this section, CMS may classify SNFs and HHAs by factors that CMS finds appropriate and practical, including the following:

(i) Type of services furnished.

(ii) Geographical area where services are furnished, allowing for grouping of noncontiguous areas having similar demographic and economic characteristics.

(iii) Size of institution.

(iv) Nature and mix of services furnished.

(v) Type and mix of patients treated.

(2) CMS bases its estimates of the costs necessary for efficient delivery of health services on cost reports or other data providing indicators of current costs. CMS adjusts current and past period data to arrive at estimated costs for the prospective periods to which limits are applied.

(3) Before the beginning of a cost period to which revised limits will be applied, CMS publishes a notice in the FEDERAL REGISTER, establishing cost limits and explaining the basis on which they are calculated.

(4) In establishing limits under paragraph (b)(1) of this section, CMS may find it inappropriate to apply particular limits to a class of SNFs or HHAs due to the characteristics of the SNF or HHA class, the data on which CMS bases those limits, or the method by which CMS determines the limits. In these cases, CMS may exclude that class of SNFs or HHAs from the limits, explaining the basis of the exclusion in the notice setting forth the limits for the appropriate cost reporting periods.

(c) *Requests regarding applicability of cost limits.* For cost reporting periods beginning before July 1, 1998, a SNF may request an exception or exemption to the cost limits imposed under this section. An HHA may request only an exception to the cost limits. The SNF or HHA must make its request to its contractor within 180 days of the date on the contractor's notice of program reimbursement.

(1) *Home health agencies.* The contractor makes a recommendation on the HHA's request to CMS, which makes the decision. CMS responds to the request within 180 days from the date CMS receives the request from the contractor. The contractor notifies the HHA of CMS's decision. The time required by CMS to review the request is considered good cause for the granting of an extension of the time limit for requesting an contractor hearing or a Provider Reimbursement Review Board (Board) hearing as specified in

§§ 405.1813 and 405.1836 of this chapter, respectively.

(2) *Skilled nursing facility exception.* The contractor makes the final determination on the SNF's exception request and notifies the SNF of its determination within 90 days from the date that the contractor receives the request from the SNF. If the contractor determines that the SNF did not provide adequate documentation from which a proper determination can be made, the contractor notifies the SNF that the request is denied. The contractor also notifies the SNF that it has 45 days from the date on the contractor's denial letter to submit a new exception request with the complete documentation and that otherwise, the denial is the final determination. The time required by the contractor to review the request is considered good cause for the granting of an extension of the time limit for requesting an contractor hearing or a Board hearing as specified in §§ 405.1813 and 405.1836 of this chapter, respectively.

(d) *Exemptions.* Exemptions from the limits imposed under this section may be granted to a new SNF with cost reporting periods beginning before July 1, 1998 as stated in § 413.1(g)(1). The contractor makes a recommendation on the provider's request to CMS, which makes the decision. A new SNF is a provider of inpatient services that has operated as a SNF (or the equivalent) for which it is certified for Medicare, under present and previous ownership, for less than 3 full years. An exemption granted under this paragraph expires at the end of the SNF's first cost reporting period beginning at least 2 years after the provider accepts its first inpatient.

(e) *Exceptions.* Limits established under this section may be adjusted upward for a SNF or HHA under the circumstances specified in paragraphs (e)(1) through (e)(5) of this section. An adjustment is made only to the extent that the costs are reasonable, attributable to the circumstances specified, separately identified by the SNF or HHA, and verified by the contractor.

(1) *Atypical services.* The SNF or HHA can show that the—

(i) Actual cost of services furnished by a SNF or HHA exceeds the applicable limit because the services are atypical in nature and scope, compared to the services generally furnished by SNFs or HHAs similarly classified; and

(ii) Atypical services are furnished because of the special needs of the patients treated and are necessary in the efficient delivery of needed health care.

(2) *Extraordinary circumstances.* The SNF or HHA can show that it incurred higher costs due to extraordinary circumstances beyond its control. These circumstances include, but are not limited to, strikes, fire, earthquake, flood, or other unusual occurrences with substantial cost effects.

(3) *Areas with fluctuating populations.* The SNF meets the following conditions:

(i) Is located in an area (for example, a resort area) that has a population that varies significantly during the year.

(ii) Is furnishing similar services in an area for which the appropriate health planning agency has determined does not have a surplus of beds or similar services and has certified that the beds or similar services furnished by the SNF are necessary.

(iii) Meets occupancy or capacity standards established by the Secretary.

(4) *Medical and paramedical education.* The SNF or HHA can demonstrate that, if compared to other SNFs or HHAs in its group, it incurs increased costs for services covered by limits under this section because of its operation of an approved education program specified in § 413.85.

(5) *Unusual labor costs.* The SNF or HHA has a percentage of labor costs that varies more than 10 percent from that included in the promulgation of the limits.

(f) *Operational review.* Any SNF or HHA that applies for an exception to the limits established under paragraph (e) of this section must agree to an operational review at the discretion of CMS. The findings from this review may be the basis for recommendations for improvements in the efficiency and economy of the SNF's or the HHA's operations. If recommendations are

made, any future exceptions are contingent on the SNF's or HHA's implementation of these recommendations.

[64 FR 42612, Aug. 5, 1999; 65 FR 60104, Oct. 10, 2000, as amended at 67 FR 48802, July 26, 2002; 73 FR 30267, May 23, 2008; 73 FR 49357, Aug. 21, 2008]

§ 413.35 Limitations on coverage of costs: Charges to beneficiaries if cost limits are applied to services.

(a) *Principle.* A provider of services that customarily furnishes an individual items or services that are more expensive than the items or services determined to be necessary in the efficient delivery of needed health services described in § 413.30, may charge an individual entitled to benefits under Medicare for such more expensive items or services even though not requested by the individual. The charge, however, may not exceed the amount by which the cost of (or, if less, the customary charges for) such more expensive items or services furnished by such provider in the second cost reporting period immediately preceding the cost reporting period in which such charges are imposed exceeds the applicable limit imposed under the provisions of § 413.30. This charge may be made only if—

(1) The contractor determines that the charges have been calculated properly in accordance with the provisions of this section;

(2) The services are not emergency services as defined in paragraph (d) of this section;

(3) The admitting physician has no direct or indirect financial interest in such provider;

(4) CMS has provided notice to the public through notice in a newspaper of general circulation servicing the provider's locality and such other notice as the Secretary may require, of any charges the provider is authorized to impose on individuals entitled to benefits under Medicare on account of costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare; and

(5) The provider has, in the manner described in paragraph (e) of this section, identified such charges to such individual or person acting on his behalf as charges to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare.

(b) *Provider request to charge beneficiaries for costs in excess of limits.* (1) If a provider's actual costs (or, if less, the customary charges) in the second preceding cost period exceed the prospective limits established for such costs, the contractor will, at the provider's request, validate in advance the charges that may be made to the beneficiaries for the excess.

(2) If a provider does not have a second preceding cost period and is a new provider as defined in § 413.30(e), the provider, subject to validation by the contractor, will estimate the current cost of the service to which a limit is being applied. Such amount will be adjusted to an amount equivalent to costs in the second preceding year by use of a factor to be developed based on estimates of cost increases during the preceding two years and published by SSA or CMS. The amount thus derived will be used in lieu of the second preceding cost period amount in determining the charge to the beneficiary.

(3) To obtain consideration of such a request, the provider must submit to the contractor a statement indicating the chagre for which it is seeking validation and providing the data and method used to determine the amount. Such statement should include the—

(i) Provider's name and number;

(ii) Identity of class and prospective cost limit for the class in which the provider has been included;

(iii) Amount of charge and cost period in which the charge is to be imposed;

(iv) Cost and customary charge for items and services furnished to beneficiaries; and

(v) Cost period ending date of the second reporting period immediately preceding the cost period in which the charge is to be imposed. The contractor may request such additional information as it finds necessary with respect to the request.

(c) *Provider charges*—(1) *Establishing the charges.* If the actual cost incurred (or, if less, the customary charges) in the prior period determined under paragraph (a) of this section exceeds

the limits applicable to the pertinent period, the provider may charge the beneficiary to the extent costs in the second preceding cost reporting period (or the equivalent when there is no second preceding period) exceed the current cost limits. (Data from the most recently submitted appropriate cost report will be used in determining the actual cost.) For example, if a limit of $58 per day is applied to the cost of general routine services for the provider's cost reporting period starting in calendar year 1975 and if the provider's actual general routine cost in the second preceding reporting period, that is, the reporting period starting in calendar year 1973, was $60 per day, the provider (after first having obtained contractor validation and subject to the considerations and requirements specified in paragraph (a) of this section) may charge Medicare Part A beneficiaries up to $2 per day for general routine services.

(2) *Adjusting cost.* Program reimbursement for the costs to which limits imposed under § 413.30 are applied in any cost reporting period will not exceed the lesser of the provider's actual cost or the limits imposed under § 413.30. If program reimbursement for items or services to which such limits are applied plus the charges to beneficiaries for such items or services imposed under this section exceed the provider's actual cost for such items or services, program payment to the provider will be reduced to the extent program payment plus charges to the beneficiaries exceed actual cost. If the provider's actual cost for general routine services in 1975 was $57,000, the cost limit was $58,000, and billed charges to Medicare Part A beneficiaries were $2,000, the provider would receive $55,000 from the program ($57,000 actual cost minus the $2,000 in charges to the beneficiaries).

(d) *Definition of emergency services.* For purposes of paragraph (a)(2) of this section, emergency services are those hospital services that are necessary to prevent the death or serious impairment of the health of the individual, and which, because of the threat to the life or health of the individual, necessitate the use of the most accessible hospital (as determined under § 424.106 of this chapter) available and equipped to furnish such services. If an individual has been admitted to such hospital as an inpatient because of an emergency, the emergency will be deemed to continue until it is safe from a medical standpoint to move the individual to another hospital or other institution or to discharge him.

(e) *Identification of charges to individual.* For purposes of paragraph (a)(5) of this section, a provider must give or send to the individual or his representative, a schedule of all items and services that the individual might need and for which the provider imposes charges under this section, and the charge for each. Such schedule must specify that the charges are necessary to meet the costs in excess of the costs determined to be necessary in the efficient delivery of needed health services under Medicare and include such other information as CMS considers necessary to protect the individual's rights under this section. The provider, in arranging for the individual's admission, first service, or start of care, must give or send this schedule to the individual or his representative when arrangements are being made for such services or if this is not feasible, as soon thereafter as is practicable but no later than at the initiation of services.

[51 FR 34793, Sept. 30, 1986, as amended at 53 FR 6648, Mar. 20, 1988; 60 FR 45849, Sept. 1, 1995]

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

(a) *Introduction*—(1) *Scope.* This section implements section 1886(b) of the Act, establishing a ceiling on the rate of increase in operating costs per case for hospital inpatient services furnished to Medicare beneficiaries that will be recognized as reasonable for purposes of determining the amount of Medicare payment. This rate-of-increase ceiling applies to hospital cost reporting periods beginning on or after October 1, 1982. This section also sets forth rules governing exemptions from and adjustments to the ceiling.

(2) *Applicability.* (i) This section is not applicable to—

(A) Hospitals reimbursed in accordance with section 1814(b)(3) of the Act or under State reimbursement control systems that have been approved under

section 1886(c) of the Act and subpart C of part 403 of this chapter; or

(B) Hospitals that are paid under the prospective payment systems for inpatient hospital services in accordance with section 1886 (d) and (g) of the Act and part 412 of this chapter.

(C) Psychiatric hospitals and psychiatric units that are paid under the prospective payment system for inpatient psychiatric facilities described in subpart N of part 412 of this chapter for cost reporting periods beginning on or after January 1, 2005.

(D) Rehabilitation hospitals and rehabilitation units that are paid under the prospective payment system for inpatient hospital services in accordance with section 1886(j) of the Act and subpart P of part 412 of this subchapter for cost reporting periods beginning on or after January 1, 2002.

(E) Long-term care hospitals, as defined in section 1886(d)(1)(B)(iv) of the Act, that are paid based on 100 percent of the Federal prospective payment rate for inpatient hospital services in accordance with section 123 of Public Law 106–113 and section 307 of Public Law 106–554 and § 412.533(b) and (c) of subpart O of part 412 of this subchapter for cost reporting periods beginning on or after October 1, 2002.

(ii) For cost reporting periods beginning on or after October 1, 1983, this section applies to—

(A) Hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter;

(B) Psychiatric and rehabilitation units excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter and in accordance with § 412.25 through § 412.30 of this chapter, except as limited by paragraphs (a)(2)(iii) and (a)(2)(iv) of this section with respect to psychiatric and rehabilitation hospitals and psychiatric and rehabilitation units as specified in §§ 412.22, 412.23, 412.25, 412.27, 412.29 and 412.30 of this chapter.

(C) Long-term care hospitals excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter and in accordance with § 412.23 of this subchapter, except as limited by paragraph (a)(2)(v) of this section with respect to long-term care hospitals specified in § 412.23(e) of this subchapter.

(iii) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2005 this section applies to psychiatric hospitals and psychiatric units that are excluded from the prospective payment systems as specified in § 412.1(a)(1) of this chapter and paid under the prospective payment system as specified in § 412.1(a)(2) of this chapter.

(iv) For cost reporting periods beginning on or after October 1, 1983 and before January 1, 2002, this section applies to rehabilitation hospitals and rehabilitation units that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter.

(v) For cost reporting periods beginning on or after October 1, 1983 and before October 1, 2002, this section applies to long-term care hospitals that are excluded from the prospective payment systems described in § 412.1(a)(1) of this subchapter. For cost reporting periods beginning on or after October 1, 2002, and before October 1, 2006, this section also applies to long-term care hospitals, subject to paragraph (a)(2)(i)(D) of this section.

(3) *Definitions.* As used in this section—

Ceiling is the aggregate upper limit on the amount of a hospital's net Medicare inpatient operating costs that the program will recognize for payment purposes. For each cost reporting period, the ceiling is determined by multiplying the updated target amount, as defined in this paragraph, for that period by the number of Medicare discharges during that period. For a hospital-within-a-hospital, as described in § 412.22(e) of this chapter, the number of Medicare discharges in a cost reporting period does not include discharges of a patient to another hospital in the same building on or on the same campus, if—

(A) The patient is subsequently readmitted to the hospital-within-a-hospital directly from the other hospital; and

(B) The hospital-within-a-hospital has discharged to the other hospital and subsequently readmitted more than 5 percent (that is, in excess of 5.0

percent) of the total number of Medicare inpatients discharged from the hospital-within-a-hospital in that cost reporting period.

Date of discharge is the earliest of the following dates:

(A) The date the patient has exhausted Medicare Part A hospital inpatient benefits (including the election to use lifetime reserve days) during his or her spell of illness.

(B) The date the patient is formally released as specified in §412.4(a)(1) of this chapter.

(C) The date the patient is transferred to another facility.

(D) The date the patient dies.

Market basket index is CMS's projection of the annual percentage increase in hospital inpatient operating costs. The market basket index is a wage and price index that incorporates weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in the most common categories of hospital inpatient operating costs subject to the ceiling, as described in paragraph (c)(1) of this section.

Net inpatient operating costs include the costs of certain preadmission services as specified in paragraph (c)(2) of this section, the costs of routine services, ancillary services, and intensive care services (as defined in §413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in §413.130, the costs of approved medical education programs as described in §§413.75 through 413.83 and 413.85, and organ acquisition costs as specified in subpart L of this part incurred by approved transplant programs. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

Rate-of-increase percentage is the percentage by which each hospital's target amount from the preceding Federal fiscal year is increased.

Target amount is the per discharge (case) limitation, derived from the hospital's allowable net Medicare inpatient operating costs in the hospital's base year, and updated for each subsequent hospital cost reporting period by the appropriate annual rate-of-increase percentage.

Update adjustment percentage is the percentage by which a hospital's allowable inpatient operating service costs for the 12-month cost reporting period beginning in Federal fiscal year 1990 exceeds the hospital's ceiling for that period.

Update factor is the decimal equivalent of the rate-of-increase percentage. The update factor is the value by which a hospital's target amount for the preceding year is multiplied in order to determine the target amount for the following year. For example, if the rate-of-increase percentage for a year is 2.7 percent, the update factor for that year is 1.027.

(b) *Cost reporting periods subject to the rate-of-increase ceiling*—(1) *Base period.* Each hospital's target amount is based on its allowable net inpatient operating costs per case from the cost reporting period of at least 12 months immediately preceding the first cost reporting period subject to the rate-of-increase ceiling established under this section. If the immediately preceding cost reporting period is a short reporting period (fewer than 12 months), the first period of at least 12 months subsequent to that short period is the base period.

(i) The target amount established under this provision remains applicable to a hospital or excluded hospital unit, as described in §§412.25 through 412.30 of this chapter, despite intervening cost reporting periods during which the hospital or excluded hospital unit is not subject to the ceiling as a result of other provisions of the law or regulations, or nonparticipation in the Medicare program, unless the hospital or excluded hospital unit qualifies as a new hospital or excluded part hospital unit under the provisions of paragraph (f) of this section.

(ii) The base period for a newly established excluded unit is the first cost reporting period of at least 12 months following the unit's certification to participate in the Medicare program.

(iii) When the operational structure of a hospital or unit changes (that is, a freestanding hospital becomes an excluded unit or an excluded unit becomes a freestanding hospital, or an

entity of a multicampus hospital becomes a newly created hospital or unit or a hospital or unit becomes a part of a multicampus hospital), the base period for the hospital or unit that changed its operational structure is the first cost reporting period of at least 12 months effective with the revised Medicare certification classification.

(iv) *Request for rebased target amount for the cost reporting period beginning on or after October 1, 1997 and on or before September 30, 1998.* Except for qualified long-term care hospitals as defined in paragraph (b)(1)(v) of this section, each hospital or unit under present or previous ownership that received payment under section 1886(b) of the Act during cost reporting periods beginning before October 1, 1990, may submit a request to its contractor to rebase its target amount. The request must be received by the contractor by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased target amount for the cost reporting period beginning during fiscal year 1998 is determined as follows:

(A) Determine the hospital's inpatient operating costs per case for each of the five most recent settled cost reports as of August 5, 1997.

(B) For each of the five cost reports, update the operating costs per case by the applicable update factors up to the hospital's cost reporting period beginning during FY 1998.

(C) Exclude the highest and lowest of the five updated amounts determined under paragraph (b)(1)(iv)(B) of this section.

(D) Compute the average for the remaining three updated amounts for operating cost per case.

(v) *Request by qualified long-term care hospital.* A qualified long-term care hospital may file a request to its contractor for a rebased FY 1998 target amount. The request must be received by the contractor by the later of November 1, 1997 or 60 days before the beginning of its cost reporting period beginning during fiscal year 1998. The rebased FY 1998 target amount is the hospital's FY 1996 inpatient operating costs updated to FY 1997. A qualified long-term care hospital means a long-term care hospital that meets the following two conditions for its two most recent settled cost reports as of August 5, 1997:

(A) Its Medicare inpatient operating costs exceed 115 percent of the ceiling.

(B) The hospital would have had a disproportionate patient percentage (as defined in § 412.106) equal to or greater than 70 percent if it were a prospective payment hospital.

(2) *Periods subject to the ceiling.* The ceiling established under this section applies to all cost reporting periods that—

(i) Begin on or after October 1, 1982; and

(ii) Immediately follow the base period established under paragraph (b)(1) of this section unless the exception in paragraph (b)(3) of this section is applicable.

(3) *Periods of other than 12 months.* The ceiling established under this section does not apply to cost reporting periods of fewer than 12 months that occur in conjunction with a change in operation of the facility, as defined in paragraph (b)(1)(iii) of this section, as a result of changes in ownership, merger, or consolidation. However, the ceiling applies to cost reporting periods of fewer than 12 months that result solely from the approval of a hospital's request for a change in accounting cycle, as specified in § 413.24(f)(3).

(c) *Costs subject to the ceiling*—(1) *Applicability.* The ceiling established under this section applies to net operating costs incurred by a hospital in furnishing inpatient hospital services to Medicare beneficiaries.

(2) Preadmission services otherwise payable under Medicare Part B furnished to a beneficiary on the date of the beneficiary's admission to the hospital and during the calendar day immediately preceding the date of the beneficiary's admission to the hospital that meet the condition specified in paragraph (c)(2)(i) of this section and at least one of the conditions specified in paragraphs (c)(2)(ii) through (c)(2)(iv):

(i) The services are furnished by the hospital or any entity wholly owned or operated by the hospital. An entity is wholly owned by the hospital if the hospital is the sole owner of the entity.

An entity is wholly operated by a hospital if the hospital has exclusive responsibility for conducting and overseeing the entity's routine perations, regardless of whether the hospital also has policymaking authority over the entity.

(ii) For services furnished after January 1, 1991, the services are diagnostic (including clinical diagnostic laboratory tests).

(iii) For services furnished on or after October 1, 1991 through June 24, 2010, the services are furnished in connection with the principal diagnosis that requires the beneficiary to be admitted as an inpatient and are not the following:

(A) Ambulance services.

(B) Maintenance renal dialysis services.

(iv) Nondiagnostic services furnished on or after June 25, 2010, other than ambulance services and maintenance renal dialysis services, that are furnished on the date of the beneficiary's inpatient admission or on the calendar day immediately preceding the date of the beneficiary's inpatient admission and the hospital does not attest that such services are unrelated to the beneficiary's inpatient admission.

(3) *Rate-of-increase percentages and update factors.* The applicable rate-of-increase percentages and update factors are determined as follows:

(i) *Federal fiscal year 1986.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1985 and before September 30, 1986 is five twenty-fourths of one percent, and the update factor is 1.00208333. For purposes of determining the target amount for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase for cost reporting periods beginning during Federal fiscal year 1986 is deemed to have been one-half percent, and the update factor is 1.005.

(ii) *Federal fiscal year 1987.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1986 and before September 30, 1987 is 1.15 percent; the update factor is 1.0115.

(iii) *Federal fiscal year 1988.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988 is 2.3238 percent; the update factor is 1.023238. For purposes of updating the target amount for cost reporting periods beginning on or after October 1, 1988, the rate-of-increase percentage for cost reporting periods beginning during FY 1988 is deemed to have been 2.7 percent; the update factor is deemed to have been 1.027.

(iv) *Federal fiscal year 1989 through Federal fiscal year 1993.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1988, and before October 1, 1993, is the percentage increase projected by the hospital market basket index (as defined in paragraph (a)(3) of this section).

(v) *Federal fiscal year 1994 through Federal fiscal year 1997.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1993, and before October 1, 1998, is the market basket percentage increase minus the lesser of, 1 percentage point, or the percentage point difference between 10 percent and the hospital's ''update adjustment percentage'' (as defined in paragraph (a)(3) of this section); for hospitals with an ''update adjustment percentage'' of at least 10 percent, the applicable rate-of-increase percentage is the market basket percentage increase. The ''update adjustment percentage'' is increased in each Federal fiscal year by the sum of the hospital's applicable reductions applied to the market basket percentage increase for previous Federal fiscal years.

(vi) *Federal fiscal year 1998.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1997 is 0 percent.

(vii) *Federal fiscal year 1999 through Federal fiscal year 2002.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 1998, and before October 1, 2002, based on data from the most recent available cost report, is:

(A) The percentage increase in the market basket, if inpatient operating costs are equal to or exceed the ceiling amount by 10 percent or more of the ceiling.

(B) The percentage increase in the market basket minus .25 percentage

points for each percentage point by which inpatient operating costs are less than 10 percent over the ceiling (but not less than 0), if inpatient operating costs exceed the ceiling by less than 10 percent of the ceiling.

(C) The greater of the percentage increase in the market basket minus 2.5 percentage points or 0 percent, if inpatient operating costs are equal to or less than the ceiling but greater than 66.7 percent of the ceiling.

(D) 0 percent, if inpatient operating costs do not exceed 66.7 percent of the ceiling.

(viii) *Federal fiscal year 2003 and following.* The applicable rate-of-increase percentage for cost reporting periods beginning on or after October 1, 2002, is the percentage increase projected by the hospital market basket index.

(4) *Target amounts.* The contractor will establish a target amount for each hospital. The target amount for a cost reporting period is determined as follows:

(i) Except as provided in paragraph (c)(4)(iv) of this section, and subject to the provisions of paragraph (c)(4)(iii) of this section, for the first cost reporting period to which this ceiling applies, the target amount equals the hospital's allowable net inpatient operating costs per case for the hospital's base period increased by the update factor for the subject period.

(ii) Subject to the provisions of paragraph (c)(4)(iii) of this section, for subsequent cost reporting periods, the target amount equals the hospital's target amount for the previous cost reporting period increased by the update factor for the subject cost reporting period, unless the provisions of paragraph (c)(5)(ii) of this section apply.

(iii) For cost reporting periods beginning on or after October 1, 1997 through September 30, 2002, in the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the target amount is the lower of the amounts specified in paragraph (c)(4)(iii)(A) or paragraph (c)(4)(iii)(B) of this section.

(A) The hospital-specific target amount.

(*1*) In the case of all hospitals and units, except long-term care hospitals for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors .

(*2*) In the case of long-term care hospitals, for cost reporting periods beginning during FY 2001, the hospital-specific target amount is the net allowable costs in a base period increased by the applicable update factors multiplied by 1.25.

(B) One of the following for the applicable cost reporting period—

(*1*) For cost reporting periods beginning during fiscal year 1998, the 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1997.

(*2*) For cost reporting periods beginning during fiscal year 1999, the amount determined under paragraph (c)(4)(iii)(B)(*1*) of this section, increased by the market basket percentage up through the subject period, subject to the provisions of paragraph (c)(4)(iv) of this section.

(*3*) For cost reporting periods beginning during fiscal year 2000—

(*i*) The labor-related portion and the nonlabor-related portion of the wage-neutralized 75th percentile of target amounts for hospitals in the same class (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) for cost reporting periods ending during FY 1996, are increased by the applicable market basket percentage up to the first cost reporting period beginning on or after October 1, 1999.

(*ii*) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section is wage adjusted by multiplying it by the hospital's FY 2000 hospital inpatient prospective payment system wage index.

(*iii*) The wage-adjusted 75th percentile target amounts for hospitals in the same class is determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph

(c)(4)(iii)(B)(*3*)(*i*) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(*3*)(*ii*) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(*4*) For cost reporting periods beginning during fiscal years 2001 and 2002—

(*i*) The amounts determined under paragraph (c)(4)(iii)(B)(3)(*i*) of this section are: increased by the market basket percentage up through the subject period; or in the case of a long-term care hospital for cost reporting periods beginning during FY 2001, the amounts determined under paragraph (c)(4)(iii)(B)(*3*)(*i*) of this section, increased by the market basket percentage up through the subject period and further increased by 2 percent.

(*ii*) The labor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section is wage-adjusted by multiplying by the hospital's FY 2001 hospital inpatient prospective payment system wage index, for cost reporting periods beginning during fiscal year 2001 and the hospital's FY 2002 hospital inpatient prospective payment system wage index for cost reporting periods beginning during fiscal year 2002.

(*iii*) The wage-adjusted 75th percentile target amounts for hospitals in the same class are determined by adding the nonlabor-related portion of the wage-neutralized 75th percentile target amounts under paragraph (c)(4)(iii)(B)(*4*)(*i*) of this section and the hospital's wage-adjusted labor-related portion of the wage-neutralized 75th percentile target amounts determined under paragraph (c)(4)(iii)(B)(*4*)(*ii*) of this section, subject to the provisions of paragraph (c)(4)(iv) of this section.

(iv) For purposes of the limits on target amounts established under paragraph (c)(4)(iii) of this section, each hospital or unit that qualifies for exclusion as a member of only one class of excluded facility (psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital) will be subject to the limit applicable to that class. If a hospital or unit qualifies to be classified in more than one way under the exclusion criteria in subpart B of part 412 of this chapter, the hospital's or unit's target amount may not exceed the lowest applicable limit.

(v) In the case of a hospital that received payments under paragraph (f)(2)(ii) of this section as a newly created hospital or unit, to determine the hospital's target amount for the hospital's third 12-month cost reporting period, the payment amount determined under paragraph (f)(2)(ii)(A) of this section for the preceding cost reporting period is updated to the third cost reporting period.

(5) *Applicable update factor.* (i) The applicable update factor is derived from the prospectively determined rate-of-increase percentage published by CMS. The update factor for each Federal fiscal year is applied prospectively to the target amount for each cost reporting period beginning during the Federal fiscal year.

(ii) In the case of cost reporting periods of less than 12 months, the target amount determined for a hospital's first cost reporting period beginning in a Federal fiscal year applies to subsequent periods beginning in the same Federal fiscal year.

(d) *Application of the target amount in determining the amount of payment*—(1) *General process.* (i) At the end of each cost reporting period subject to this section, the hospital's contractor will compare a hospital's allowable net inpatient operating costs with that hospital's ceiling (as defined in paragraph (a)(3) of this section) for that period.

(ii) The hospital's actual allowable costs will be determined without regard to the lesser of cost or charges provisions of §413.13, and in accordance with the provisions of paragraphs (d)(2) or (d)(3) of this section, as applicable.

(2) *Net inpatient operating costs are less than or equal to the ceiling.* (i) For cost reporting periods beginning on or after October 1, 1997, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient operating costs plus 2 percent of the ceiling.

(ii) For psychiatric hospitals and units, for cost reporting periods beginning on or after October 1, 2000 and before October 1, 2001, if a hospital's allowable net inpatient operating costs do not exceed the hospital's ceiling, payment to the hospital will be determined on the basis of the lower of the—

(A) Net inpatient operating costs plus 15 percent of the difference between inpatient operating costs and the ceiling; or

(B) Net inpatient costs plus 3 percent of the ceiling.

(3) *Net inpatient operating costs are greater than the ceiling.* For cost reporting periods beginning on or after October 1, 1997—

(i) If a hospital's allowable net inpatient operating costs do not exceed 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable);

(ii) If a hospital's allowable net inpatient operating costs are greater than 110 percent of the ceiling (or the adjusted ceiling, if applicable), payment will be the ceiling (or the adjusted ceiling, if applicable) plus the lesser of:

(A) 50 percent of the allowable net inpatient operating costs in excess of 110 percent of the ceiling (or the adjusted ceiling, if applicable); or

(B) 10 percent of the ceiling (or the adjusted ceiling, if applicable).

(4) *Continuous improvement bonus payments.* (i) For cost reporting periods beginning on or after October 1, 1997, eligible hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1 percent of the ceiling.

(ii) For cost reporting periods beginning on or after October 1, 2000, and before September 30, 2001, eligible psychiatric hospitals and units and long-term care hospitals (as defined in paragraph (d)(5) of this section) receive payments in addition to those in paragraph (d)(2) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the period; or

(B) 1.5 percent of the ceiling.

(iii) For cost reporting periods beginning on or after October 1, 2001, and before September 30, 2002, eligible psychiatric hospitals and units and long-term care hospitals receive payments in addition to those in paragraph (d)(5) of this section, as applicable. These payments are equal to the lesser of—

(A) 50 percent of the amount by which the operating costs are less than the expected costs for the periods; or

(B) 2 percent of the ceiling.

(5) *Eligibility requirements for continuous improvement bonus payments.* To qualify, a hospital must have been paid as a prospective payment excluded hospital for at least three full cost reporting periods prior to the applicable period, and the hospital's operating costs per discharge for the period must be less than the least of the following:

(i) The hospital's target amount.

(ii) The hospital's trended costs.

(A) For a hospital for which its cost reporting period ending during fiscal year 1996 was its third or subsequent full cost reporting period, trended costs are the lesser of the allowable inpatient operating costs per discharge or the target amount for the cost reporting period ending in fiscal year 1996, increased in a compounded manner for each succeeding fiscal year by the market basket percentage increase;

(B) For all other hospitals, trended costs are the allowable inpatient operating costs per discharge for its third full cost reporting period increased in a compounded manner for each succeeding fiscal year by the market basket increase.

(iii) The hospital's expected costs. The hospital's expected costs are the lesser of its allowable inpatient operating costs per discharge or the target amount for the previous cost reporting period, updated by the market basket percentage increase for the fiscal year.

(e) *Hospital requests regarding adjustments to the payment allowed under the rate-of-increase ceiling*—(1) *Timing of application.* A hospital may request an adjustment to the rate-of-increase ceiling

imposed under this section. The hospital's request must be received by the hospital's contractor no later than 180 days after the date on the contractor's initial notice of amount of program reimbursement (NPR) for the cost reporting period for which the hospital requests an adjustment.

(2) *Contractor recommendation.* Unless CMS has authorized the contractor to make the decision, the contractor makes a recommendation on the hospital's request to CMS, which makes the decision. CMS issues a decision to the contractor no later than 180 days after receipt of the completed application and the contractor's recommendation.

(3) *Contractor decision.* If CMS has authorized the contractor to make the decision, the contractor issues a decision no later than 180 days after receipt of the completed application.

(4) *Notification and review.* (i) The contractor notifies the hospital of the decision, including a full explanation of the grounds for the decision. A decision issued under paragraph (e)(2) or (e)(3) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the contractor's notice of the decision.

(ii) The final decision is subject to review under the provider reimbursement determination and appeal procedures in subpart R of part 405 of this chapter, provided the hospital has received an NPR for the cost reporting period in question, and the NPR disallows costs for which the hospital had requested an adjustment (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(5) *Extending the time limit for review of NPR.* The time required to review the request is considered good cause for the granting of an extension of the time limit for requesting an contractor hearing or a Board hearing as specified in §§ 405.1813 and 405.1836 of this chapter, respectively.

(6) *Applicability.* The provisions in paragraphs (e)(1) through (e)(5) of this section apply to a hospital's initial request for an adjustment and to a request for a review of the original decision based on additional data.

(f) *Comparison to the target amount for new hospitals and units*—(1) *New hospitals and units*—(i) *New hospitals.* For purposes of this section, a new hospital is a provider of hospital inpatient services that—

(A) Has operated as the type of hospital for which CMS granted it approval to participate in the Medicare program, under present or previous ownership (or both), for less than 2 full years; and

(B) Has provided the type of hospital inpatient services for which CMS granted it approval to participate in the Medicare program, for less than 2 years.

(ii) *New units.* A newly established unit that is excluded from the prospective payments system under the provisions of §§ 412.25 through 412.30 of this chapter does not qualify for the exemption afforded to a new hospital under paragraph (f)(2)(i) of this section unless the unit is located in an acute care hospital that, if it were subject to the provisions of this section, would qualify as a new hospital under paragraph (f)(1)(i) of this section.

(2) *Comparison*—(i) *Exemptions.* (A) A new children's hospital is exempt from the rate-of-increase ceiling imposed under this section. The exemption begins when the hospital accepts its first patient and ends at the end of the first cost reporting period ending at least 2 years after the hospital accepts its first patient. The first cost reporting period of at least 12 months beginning at least 1 year after the hospital accepts its first patient is the base year, in accordance with paragraph (b) of this section.

(B) Within 180 days of the date a hospital is excluded from the prospective payment system, the contractor determines whether the hospital is exempt from the rate-of-increase ceiling. The contractor notifies the hospital of its determination and the hospital's base period.

(C) A decision issued under paragraph (f)(2)(ii)(B) of this section is considered final unless the hospital submits additional information and requests a review of the decision no later than 180 days after the date on the contractor's

notice of the decision. The final decision is subject to review under subpart R of part 405 of this chapter, provided the hospital has received a notice of program reimbursement (NPR) for the cost reporting period in question and the NPR does not reflect an exemption (see the definitions in § 405.1801(a) of this chapter and the provisions regarding a provider's right to a Board hearing in § 405.1835 of this chapter).

(ii) *Median target amount.* (A) For cost reporting periods beginning on or after October 1, 1997, the amount of payment for a new psychiatric hospital or unit, a new rehabilitation hospital or unit, or a new long-term care hospital that was not paid as an excluded hospital prior to October 1, 1997, is the lower of the hospital's net inpatient operating cost per case or 110 percent of the national median of the target amounts for the class of excluded hospitals and units (psychiatric, rehabilitation, long-term care) as adjusted for differences in wage levels and updated to the first cost reporting period in which the hospital receives payment. The second cost reporting period is subject to the same target amount as the first cost reporting period.

(B) The national median of the target amounts is the FY 1996 median target amount—

(*1*) Adjusted to account for differences in area wage levels;

(*2*) Updated by the market basket percentage increase to the fiscal year in which the hospital first received payments as an excluded provider.

(3) *Risk-basis HMOs.* Items or services that are furnished to beneficiaries enrolled in an HMO by a hospital that is either owned or operated by a risk-basis HMO or related to a risk-basis HMO by common ownership or control are exempt from the rate-of-increase ceiling (see the definition of an entity with a risk sharing contract in § 417.401 of this chapter).

(g) *Adjustments*—(1) *General rules.* (i) CMS adjusts the amount of the operating costs considered in establishing the rate-of-increase ceiling for one or more cost reporting periods, including both periods subject to the ceiling and the hospital's base period, under the circumstances specified in paragraphs (g)(2), (g)(3), and (g)(4) of this section.

(ii) When the hospital requests an adjustment, CMS makes an adjustment only to the extent that the hospital's operating costs are reasonable, attributable to the circumstances specified separately, identified by the hospital, and verified by the contractor.

(iii) When the hospital requests an adjustment, CMS makes an adjustment only if the hospital's operating costs exceed the rate-of-increase ceiling imposed under this section.

(iv) In the case of a psychiatric hospital or unit, rehabilitation hospital or unit, or long-term care hospital, the amount of payment under paragraph (g)(3) of this section may not exceed the payment amount based on the target amount determined under paragraph (c)(4)(iii) of this section.

(v) In the case of a hospital or unit that received a revised FY 1998 target amount under the rebasing provisions of paragraph (b)(1)(iv) of this section, the amount of an adjustment payment for a cost reporting period is based on a comparison of the hospital's operating costs for the cost reporting period to the average costs and statistics for the cost reporting periods used to determine the FY 1998 rebased target amount.

(2) *Extraordinary circumstances.* CMS may make an adjustment to take into account unusual costs (in either a cost reporting period subject to the ceiling or the hospital's base period) due to extraordinary circumstances beyond the hospital's control. These circumstances include, but are not limited to, strikes, fire, earthquakes, floods, or similar unusual occurrences with substantial cost effects.

(3) *Comparability of cost reporting periods*—(i) *Adjustment for distortion.* CMS may make an adjustment to take into account factors that would result in a significant distortion in the operating costs of inpatient hospital services between the base year and the cost reporting period subject to the limits.

(ii) *Factors.* The adjustments described in paragraph (g)(3)(i) of this section, include, but are not limited to, adjustments to take into account:

(A) FICA taxes (if the hospital did not incur costs for FICA taxes in its base period).

(B) Services billed under part B of Medicare during the base period, but paid under part A during the subject cost reporting period.

(C) Malpractice insurance costs (if malpractice costs were not included in the base year operating costs).

(D) Increases in service intensity or length of stay attributable to changes in the type of patient served.

(E) A change in the inpatient hospital services that a hospital provides, and that are customarily provided directly by similar hospitals, such as an addition or discontinuation of services or treatment programs.

(F) The manipulation of discharges to increase reimbursement.

(iii) *Adjusting operating costs.* Without a formal request from a hospital, CMS may adjust the amount of operating costs determined under paragraph (c)(1) of this section to take into account certain adjustments. These adjustments include, but are not limited to, adjustments under paragraphs (g)(3)(ii)(A), (B), (C), (E), and (F) of this section.

(4) *Significant wage increase.* (i) *Criteria.* CMS may make an adjustment to take into account a significant increase in wages occurring between the base period and the cost reporting period subject to the ceiling if there is a significant increase in the average hourly wage for the geographic area in which the hospital is located (determined by reference to the wage index for prospective payment hospitals without regard to geographic reclassifications under sections 1886(d)(8) and (10) of the Act). For this purpose, there is a significant wage increase if the wage index value based on wage survey data collected for the cost reporting period subject to the ceiling is at least 8.0 percent higher than the wage index value based on survey data collected for the base year cost reporting period. If survey data are not available for the cost reporting periods used in the comparison, the wage index value based on the latest available survey data collected prior to that cost reporting period is used.

(ii) *Amount of the adjustment.* The adjustment for a significant wage increase equals the amount by which the lesser of the following calculations exceeds 108 percent of the increase in the national average hourly earnings for hospital workers:

(A) The rate of increase in the average hourly wage in the geographic area (determined by applying the applicable increase in the area wage index value to the rate of increase in the national average hourly earnings for hospital workers).

(B) The rate of increase in the hospital's average hourly wage.

(5) *Adjustment limitations.* For cost reporting periods beginning on or after October 1, 1993, and before October 1, 2003, the payment reductions under paragraph (c)(3)(v) through (c)(3)(vii) of this section will not be considered when determining adjustments under this paragraph.

(h) [Reserved]

(i) *Assignment of a new base period*—(1) *General rule.* (i) Effective with cost reporting periods beginning on or after April 1, 1990, CMS may assign a new base period to establish a revised ceiling if the new base period is more representative of the reasonable and necessary cost of furnishing inpatient services and all the following conditions apply:

(A) The actual allowable inpatient costs of the hospital in the cost reporting period that would be affected by the revised ceiling exceed the target amount established under paragraph (c) of this section.

(B) The hospital documents that the higher costs are the result of substantial and permanent changes in furnishing patient care services since the base period. In making this determination, CMS takes into consideration the following factors:

(*1*) Changes in the services provided by the hospital.

(*2*) Changes in applicable technologies and medical practices.

(*3*) Differences in the severity of illness among patients or types of patients served.

(C) The adjustments described in paragraph (g) of this section would not result in recognition of the reasonable and necessary costs of providing inpatient services.

(ii) The revised ceiling is based on the necessary and proper costs incurred during the new base period.

(A) Increases in overhead costs (for example, administrative and general costs and housekeeping costs) are not taken into consideration unless the hospital documents that these increases result from substantial and permanent changes in furnishing patient care services.

(B) In determining whether wage increases are necessary and proper, CMS takes into consideration whether increases in wages and wage-related costs for hospitals in the labor market area exceed the national average increase.

(2) *New base period.* The new base period is the first cost reporting period that is 12 months or longer that reflects the substantial and permanent change.

(3) *New applicable rate-of-increase percentages and update factors.* The revised target amount resulting from the assignment of a new base period is increased by the applicable rate-of-increase percentages (update factors) described in paragraph (c)(3) of this section.

(j) *Reduction to capital-related costs.* For psychiatric hospital and units, rehabilitation hospitals and units, and long-term care hospitals, the amount otherwise payable for capital-related costs for hospital inpatient services is reduced by 15 percent for portions of cost reporting periods occurring on or after October 1, 1997 through September 30, 2002.

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.40, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

Subpart D—Apportionment

§ 413.50 Apportionment of allowable costs.

(a) Consistent with prevailing practice in which third-party organizations pay for health care on a cost basis, reimbursement under the Medicare program involves a determination of—

(1) Each provider's allowable costs for producing services; and

(2) The share of these costs which is to be borne by Medicare. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs. The share to be borne by Medicare is to be determined in accordance with principles relating to apportionment of cost.

(b) In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under Medicare that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

(c) A basic factor bearing upon apportionment of costs is that Medicare beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the Medicare share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients serviced by the provider.

(d) The method of cost reimbursement most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average-per-diem cost, does not take into account, variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

(e) In considering the average-per-diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance

of presently available evidence strongly indicates that the over-age 65 patient is not typical from the standpoint of average-per-diem cost. On the average this patient stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average-per-diem cost for the aged alone, significantly below the average-per-diem for all patients.

(f) Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only for services to beneficiaries.

(g) A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

(h) An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs in which individuals are indemnified for incurred expenses, a form of health insurance widely held throughout the United States. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay ''costs or charges, whichever is less'' and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

(i) An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods that utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained through a breakdown of data from the provider's accounting records.

(j) For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by ''cost-finding'' techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are furnished.

§ 413.53 Determination of cost of services to beneficiaries.

(a) *Principle.* Total allowable costs of a provider will be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. The methods of apportionment are defined as follows:

(1) *Departmental method*—(i) *Methodology.* Except as provided in paragraph (a)(1)(ii) of this section with respect to the treatment of the private room cost differential for cost reporting periods starting on or after October 1, 1982, the ratio of beneficiary charges to total patient charges for the services of each ancillary department is applied to the cost of the department; to this is added the cost of routine services for program beneficiaries, determined on the basis of a separate average cost per diem for general routine patient care areas as

defined in paragraph (b) of this section, taking into account, in hospitals, a separate average cost per diem for each intensive care unit, coronary care unit, and other intensive care type inpatient hospital units.

(ii) *Exception: Indirect cost of private rooms.* For cost reporting periods starting on or after October 1, 1982, except with respect to a hospital receiving payment under part 412 of this chapter (relating to the prospective payment system), the additional cost of furnishing services in private room accommodations is apportioned to Medicare only if these accommodations are furnished to program beneficiaries, and are medically necessary. To determine routine service cost applicable to beneficiaries—

(A) Multiply the average cost per diem (as defined in paragraph (b) of this section) by the total number of Medicare patient days (including private room days whether or not medically necessary);

(B) Add the product of the average per diem private room cost differential (as defined in paragraph (b) of this section) and the number of medically necessary private room days used by beneficiaries; and

(C) Effective October 1, 1990, do not include private rooms furnished for SNF-type and NF-type services under the swing-bed provision in the number of days in paragraphs (a)(1)(ii)(A) and (B) of this section.

(2) *Carve-out out method.* (i) The carve-out out method is used to allocate hospital inpatient general routine service costs in a participating swing-bed hospital, as defined in § 413.114(b). Under this method, effective for services furnished on or after October 1, 1990, the reasonable costs attributable to the inpatient routine SNF-type and NF-type services furnished to all classes of patients are subtracted from total inpatient routine service costs before computing the average cost per diem for inpatient routine hospital care.

(ii) The cost per diem attributable to the routine SNF-type services covered by Medicare is based on the regional Medicare swing-bed SNF rate in effect for a given calendar year, as described in § 413.114(c). The Medicare SNF rate applies only to days covered and paid as Medicare days. When Medicare coverage runs out, the Medicare rate no longer applies.

(iii) The cost per diem attributable to all non-Medicare swing-bed days is based on the average statewide Medicaid NF rate for the prior calendar year, adjusted to approximate the average NF rate for the current calendar year.

(iv) The sum of total Medicare SNF-type days multiplied by the cost per diem attributable to Medicare SNF-type services and the total NF-type days multiplied by the cost per diem attributable to all non-Medicare days is subtracted from total inpatient general routine service costs. The cost per diem for inpatient routine hospital care is computed based on the remaining inpatient routine service costs.

(3) *Cost per visit by type-of-service method—HHAs.* For cost reporting periods beginning on or after October 1, 1980, all HHAs must use the cost per visit by type-of-service method of apportioning costs between Medicare and non-Medicare beneficiaries. Under this method, the total allowable cost of all visits for each type of service is divided by the total number of visits for that type of service. Next, for each type of service, the number of Medicare covered visits is multiplied by the average cost per visit just computed. This represents the cost Medicare will recognize as the cost for that service, subject to cost limits published by CMS (see § 413.30).

(b) *Definitions.* As used in this section—

Ancillary services means the services for which charges are customarily made in addition to routine services.

Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the Medicare program and other patients.

Average cost per diem for general routine services means the following:

(1) For cost reporting periods beginning on or after October 1, 1982, subject to the provisions on swing-bed hospitals, the average cost of general routine services net of the private room cost differential. The average cost per diem is computed by the following methodology:

(i) Determine the total private room cost differential by multiplying the average per diem private room cost differential determined in paragraph (c) of this section by the total number of private room patient days.

(ii) Determine the total inpatient general routine service costs net of the total private room cost differential by subtracting the total private room cost differential from total inpatient general routine service costs.

(iii) Determine the average cost per diem by dividing the total inpatient general routine service cost net of private room cost differential by all inpatient general routine days, including total private room days.

(2) For swing-bed hospitals, the amount computed by—

(i) Subtracting the routine costs associated with Medicare SNF-type days and non-Medicare NF-type days from the total allowable inpatient cost for routine services (excluding the cost of services provided in intensive care units, coronary care units, and other intensive care type inpatient hospital units and nursery costs); and

(ii) Dividing the remainder (excluding the total private room cost differential) by the total number of inpatient hospital days of care (excluding Medicare SNF-type days and non-Medicare NF-type days of care, days of care in intensive care units, coronary care units, and other intensive care type inpatient hospital units; and newborn days; but including total private room days).

Average cost per diem for hospital intensive care type units means the amount computed by dividing the total allowable costs for routine services in each of these units by the total number of inpatient days of care furnished in each of these units.

Average per diem private room cost differential means the difference in the average per diem cost of furnishing routine services in a private room and in a semi-private room. (This differential is not applicable to hospital intensive care type units.) (The method for computing this differential is described in paragraph (c) of this section.)

Charges means the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

Intensive care type inpatient hospital unit means a hospital unit that furnishes services to critically ill inpatients. Examples of intensive care type units include, but are not limited to, intensive care units, trauma units, coronary care units, pulmonary care units, and burn units. Excluded as intensive care type units are post-operative recovery rooms, postanesthesia recovery rooms, maternity labor rooms, and subintensive or intermediate care units. (The unit must also meet the criteria of paragraph (d) of this section.)

Nursing facility (NF)-type services, formerly known as ICF and SNF-type services, are routine services furnished by a swing-bed hospital to Medicaid and other non-Medicare patients. Under the Medicaid program, effective October 1, 1990, facilities are no longer certified as SNFs or ICFs but instead are certified only as NFs and can provide services as defined in section 1919(a)(1) of the Act.

Skilled nursing facility (SNF)-type services are routine services furnished by a swing-bed hospital that would constitute extended care services if furnished by an SNF. SNF-type services include routine SNF services furnished in the distinct part SNF of a hospital complex that is combined with the hospital general routine service area cost center under § 413.24(d)(5). Effective October 1, 1990, only Medicare covered services are included in the definition of SNF-type services.

Ratio of beneficiary charges to total charges on a departmental basis means the ratio of charges to beneficiaries of the Medicare program for services of a revenue-producing department or center to the charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services furnished to beneficiaries of the Medicare program is computed by applying the individual ratio for the center to the cost of the related center for the period.

Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(c) *Method for computing the average per diem private room cost differential.* Compute the average per diem private room cost differential as follows:

(1) Determine the average per diem private room charge differential by subtracting the average per diem charge for all semi-private room accommodations from the average per diem charge for all private room accommodations. The average per diem charge for private room accommodations is determined by dividing the total charges for private room accommodations by the total number of days of care furnished in private room accommodations. The average per diem charge for semi-private accommodations is determined by dividing the total charges for semi-private room accommodations by the total number of days of care furnished in semi-private accommodations.

(2) Determine the inpatient general routine cost to charge ratio by dividing total inpatient general routine service cost by the total inpatient general routine service charges.

(3) Determine the average per diem private room cost differential by multiplying the average per diem private room charge differential determined in paragraph (c)(1) of this section by the ratio determined in paragraph (c)(2) of this section.

(d) *Criteria for identifying intensive care type units.* For purposes of determining costs under this section, a unit will be identified as an intensive care type inpatient hospital unit only if the unit—

(1) Is in a hospital;

(2) Is physically and identifiably separate from general routine patient care areas, including subintensive or intermediate care units, and ancillary service areas. There cannot be a concurrent sharing f nursing staff between an intensive care type unit and units or areas furnishing different levels or types of care. However, two or more intensive care type units that concurrently share nursing staff can be reimbursed as one combined intensive care type unit if all other criteria are met. Float nurses (nurses who work in different units on an as-needed basis) can be utilized in the intensive care type unit. If a float nurse works in two different units during the same eight hour shift, then the costs must be allocated to the appropriate units depending upon the time spent in those units. The hospital must maintain adequate records to support the allocation. If such records are not available, then the costs must be allocated to the general routine services cost areas;

(3) Has specific written policies that include criteria for admission to, and discharge from, the unit;

(4) Has registered nursing care available on a continuous 24-hour basis with at least one registered nurse present in the unit at all times;

(5) Maintains a minimum nurse-patient ratio of one nurse to two patients per patient day. Included in the calculation of this nurse-patient ratio are registered nurses, licensed vocational nurses, licensed practical nurses, and nursing assistants who provide patient care. Not included are general support personnel such as ward clerks, custodians, and housekeeping personnel; and

(6) Is equipped, or has available for immediate use, life-saving equipment necessary to treat the critically ill patients for which it is designed. This equipment may include, but is not limited to, respiratory and cardiac monitoring equipment, respirators, cardiac defibrillators, and wall or canister oxygen and compressed air.

(e) *Application*—(1) *Departmental method; Cost reporting periods beginning on or after October 1, 1982.* (i) The following example illustrates how costs would be determined, using only inpatient data, for cost reporting periods beginning on or after October 1, 1982, based on apportionment of—

(A) The average cost per diem for general routine services (subject to the private room differential provisions of paragraph (a)(1)(iii) of this section);

(B) The average cost per diem for each intensive care type unit;

(C) The ratio of beneficiary charges to total charges applied to cost by department.

HOSPITAL Y

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
	Percent				
Operating rooms	$20,000	$70,000	28⅔	$77,000	$22,000
Delivery rooms	0	12,000	0	30,000	0
Pharmacy	20,000	60,000	33⅓	45,000	15,000
X-ray	24,000	100,000	24	75,000	18,000
Laboratory	40,000	140,000	28⅔	98,000	28,000
Others	6,000	30,000	20	25,000	5,000
Total	110,000	412,000	.....	350,000	88,000

	Total inpatient days	Total cost	Average cost per diem	Program in patient days	Cost of beneficiary services
General routine	30,000	$630,000	$21	8,000	$168,000
Coronary care unit	500	20,000	40	200	8,000
Intensive care unit	3,000	108,000	36	1,000	36,000
	33,500	758,000	.....	9,200	212,000
Total	.....	.....	.....	.....	300,000

(ii) The following illustrates how apportionment based on an average cost per diem for general routine services is determined.

HOSPITAL E

Facts	Private accommodations	Semi-private accommodations	Total
Total charges	$20,000	$175,000	$195,000
Total days	100	1,000	1,100
Programs days	70	400	470
Medically necessary for program beneficiaries	20	.....	20
Total general routine service costs	.....	.....	165,000
Average private room per diem charge ($20,000 private room charges ÷ 100 days)			[1] $200
Average semi-private room per diem charge ($175,000 semi-private charge ÷ 1,000 days)			[1] $175

[1] Per diem.

Average per diem private room cost differential.

1. Average per diem private room charge differential ($200 private room per diem—$175, semi-private room per diem), $25.
2. Inpatient general routine cost/charge ratio ($165,000 total costs ÷ $195,000 total charges), 0.8461538.
3. Average per diem private room cost differential ($25 charge differential × .8461538 cost/charge ratio), $21.15.

Average cost per diem for inpatient general routine services.

4. Total private room cost differential ($21.15 average per diem cost differential × 100 private room days), $2,115.
5. Total inpatient general routine service costs net of private room cost differential ($165,000 total routine cost −$2,115 private room cost differential), $162,885.
6. Average cost per diem for inpatient general routine services ($162,885 routine cost net of private room cost differential ÷ 1,100 patient days), $148.08.

Medicare general routine service cost.

7. Total routine per diem cost applicable to Medicare ($148.08 average cost per diem × 470 Medicare private and semi-private patient days), $69,598.
8. Total private room cost differential applicable to Medicare ($21.15 average per diem private room cost differential × 20 medically necessary private room days), $423.
9. Medicare inpatient general routine service cost ($423 Medicare private room cost differential + $69,598 Medicare cost of general routine inpatient services), $70,021.

(2) *Carve out method.* The following illustrates how apportionment is determined in a hospital reimbursed under the carve out method (subject to the private room differential provisions of paragraph (a)(1)(ii) of this section):

HOSPITAL K

[Determination of cost of routine SNF-type and ICF-type services and general routine hospital services [1]]

Facts	Days of care		
	General routine hospital	SNF-type	ICF-type
Total days of care	2,000	400	100
Medicare days of care ...	600	300	
Average Medicaid rate ..	N/A	$35	$20
Total inpatient general routine service costs: $250,000			

Calculation of cost of routine SNF-type services applicable to Medicare:

$35 × 300 = $10,500

Calculation of cost of general routine hospital services:

Cost of SNF-type services: $35 × 400 ..	$14,000
Cost of ICF-type services: $20 × 100 ...	2,000
Total	$16,000

Average cost per diem of general routine hospital services:

$250,000 − $16,000 ÷ 2,000 days = $117

Medicare general routine hospital cost:

$117 × 600 = $70,200

Total Medicare reasonable cost for general routine inpatient days:

$10,500 + $70,200 = $80,700

[51 FR 34793, Sept. 30, 1986, as amended at 59 FR 45401, Sept. 1, 1994; 61 FR 51616, Oct. 3, 1996; 61 FR 58631, Nov. 18, 1996]

§ 413.56 [Reserved]

Subpart E—Payments to Providers

§ 413.60 Payments to providers: General.

(a) The fiscal contractors will establish a basis for interim payments to each provider. This may be done by one of several methods. If an contractor is already paying the provider on a cost basis, the contractor may adjust its rate of payment to an estimate of the result under the Medicare principles of reimbursement. If no organization is paying the provider on a cost basis, the contractor may obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per diem, or to charges, or to any other ready basis of approximating costs.

(b) At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, determines the Medicare reimbursement for the actual services provided to beneficiaries during the period.

(c) Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

§ 413.64 Payments to providers: Specific rules.

(a) *Reimbursement on a reasonable cost basis.* Providers of services paid on the basis of the reasonable cost of services furnished to beneficiaries will receive interim payments approximating the actual costs of the provider. These payments will be made on the most expeditious schedule administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of a reporting period.

(b) *Amount and frequency of payment.* Medicare states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While Medicare provides that interim payments will be made no less often than monthly, contractors are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

(c) *Interim payments during initial reporting period.* At the beginning of the

program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the Medicare program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) If the contractor is already paying the provider on a cost or cost-related basis, the contractor will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services furnished to the program's beneficiaries.

(2) If an organization other than the contractor is paying the provider for services on a cost or cost-related basis, the contractor may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) It no organization is paying the provider on a cost or cost-related basis, the contractor will obtain the previous year's financial statement from the provider. By analysis of such statement in light of the principles of reimbursement, the contractor will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the contractor that costs have increased. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(d) *Interim payments for new providers.* (1) Newly-established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the contractor will use the following methods to determine an appropriate rate:

(i) If there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the contractor will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the contractor will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the contractor will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

(e) *Interim payments after initial reporting period.* Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering Medicare services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the contractor during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the contractor may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

(f) *Retroactive adjustment.* (1) Medicare provides that providers of services will be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the

period into agreement with the reimbursable amount payable to the provider for the services furnished to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services furnished during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

(g) *Accelerated payments to providers.* Upon request, an accelerated payment may be made to a provider of services that is not receiving periodic interim payments under paragraph (h) of this section if the provider has experienced financial difficulties due to a delay by the contractor in making payments or in exceptional situations, in which the provider has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle. Any such payment must be approved first by the contractor and then by CMS. The amount of the payment is computed as a percentage of the net reimbursement for unbilled or unpaid covered services. Recovery of the accelerated payment may be made by recoupment as provider bills are processed or by direct payment.

(h) *Periodic interim payment method of reimbursement*—(1) *Covered services furnished before July 1, 1987.* In addition to the regular methods of interim payment on individual provider billings for covered services, the periodic interim payment (PIP) method is available for Part A hospital and SNF inpatient services.

(2) *Covered services furnished on or after July 1, 1987.* Effective with claims received on or after July l, 1987, or as otherwise specified, the periodic interim payment (PIP) method is available for the following:

(i) Part A inpatient services furnished in hospitals that are excluded from the prospective payment systems, as specified in § 412.1(a)(1) of this chapter under subpart B of part 412 of this subchapter, or are paid under the prospective payment systems described in subpart N, O, and P of part 412 of this chapter.

(ii) Part A services furnished in hospitals receiving payment in accordance with a demonstration project authorized under section 402(a) of Public Law 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Public Law 92–603 (42 U.S.C. 1395b–1 (note)), or a State reimbursement control system approved under section 1886(c) of the Act and subpart C of part 403 of this chapter, if that type of payment is specifically approved by CMS as an integral part of the demonstration or control system. If that type of payment is not an integral part of the demonstration or control system, PIP is available for the hospital under paragraph (h)(1)(i) of this section for hospitals excluded from the prospective payment systems or under § 412.116(b) of this chapter for prospective payment hospitals.

(iii) Part A SNF services furnished in cost reporting periods beginning before July 1, 1998. (For services furnished in subsequent cost reporting periods, see § 413.350 regarding periodic interim payments for skilled nursing facilities).

(iv) Part A services furnished in hospitals paid under the prospective payment system, including distinct part psychiatric or rehabilitation units, as described in § 412.116(b) of this chapter.

(v) Services furnished in a hospice as specified in part 418 of this chapter. Payment on a PIP basis is described in § 418.307 of this chapter.

(vi) Effective for payments made on or after July 1, 2004, inpatient CAH services furnished by a CAH as specified in § 413.70. Payment on a PIP basis is described in § 413.70(d).

(3) Any participating provider furnishing the services described in paragraphs (h)(1) and (h)(2) of this section that establishes to the satisfaction of the contractor that it meets the following requirements may elect to be reimbursed under the PIP method, beginning with the first month after its request that the contractor finds administratively feasible:

(i) The provider's estimated total Medicare reimbursement for inpatient services is at least $25,000 a year computed under the PIP formula or, in the case of an HHA, either its estimated—

(A) Total Medicare reimbursement for Part A and Part B services is at least $25,000 a year computed under the PIP formula; or

(B) Medicare reimbursement computed under the PIP formula is at least 50 percent of estimated total allowable cost.

(ii) The provider has filed at least one completed Medicare cost report accepted by the contractor as providing an accurate basis for computation of program payment (except in the case of a provider requesting reimbursement under the PIP method upon first entering the Medicare program).

(iii) The provider has the continuing capability of maintaining in its records the cost, charge, and statistical data needed to accurately complete a Medicare cost report on a timely basis.

(4) [Reserved]

(5) The contractor's approval of a provider's request for reimbursement under the PIP method will be conditioned upon the contractor's best judgment as to whether payment can be made to the provider under the PIP method without undue risk of its resulting in an overpayment because of greatly varying or substantially declining Medicare utilization, inadequate billing practices, or other circumstances. The contractor may terminate PIP reimbursement to a provider at any time it determines that the provider no longer meets the qualifying requirements or that the provider's experience under the PIP method shows that proper payment cannot be made under this method.

(6) Payment will be made biweekly under the PIP method unless the provider requests a longer fixed interval (not to exceed one month) between payments. The payment amount will be computed by the contractor to approximate, on the average, the cost of covered inpatient or home health services furnished by the provider during the period for which the payment is to be made, and each payment will be made two weeks after the end of such period of services. Upon request, the contractor will, if feasible, compute the provider's payments to recognize significant seasonal variation in Medicare utilization of services on a quarterly basis starting with the beginning of the provider's reporting year.

(7) A provider's PIP amount may be appropriately adjusted at any time if the provider presents or the contractor otherwise obtains evidence relating to the provider's costs or Medicare utilization that warrants such adjustment. In addition, the contractor will recompute the payment immediately upon completion of the desk review of a provider's cost report and also at regular intervals not less often than quarterly. The contractor may make a retroactive lump sum interim payment to a provider, based upon an increase in its PIP amount, in order to bring past interim payments for the provider's current cost reporting period into line with the adjusted payment amount. The objective of contractor monitoring of provider costs and utilization is to assure payments approximating, as closely as possible, the reimbursement to be determined at settlement for the cost reporting period. A significant factor in evaluating the amount of the payment in terms of the realization of the projected Medicare utilization of services is the timely submittal to the contractor of completed admission and billing forms. All providers must complete billings in detail under this method as under regular interim payment procedures.

(i) *Bankruptcy or insolvency of provider.* If on the basis of reliable evidence, the contractor has a valid basis for believing that, with respect to a provider, proceedings have been or will shortly be instituted in a State or Federal court for purposes of determining whether such provider is insolvent or bankrupt under an appropriate State or Federal law, any payments to the

provider will be adjusted by the contractor, notwithstanding any other regulation or program instruction regarding the timing or manner of such adjustments, to a level necessary to insure that no overpayment to the provider is made.

(j) *Interest payments resulting from judicial review*—(1) *Application.* If a provider of services seeks judicial review by a Federal court (see §405.1877 of this chapter) of a decision furnished by the Provider Reimbursement Review Board or subsequent reversal, affirmation, or modification by the Secretary, the amount of any award of such Federal court will be increased by interest payable by the party against whom the judgment is made (see §413.153 for treatment of interest). The interest begins to accrue on the first day of the first month following the 180-day period described in §405.1835(a)(3)(i) or (a)(3)(ii) of this chapter, as applicable.

(2) *Amount due.* Section 1878(f) of the Act, 42 U.S.C. 1395oo(f), authorizes a court to award interest in favor of the prevailing party on any amount due as a result of the court's decision. If the contractor withheld any portion of the amount in controversy prior to the date the provider seeks judicial review by a Federal court, and the Medicare program is the prevailing party, interest is payable by the provider only on the amount not withheld. Similarly, if the Medicare program seeks to recover amounts previously paid to a provider, and the provider is the prevailing party, interest on the amounts previously paid to a provider is not payable by the Medicare program since that amount had been paid and is not due the provider.

(3) *Rate.* The amount of interest to be paid is equal to the rate of return on equity capital (see §413.157) in effect for the month in which the civil action is commenced.

Example: An contractor made a final determination on the amount of Medicare program reimbursement on June 15, 1974, and the provider appealed that determination to the Provider Reimbursement Review Board. The Board heard the appeal and rendered a decision adverse to the provider. On October 28, 1974, the provider commenced civil action to have such decision reviewed. The rate of return on equity capital for the month of October 1974 was 11.625 percent. The period for which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994; 64 FR 41682, July 30, 1999; 65 FR 41211, July 3, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 56056, Aug. 30, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004; 73 FR 30267, May 23, 2008]

§413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions.* (1) *Scope.* (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in §§412.22(h)(1) and 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

(A) Ambulatory surgical centers (ASCs).

(B) Comprehensive outpatient rehabilitation facilities (CORFs).

(C) Home health agencies (HHAs).

(D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in §483.5 of this chapter).

(E) Hospices.

(F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, other than those clinical diagnostic laboratories operating as parts of CAHs on or after October 1, 2010, or facilities that furnish only some combination of these services.

(H) Facilities, other than those operating as parts of CAHs, furnishing only

physical, occupational, or speech therapy to ambulatory patients, throughout any period during which the annual financial cap amount on payment for coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, is suspended by legislation.

(I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(K) Ambulances.

(L) Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds.

(2) *Definitions.* In this subpart E, unless the context indicates otherwise—

Campus means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

Department of a provider means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term ''department of a provider'' does not include an RHC or, except as specified in paragraph (n) of this section, an FQHC.

Free-standing facility means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

Main provider means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

Provider-based entity means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

Provider-based status means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

Remote location of a hospital means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital

comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ''remote location of a hospital'' does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

(b) *Provider-based determinations.* (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request. If the facility is operated as a joint venture, the provider would also have to attest that it will comply with the requirements of paragraph (f) of this section.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services

of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.

(5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as

evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

(ii) The main provider and the facility or organization seeking status as a department of the main provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organization are integrated with those of the

provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.

(i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under §412.106 of this chapter) greater than 11.75 percent or is described in §412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).

(iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(v) The facility or organization meets all of the following criteria:

(A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in §412.23(d) for reimbursement under Medicare as a children's hospital;

(B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under §413.53(d).

(C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

(D) The hospital in which the facility or organization is physically located is in a rural area as defined in §412.64(b)(1)(ii)(C) of this chapter.

(E) The facility or organization is located within a 100-mile radius of the children's hospital that is the potential main provider.

(F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.

(G) The facility or organization meets all other requirements for provider-based status under this section.

(vi) Both of the following criteria are met:

(A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under § 412.105(b) of this chapter; and

(B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in § 412.64(b)(1)(ii)(C) of this subchapter.

(vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(f) *Provider-based status for joint ventures.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

(1) The following departments must comply with the antidumping rules of §§ 489.20(l), (m), (q), and (r) and 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in § 489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at § 412.2(c)(5) of this chapter and at § 413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, and the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the

physician service, the following requirements must be met:

(i) The hospital must provide written notice to the beneficiary, before the delivery of services, of—

(A) The amount of the beneficiary's potential financial liability; or

(B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.

(ii) The notice must be one that the beneficiary can read and understand.

(iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of §489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of ''leased'' employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based*—(1) *Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this section, and continue payments to the

provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will not recover any payments for any period before the beginning of the hospital's first cost reporting period beginning on or after January 10, 2001, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date

CMS issues notice that necessary applications or information have not been submitted.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(l) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Services and Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if they furnish only services that are billed, using the CCN of the main provider and with the consent of the main provider, as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes: or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93–638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(n) *FQHCs and ''look alikes.''* A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility—

(1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000

under section 330 of the Public Health Service Act under a contract with the beneficiary of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.

(o) *Effective date of provider-based status*—(1) *General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

[65 FR 18538, Apr. 7, 2000, as amended at 65 FR 58920, Oct. 3, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59920, Nov. 30, 2001; 67 FR 50114, Aug. 1, 2002; 68 FR 46070, Aug. 4, 2003; 68 FR 53261, Sept. 9, 2003; 70 FR 47487, Aug. 12, 2005; 74 FR 44000, Aug. 27, 2009; 82 FR 38515, Aug. 14, 2017]

§ 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH and other than the items included in the incentive payment described in paragraph (a)(5) of this section and subject to the adjustments described in paragraph (a)(6) of this section, is 101 percent of the reasonable costs of the CAH in providing CAH services to its inpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH inpatient services:

(i) Lesser of cost or charges;

(ii) Ceilings on hospital operating costs;

(iii) Reasonable compensation equivalent (RCE) limits for physician services to providers; and

(iv) The payment window provisions for preadmission services, specified in § 412.2(c)(5) of this subchapter and § 413.40(c)(2) of this part.

(2) Except as specified in paragraph (a)(3) of this section, payment to a CAH for inpatient services does not include any costs of physician services or other professional services to CAH inpatients, and is subject to the Part A hospital deductible and coinsurance, as determined under subpart G of part 409 of this chapter.

(3) If a CAH meets the criteria in § 412.113(c) of this subchapter for passthrough of costs of anesthesia services furnished by qualified nonphysician anesthetists employed by the CAH or obtained under arrangements, payment to the CAH for the costs of those services is made in accordance with § 412.113(c).

(4) Payment for inpatient services of distinct part psychiatric or rehabilitation units is described in paragraph (e) of this section.

(5) A qualifying CAH receives an incentive payment for the reasonable costs of purchasing certified EHR technology in a cost reporting period during a payment year as determined under § 495.106 of this chapter in lieu of payment for such reasonable costs under paragraph (a)(1) of this section.

(6)(i) For cost reporting periods beginning in or after FY 2015, if a CAH is not a qualifying CAH for the applicable

EHR reporting period, as defined in §§ 495.4 and 495.106(a) of this chapter, then notwithstanding the percentage applicable in paragraph (a)(1) of this section, the reasonable costs of the CAH in providing CAH services to its inpatients are adjusted by the following applicable percentage:

(A) For cost reporting periods beginning in FY 2015, 100.66 percent.

(B) For cost reporting periods beginning in FY 2016, 100.33 percent.

(C) For cost reporting periods beginning in FY 2017 and each subsequent fiscal year, 100 percent.

(ii) The Secretary may on a case-by-case basis, exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful user would result in a significant hardship for the CAH. In order to be considered for an exception, a CAH must submit an application demonstrating that it meets one or more of the criteria specified in this paragraph (a)(6) for the applicable payment adjustment year no later than November 30 after the close of the applicable EHR reporting period, or a later date specified by CMS. The Secretary may grant an exception for one or more of the following:

(A) During any 90-day period from the beginning of the cost reporting period that begins in the fiscal year before the payment adjustment year to November 30 after the end of the payment adjustment year, or a later date specified by CMS, the hospital was located in an area without sufficient Internet access to comply with the meaningful use objectives requiring Internet connectivity, and faced insurmountable barriers to obtaining such Internet connectivity.

(B) A CAH that faces extreme and uncontrollable circumstances that prevent it from becoming a meaningful EHR user during the payment adjustment year.

(C) The CAH is new in the payment adjustment year and has not previously operated (under previous or present ownership). This exception expires beginning with the first Federal fiscal year that begins on or after the hospital has had at least one 12-month (or longer) cost reporting period after they accept their first Medicare-covered patient. For the purposes of this exception, the following CAHs are not considered new CAHs:

(*1*) A CAH that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management, or a lease arrangement.

(*2*) A CAH that closes and subsequently reopens.

(*3*) A CAH that has been converted from an eligible hospital as defined at § 495.4 of this chapter.

(iii) *Exception for decertified EHR technology*. Beginning with the fiscal year 2018 payment adjustment year, the Secretary shall exempt a CAH that is not a qualifying CAH from the application of the payment adjustment under paragraph (a)(6)(i) of this section if the Secretary determines that compliance with the requirement for being a meaningful EHR user is not possible because the certified EHR technology used by the CAH has been decertified under ONC's Health IT Certification Program. In order to be considered for an exception, a CAH must submit an application, in the manner specified by CMS, demonstrating that the certified EHR technology was decertified during the 12-month period preceding the applicable EHR reporting period for the payment adjustment year, or during the applicable EHR reporting period for the payment adjustment year, and that the CAH made a good faith effort to obtain another certified EHR technology for that EHR reporting period. Applications requesting this exception must be submitted by November 30 after the end of the applicable payment adjustment year, or a later date specified by CMS.

(iv) Exceptions granted under paragraphs (a)(6)(ii) and (iii) of this section are subject to annual renewal, but in no case may a CAH be granted such an exception for more than 5 years.

(7) There is no administrative or judicial review under section s1869 and 1878 of the Actor otherwise of the following:

(i) The methodology and standards for determining the amount of payment under paragraph (a)(5) of this section, including the calculation of reasonable costs under § 495.106(c) of this chapter.

(ii) The methodology and standards for determining the amount of payment adjustments made under paragraph (a)(6).

(iii) The methodology and standards for determining a CAH to be a qualifying CAH under § 495.106 of this chapter.

(iv) The methodology and standards for determining if the hardship exemption applies to a CAH under paragraph (a)(6)(ii) of this section.

(v) The specification of the cost reporting periods, payment years, or fiscal years as applied under this paragraph.

(b) *Payment for outpatient services furnished by CAH*—(1) *General.* (i) Unless the CAH elects to be paid for services to its outpatients under the method specified in paragraph (b)(3) of this section, the amount of payment for outpatient services of a CAH is determined under paragraph (b)(2) of this section.

(ii) Except as specified in paragraph (b)(6) of this section, payment to a CAH for outpatient services does not include any costs of physician services or other professional services to CAH outpatients.

(2) *Reasonable costs for facility services.* (i) Effective for cost reporting periods beginning on or after January 1, 2004, payment for outpatient services of a CAH is 101 percent of the reasonable costs of the CAH in providing CAH services to its outpatients, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in this part and in part 415 of this chapter, except that the following payment principles are excluded when determining payment for CAH outpatient services:

(A) Lesser of cost or charges; and

(B) RCE limits.

(ii) Payment to a CAH under paragraph (b)(2) of this section does not include any costs of physician services or other professional services to CAH outpatients and, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts as determined under §§ 410.152(k), 410.160, and 410.161 of this chapter.

(iii) [Reserved]

(3) *Election to be paid reasonable costs for facility services plus fee schedule for professional services.* (i) A CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method described in paragraphs (b)(3)(ii) and (b)(3)(iii) of this section.

(A)*(1) For cost reporting periods beginning before October 1, 2010.* The election must be made in writing, made on an annual basis, and delivered to the contractor or MAC servicing the CAH at least 30 days before the start of the cost reporting period for which the election is made. An election, once made for a cost reporting period, remains in effect for all of that period.

(2) For cost reporting periods beginning on or after October 1, 2010. If a CAH had elected the method specified in paragraph (b)(3)(i) of this section in its most recent cost reporting period beginning prior to October 1, 2010, that election remains in effect for all of that period and for all subsequent cost reporting periods, unless the CAH submits a termination request to the contractor or MAC servicing the CAH at least 30 days before the start of the next cost reporting period. However, for cost reporting periods beginning in October 2010 and November 2010, if a CAH wishes to terminate its previous election, the CAH must submit a termination request to the contractor or MAC servicing the CAH prior to December 1, 2010. If a CAH had no election in effect in its most recent preceding cost reporting period and chooses to elect the method specified in paragraph (b)(3)(i) of this section on or after October 1, 2010, the election must be made in writing and delivered to the contractor or MAC servicing the CAH at least 30 days before the start of the first cost reporting period for which the election is made. Once the election is made, it remains in effect for all of that period and for all subsequent cost reporting periods unless the CAH submits a termination request to the contractor or MAC servicing the CAH at

least 30 days before the start of the next cost reporting period.

(B) An election of the payment method specified under paragraph (b)(3)(i) of this section applies to all services furnished to outpatients by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with subpart F of part 424 of this chapter. If a physician or other practitioner does not reassign his or her billing rights to the CAH in accordance with subpart F of part 424 of this chapter, payment for the physician's or practitioner's services furnished to CAH outpatients will be made on a fee schedule or other applicable basis as specified in subpart B of part 414 of this subchapter.

(C) In the case of a CAH that made an election under this section before November 1, 2003, for a cost reporting period beginning before December 1, 2003, the rules in paragraph (b)(3)(i)(B) of this section are applicable to cost reporting periods beginning on or after July 1, 2001.

(D) An election made under paragraph (b)(3)(i) of this section is effective as provided for under paragraph (b)(3)(i)(A) or paragraph (b)(3)(i)(C) of this section and does not apply to an election that was terminated prior to the start of the cost reporting period for which it would otherwise apply.

(ii) If the CAH elects payment under this method, payment to the CAH for each outpatient visit will be the sum of the following:

(A) Effective for cost reporting periods beginning on or after January 1, 2004, for facility services not including any services for which payment may be made under paragraph (b)(3)(ii)(B) of this section, 101 percent of the reasonable costs of the services as determined under paragraph (b)(2)(i) of this section; and

(B) For professional services that are furnished by a physician or other practitioner who has reassigned his or her rights to bill for those services to the CAH in accordance with part 424, subpart F of this chapter, and that would otherwise be payable to the physician or other practitioner if the rights to bill for them had not been reassigned, 115 percent of the amounts that otherwise would be paid for the service if the CAH had not elected payment under this method. Effective for primary care services furnished by primary care practitioners (as defined in §414.80(a)) and major surgical procedures furnished by general surgeons in health professional shortage areas (as defined in §414.2) furnished on or after January 1, 2011 and before January 1, 2016, incentive payments specified under §414.80 and §414.67(b), respectively, of this title must not be included in determining payment made under this paragraph.

(iii) Payment to a CAH, other than for clinical diagnostic laboratory tests, is subject to the Part B deductible and coinsurance amounts, as determined under §§410.152(k), 410.160, and 410.161 of this chapter.

(4) *Costs of certain emergency room on-call providers.* (i) Effective for cost reporting periods beginning on or after October 1, 2001, the reasonable costs of outpatient CAH services under paragraph (b) of this section may include amounts for reasonable compensation and related costs for an emergency room physician who is on call but who is not present on the premises of the CAH involved, is not otherwise furnishing physicians' services, and is not on call at any other provider or facility. Effective for costs incurred for services furnished on or after January 1, 2005, the payment amount of 101 percent of the reasonable costs of outpatient CAH services may also include amounts for reasonable compensation and related costs for the following emergency room providers who are on call but who are not present on the premises of the CAH involved, are not otherwise furnishing physicians' services, and are not on call at any other provider or facility: physician assistants, nurse practitioners, and clinical nurse specialists.

(ii) For purposes of this paragraph (b)(4)—

(A) ''Amounts for reasonable compensation and related costs'' means all allowable costs of compensating emergency room physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on call to the extent that the costs are found to be reasonable under the rules specified in paragraph (b)(2) of this section and

the applicable sections of part 413. Costs of compensating these specified medical emergency room staff are allowable only if the costs are incurred under written contracts that require the physician, physician assistant, nurse practitioner, or clinical nurse specialist to come to the CAH when the physician's or other practitioner's presence is medically required.

(B) Effective for costs incurred on or after January 1, 2005, an ''emergency room physician, physician assistant, nurse practitioner, or clinical nurse specialist who is on call'' means a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care who is immediately available by telephone or radio contact, and is available onsite within the timeframes specified in § 485.618(d) of this chapter.

(5) *Costs of ambulance services.* (i)(A) Effective for services furnished on or after December 21, 2000 and on or before December 31, 2003, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(B) Effective for cost reporting periods beginning on or after January 1, 2004 and on or before September 30, 2011, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH or the entity.

(C) Effective for cost reporting periods beginning on or after October 1, 2011 and on or before September 30, 2019, payment for ambulance services furnished by a CAH or an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

(D) Effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by a CAH-owned and operated entity is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

(ii) For purposes of paragraph (b)(5) of this section, the distance between the CAH or the entity and the other provider or supplier of ambulance services will be determined as the shortest distance in miles measured over improved roads between the CAH or the entity and the site at which the vehicles of the closest provider or supplier of ambulance services are garaged. An improved road for this purpose is any road that is maintained by a local, State, or Federal government entity and is available for use by the general public. An improved road will be considered to include the paved surface up to the front entrance of the hospital and the front entrance of the garage.

(6) If a CAH meets the criteria in § 412.113(c) of this subchapter for pass-through of costs of anesthesia services

furnished by nonphysician anesthetists employed by the CAH or obtained under arrangement, payment to the CAH for the costs of those services is made in accordance with §412.113(c) of this chapter.

(7) *Payment for clinical diagnostic laboratory tests included as outpatient CAH services.* (i) Payment for clinical diagnostic laboratory tests is not subject to the Medicare Part B deductible and coinsurance amounts.

(ii) Subject to the provisions of paragraphs (b)(7)(iii) through (b)(7)(vi) of this section, payment to a CAH for clinical diagnostic laboratory tests will be made at 101 percent of reasonable costs of the services as determined in accordance paragraph (b)(2)(i) of this section.

(iii) For services furnished before July 1, 2009, payment to a CAH for clinical diagnostic laboratory tests will be made under paragraph (b)(7)(ii) of this section only if the individual is an outpatient of the CAH, as defined in §410.2 of this chapter, and is physically present in the CAH at the time the specimen is collected.

(iv) Except as provided in paragraphs (b)(7)(iii) and (b)(7)(v) of this section, payment to a CAH for clinical diagnostic laboratory tests will be made under paragraph (b)(7)(ii) of this section only if the individual is an outpatient of the CAH, as defined in §410.2 of this chapter, without regard to whether the individual is physically present in the CAH at the time the specimen is collected and at least one of the following conditions is met:

(A) The individual is receiving outpatient services in the CAH on the same day the specimen is collected; or

(B) The specimen is collected by an employee of the CAH.

(v) Notwithstanding paragraph (b)(7)(iv) of this section, payment for outpatient clinical diagnostic laboratory tests will not be made under paragraph (b)(7)(ii) of this section if the billing rules under §411.15(p) of this chapter apply.

(vi) Payment for clinical diagnostic laboratory tests for which payment may not be made under paragraph (b)(7)(iii) or paragraph (b)(7)(iv) of this section will be made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Act.

(c) *Final payment based on cost report.* Final payment to the CAH for CAH facility services to inpatients and outpatients furnished during a cost reporting is based on a cost report for that period, as required under §413.20(b).

(d) *Periodic interim payments.* Subject to the provisions of §413.64(h), a CAH receiving payments under this section may elect to receive periodic interim payments (PIP) for Part A inpatient CAH services, effective for payments made on or after July 1, 2004. Payment is made biweekly under the PIP method unless the CAH requests a longer fixed interval (not to exceed one month) between payments. The biweekly interim payment amount is based on the total estimated Medicare payment (after estimated beneficiary deductibles and coinsurance) for the cost reporting period. Each payment is made 2 weeks after the end of a biweekly period of service, as described in §413.64(h)(6). These PIP provisions are further described in §413.64(h)(6). Under certain circumstances that are described in §413.64(g), a CAH that is not receiving PIP may request an accelerated payment.

(e) *Payment for service of distinct part psychiatric and rehabilitation units of CAHS.* Payment for inpatient services of distinct part psychiatric units of CAHs—

(1) For cost reporting periods beginning before January 1, 2005, payment is made on a reasonable cost basis, subject to the provisions of §413.40.

(2) For cost reporting periods beginning on or after January 1, 2005, payment is made in accordance with regulations governing inpatient psychiatric facilities at subpart N (§412.400 through §412.432) of Part 412 of this subchapter.

(3) Payment for inpatient services of distinct part rehabilitation units of CAHs is made in accordance with regulations governing the inpatient rehabilitation facilities prospective payment system at subpart P (§412.600 through §412.632) of part 412 of this subchapter.

[65 FR 47109, Aug. 1, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §413.70, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 413.74 Payment to a foreign hospital.

(a) *Principle.* Section 1814(f) of the Act provides for the payment of emergency and nonemergency inpatient hospitals services furnished by foreign hospitals to Medicare beneficiaries. Subpart H of part 424 of this chapter, together with this section, specifies the conditions for payment.

(b) *Amount of payment.* Effective with admissions on or after January 1, 1980, the reasonable cost for services covered under the Medicare program furnished to beneficiaries by a foreign hospital will be equal to 100 percent of the hospital's customary charges (as defined in § 413.13(b)) for the services.

(c) *Submittal of claims.* The hospital must establish its customary charges for the services by submitting an itemized bill with each claim it files in accordance with its election under § 424.104 of this chapter.

(d) *Exchange rate.* Payment to the hospital will be subject to the official exchange rate on the date the patient is discharged and to the applicable deductible and coinsurance amounts described in §§ 409.80 through 409.83.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 41351, Nov. 14, 1986; 53 FR 6648, Mar. 2, 1988; 53 FR 12945, Apr. 20, 1988; 71 FR 48141, Aug. 18, 2006]

Subpart F—Specific Categories of Costs

§ 413.75 Direct GME payments: General requirements.

(a) *Statutory basis and scope*—(1) *Basis.* This section and §§ 413.76 through 413.83 implement section 1886(h) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities.

(2) *Scope.* This section and §§ 413.76 through 413.83 apply to Medicare payments to hospitals and hospital-based providers for the costs of approved residency programs in medicine, osteopathy, dentistry, and podiatry for cost reporting periods beginning on or after July 1, 1985.

(b) *Definitions.* For purposes of this section and §§ 413.76 through 413.83, the following definitions apply:

All or substantially all of the costs for the training program in the nonhospital setting means—

(1) Effective on or after January 1, 1999 and for cost reporting periods beginning before July 1, 2007, the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education (GME); and

(2) Effective for cost reporting periods beginning on or after July 1, 2007 and before July 1, 2010, at least 90 percent of the total of the costs of the residents' salaries and fringe benefits (including travel and lodging where applicable) and the portion of the cost of teaching physicians' salaries attributable to nonpatient care direct GME activities.

Approved geriatric program means a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs.

Approved medical residency program means a program that meets one of the following criteria:

(1) Is approved by one of the national organizations listed in § 415.152 of this chapter.

(2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(i) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610; or

(ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

(3) Is approved by the Accreditation Council for Graduate Medical Education (ACGME) as a fellowship program in geriatric medicine.

(4) Is a program that would be accredited except for the accrediting

agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether the standard provides exceptions or exemptions.

Base period means a cost reporting period that began on or after October 1, 1983 but before October 1, 1984.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

CPI-U stands for the Consumer Price Index for All Urban Consumers as compiled by the Bureau of Labor Statistics.

Emergency Medicare GME affiliated group means at least one home hospital and one or more host hospitals, as those terms are defined below, that meet the requirements at §413.79(f)(7). For purposes of an emergency Medicare GME affiliated group, the following definitions apply:

(1) *Home hospital* means a hospital that—

(i) Is located in section 1135 emergency area;

(ii) Had its inpatient bed occupancy decreased by 20 percent or more as the result of a section 1135 emergency period so that it is unable to train the number of residents it originally intended to train in that academic year; and

(iii) Needs to send the displaced residents to train at a host hospital.

(2) *Host hospital* means a hospital training residents displaced from a home hospital.

(i) *In-State host hospital* means a host hospital located in the same State as a home hospital.

(ii) *Out-of-State host hospital* means a host hospital located in a different State from the home hospital.

(3) *Section 1135 emergency area or section 1135 emergency period* mean, respectively, a geographic area in which, or a period during which, there exists—

(i) An emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(ii) A public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

Foreign medical graduate means a resident who is not a graduate of a medical, osteopathy, dental, or podiatry school, respectively, accredited or approved as meeting the standards necessary for accreditation by one of the following organizations:

(1) The Liaison Committee on Medical Education of the American Medical Association.

(2) The American Osteopathic Association.

(3) The Commission on Dental Accreditation.

(4) The Council on Podiatric Medical Education.

FMGEMS stands for the Foreign Medical Graduate Examination in the Medical Sciences (Part I and Part II).

FTE stands for full-time equivalent.

GME stands for graduate medical education.

Medicare GME affiliated group means—

(1) Two or more hospitals that are located in the same urban or rural area (as those terms are defined in subpart D of Part 412 of this subchapter) or in a contiguous area and meet the rotation requirements in §413.79(f)(2).

(2) Two or more hospitals that are not located in the same or in a contiguous urban or rural area, but meet the rotation requirement in §413.79(f)(2), and are jointly listed—

(i) As the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most current publication of the *Graduate Medical Education Directory;* or

(ii) As the sponsor or is listed under ''affiliations and outside rotations'' for one or more programs in operation in *Opportunities, Directory of Osteopathic Postdoctoral Education Programs.*

(3) Two or more hospitals that are under common ownership and, effective

for all Medicare GME affiliation agreements beginning July 1, 2003, meet the rotation requirement in § 413.79(f)(2).

Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a Medicare GME affiliated group, as defined in this section, that specifies—

(1) The term of the Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year;

(2) Each participating hospital's direct and indirect GME FTE caps in effect prior to the Medicare GME affiliation;

(3) The total adjustment to each hospital's FTE caps in each year that the Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to one hospital's direct and indirect FTE caps that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect FTE caps of at least the same amount;

(4) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's FTE caps (in accordance with paragraph (3) of this definition); and

(5) The names of the participating hospitals and their Medicare provider numbers.

Medicare patient load means, with respect to a hospital's cost reporting period, the total number of hospital inpatient days during the cost reporting period that are attributable to patients for whom payment is made under Medicare Part A divided by total hospital inpatient days. In calculating inpatient days, inpatient days in any distinct part of the hospital furnishing a hospital level of care are included and nursery days are excluded.

Nonprovider setting that is primarily engaged in furnishing patient care means a nonprovider setting in which the primary activity is the care and treatment of patients.

Orientation activities means activities that are principally designed to prepare an individual for employment as a resident in a particular setting, or for participation in a particular specialty program and patient care activities associated with that particular specialty program.

Patient care activities means the care and treatment of particular patients, including services for which a physician or other practitioner may bill, and orientation activities as defined in this section.

Primary care resident is a resident who is enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice. Effective for cost reporting periods beginning on or after October 1, 2010, *primary care resident* is a resident who is formally accepted, enrolled, and participating in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice.

Redistribution of costs occurs when a hospital counts FTE residents in medical residency programs and the costs of the program had previously been incurred by an educational institution.

Resident means an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board. Effective for cost reporting periods beginning on or after October 1, 2010, *resident* means an intern, resident, or fellow who is formally accepted, enrolled, and participating in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board.

Rural track FTE limitation means the maximum number of residents (as specified in § 413.79(k)) training in a rural track residency program that an urban hospital or rural hospital may include in its FTE count and that is in addition

to the number of FTE residents already included in the hospital's FTE cap.

Rural track or integrated rural track means, for programs started in cost reporting periods prior to October 1, 2022, an approved medical residency training program established by an urban hospital in which residents train for a portion of the program at the urban hospital and then rotate for a portion of the program to a rural hospital(s) or a rural nonhospital site(s).

Rural track Medicare GME affiliated group means an urban hospital and a rural hospital that—

(i) Participate in a rural track program defined in this paragraph (b);

(ii) Have rural track FTE limitations in effect prior to October 1, 2022; and

(iii) Comply with the regulations at § 413.79(f)(1) through (6) for Medicare GME affiliated groups.

Rural track Medicare GME affiliation agreement means a written, signed, and dated agreement by responsible representatives of each respective hospital in a rural track Medicare GME affiliated group, as defined in this paragraph (b), that specifies all of the following:

(i) A statement attesting that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program.

(ii) The term of the rural track Medicare GME affiliation agreement (which, at a minimum is 1 year), beginning on July 1 of a year.

(iii) Each participating hospital's direct and indirect GME rural track FTE limitations in effect prior to the rural track Medicare GME affiliation.

(iv) The total adjustment to each hospital's rural track FTE limitations in each year that the rural track Medicare GME affiliation agreement is in effect, for both direct GME and indirect medical education (IME), that reflects a positive adjustment to one hospital's direct and indirect rural track FTE limitations that is offset by a negative adjustment to the other hospital's (or hospitals') direct and indirect rural track FTE limitations of at least the same amount.

(v) The adjustment to each participating hospital's FTE counts resulting from the FTE resident's (or residents') participation in a shared rotational arrangement at each hospital participating in the rural track Medicare GME affiliated group for each year the Medicare GME affiliation agreement is in effect. This adjustment to each participating hospital's FTE count is also reflected in the total adjustment to each hospital's rural track FTE limitations (in accordance with paragraph (iii) of this definition).

(vi) The names of the participating hospitals and their Medicare provider numbers.

Rural Track Program means, effective for cost reporting periods beginning on or after October 1, 2022, an ACGME-accredited program in which residents/fellows gain both urban and rural experience with more than half of the education and training for a resident/fellow taking place in a rural area as defined at 42 CFR 412.62(f)(iii).

Shared rotational arrangement means a residency training program under which a resident(s) participates in training at two or more hospitals in that program.

(c) *Payment for GME costs—General rule.* Beginning with cost reporting periods starting on or after July 1, 1985, hospitals, including hospital-based providers, are paid for the costs of approved GME programs as described in §§ 413.76 through 413.83.

(d) *Documentation requirements.* To include a resident in the FTE count for a particular cost reporting period, the hospital must furnish the following information. The information must be certified by an official of the hospital and, if different, an official responsible for administering the residency program.

(1) The name and social security number of the resident.

(2) The type of residency program in which the individual participates and the number of years the resident has completed in all types of residency programs.

(3) The dates the resident is assigned to the hospital and any hospital-based providers.

(4) The dates the resident is assigned to other hospitals, or other free-standing providers, and any nonprovider setting during the cost reporting period, if any.

(5) The name of the medical, osteopathic, dental, or podiatric school from which the resident graduated and the date of graduation.

(6) If the resident is an FMG, documentation concerning whether the resident has satisfied the requirements of this section.

(7) The name of the employer paying the resident's salary.

[69 FR 49254, Aug. 11, 2004, as amended at 70 FR 47489, Aug. 12, 2005; 71 FR 18666, Apr. 12, 2006; 71 FR 48141, Aug. 18, 2006; 72 FR 26995, May 11, 2007; 72 FR 47412, Aug. 22, 2007; 72 FR 66931, Nov. 27, 2007; 75 FR 50418, Aug. 16, 2010; 75 FR 72262, Nov. 24, 2010; 79 FR 50357, Aug. 22, 2014; 86 FR 73512, Dec. 27, 2021; 87 FR 49405, Aug. 10, 2022; 89 FR 69912, Aug. 28, 2024]

§ 413.76 Direct GME payments: Calculation of payments for GME costs.

A hospital's Medicare payment for the costs of an approved residency program is calculated as follows:

(a) *Step one.* The hospital's updated per resident amount (as determined under § 413.77) is multiplied by the actual number of FTE residents (as determined under § 413.79). This result is the aggregate approved amount for the cost reporting period.

(b) *Step two.* The product derived in step one is multiplied by the hospital's Medicare patient load.

(c) *Step three.* For portions of cost reporting periods occurring on or after January 1, 1998, the product derived in step one is multiplied by the proportion of the hospital's inpatient days attributable to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1876 of the Act and who are entitled to Medicare Part A or with a Medicare + Choice organization under Title XVIII, Part C of the Act. This amount is multiplied by an applicable payment percentage equal to—

(1) 20 percent for 1998;

(2) 40 percent for 1999;

(3) 60 percent in 2000;

(4) 80 percent in 2001; and

(5) 100 percent in 2002 and subsequent years.

(d) *Step four.* Effective for portions of cost reporting periods occurring on or after January 1, 2000, the product derived from step three is reduced by a percentage equal to the ratio of the Medicare + Choice nursing and allied health payment ''pool'' for the current calendar year as described at § 413.87(f), to the projected total Medicare + Choice direct GME payments made to all hospitals for the current calendar year.

(e) *Step five.* (1) For portions of cost reporting periods beginning on or after January 1, 1998 and before January 1, 2000, add the results of steps two and three.

(2) Effective for portions of cost reporting periods beginning on or after January 1, 2000, add the results of steps two and four.

(f) *Step six.* The product derived in step two is apportioned between Part A and Part B of Medicare based on the ratio of Medicare's share of reasonable costs excluding GME costs attributable to each part as determined through the Medicare cost report.

[69 FR 49254, Aug. 11, 2004]

§ 413.77 Direct GME payments: Determination of per resident amounts.

(a) *Per resident amount for the base period.* (1) Except as provided in paragraph (d) of this section, the contractor determines a base-period per resident amount for each hospital as follows:

(i) Determine the allowable GME costs for the cost reporting period beginning on or after October 1, 1983 but before October 1, 1984. In determining these costs, GME costs allocated to the nursery cost center, research and other nonreimbursable cost centers, and hospital-based providers that are not participating in Medicare are excluded and GME costs allocated to distinct-part hospital units and hospital-based providers that participate in Medicare are included.

(ii) Divide the costs calculated in paragraph (a)(1)(i) of this section by the average number of FTE residents working in all areas of the hospital complex (including those areas whose costs were excluded under paragraph (a)(1)(i) of this section) for its cost reporting period beginning on or after

October 1, 1983 but before October 1, 1984.

(2) In determining the base-period per resident amount under paragraph (a)(1) of this section, the contractor—

(i) Verifies the hospital's base-period GME costs and the hospital's average number of FTE residents;

(ii) Excludes from the base-period GME costs any nonallowable or misclassified costs, including those previously allowed under § 412.113(b)(3) of this chapter; and

(iii) Upon a hospital's request, includes GME costs that were misclassified as operating costs during the hospital's prospective payment base year and were not allowable under § 412.113(b)(3) of this chapter during the GME base period. These costs may be included only if the hospital requests an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(3) If the hospital's cost report for its GME base period is no longer subject to reopening under § 405.1885 of this chapter, the contractor may modify the hospital's base-period costs solely for purposes of computing the per resident amount.

(4) If the contractor modifies a hospital's base-period GME costs as described in paragraph (a)(2)(ii) of this section, the hospital may request an adjustment of its prospective payment hospital-specific rate or target amount as described in § 413.82(a) of this chapter.

(5) The contractor notifies each hospital that either had direct GME costs or received indirect education payment in its cost reporting period beginning on or after October 1, 1984, and before October 1, 1985, of its base-period average per resident amount. A hospital may appeal this amount within 180 days of the date of that notice.

(b) *Per resident amount for cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986.* For cost reporting periods beginning on or after July 1, 1985, and before July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) If a hospital's base period began on or after October 1, 1983, and before July 1, 1984, the amount is adjusted by the percentage change in the CPI-U that occurred between the hospital's base period and the first cost reporting period to which the provisions of this section apply. The adjusted amount is then increased by one percent.

(2) If a hospital's base period began on or after July 1, 1984 and before October 1, 1984, the amount is increased by one percent.

(c) *Per resident amount for cost reporting periods beginning on or after July 1, 1986.* Subject to the provisions of paragraph (d) of this section, for cost reporting periods beginning on or after July 1, 1986, a hospital's base-period per resident amount is adjusted as follows:

(1) Except as provided in paragraph (c)(2) of this section, each hospital's per resident amount for the previous cost reporting is adjusted by the projected change in the CPI-U for the 12-month cost reporting period. This adjustment is subject to revision during the settlement of the cost report to reflect actual changes in the CPI-U that occurred during the cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1993 through September 30, 1995, each hospital's per resident amount for the previous cost reporting period will not be adjusted for any resident FTEs who are not either a primary care resident or an obstetrics and gynecology resident.

(d) *Per resident amount for cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013.* For cost reporting periods beginning on or after October 1, 2000 and ending on or before September 30, 2013, a hospital's per resident amount for each fiscal year is adjusted in accordance with the following provisions:

(1) *General provisions.* For purposes of this § 413.77—

(i) *Weighted average per resident amount.* The weighted average per resident amount is established as follows:

(A) Using data from hospitals' cost reporting periods ending during FY 1997, CMS calculates each hospital's single per resident amount by adding each hospital's primary care and nonprimary care per resident amounts, weighted by its respective FTEs, and dividing by the sum of the FTEs for

primary care and nonprimary care residents.

(B) Each hospital's single per resident amount calculated under paragraph (d)(1)(i)(A) of this section is standardized by the 1999 geographic adjustment factor for the physician fee schedule area (as determined under § 414.26 of this chapter) in which the hospital is located.

(C) CMS calculates an average of all hospitals' standardized per resident amounts that are determined under paragraph (d)(1)(i)(B) of this section. The resulting amount is the weighted average per resident amount.

(ii) *Primary care/obstetrics and gynecology and nonprimary care per resident amounts.* A hospital's per resident amount is an amount inclusive of any CPI-U adjustments that the hospital may have received since the hospital's base year, including any CPI-U adjustments the hospital may have received because the hospital trains primary care/obstetrics and gynecology residents and nonprimary care residents as specified under paragraph (c)(2) of this section.

(2) *Adjustment beginning in FY 2001 and ending in FY 2013.* For cost reporting periods beginning on or after October 1, 2000, and ending on or before September 30, 2013, a hospital's per resident amount is adjusted in accordance with paragraphs (d)(2)(i) through (d)(2)(iv) of this section, in that order:

(i) *Updating the weighted average per resident amount for inflation.* The weighted average per resident amount (as determined under paragraph (d)(1)(i) of this section) is updated by the estimated percentage increase in the CPI-U during the period beginning with the month that represents the midpoint of the cost reporting periods ending during FY 1997 (that is, October 1, 1996) and ending with the midpoint of the hospital's cost reporting period that begins in FY 2001.

(ii) *Adjusting for locality.* The updated weighted average per resident amount determined under paragraph (d)(2)(i) of this section (the national average per resident amount) is adjusted for the locality of each hospital by multiplying the national average per resident amount by the 1999 geographic adjustment factor for the physician fee schedule area in which each hospital is located, established in accordance with § 414.26 of this chapter.

(iii) *Determining necessary revisions to the per resident amount.* The locality-adjusted national average per resident amount, as calculated in accordance with paragraph (d)(2)(ii) of this section, is compared to the hospital's per resident amount and is revised, if appropriate, according to the following three categories:

(A) *Floor.* (*1*) For cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, if the hospital's per resident amount would otherwise be less than 70 percent of the locality-adjusted national average per resident amount for FY 2001 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 70 percent of the locality-adjusted national average per resident amount for FY 2001.

(*2*) For cost reporting periods beginning on or after October 1, 2001, and before October 1, 2002, if the hospital's per resident amount would otherwise be less than 85 percent of the locality-adjusted national average per resident amount for FY 2002 (as determined under paragraph (d)(2)(ii) of this section), the per resident amount is equal to 85 percent of the locality-adjusted national average per resident amount for FY 2002.

(*3*) For subsequent cost reporting periods beginning on or after October 1, 2002, the hospital's per resident amount is updated using the methodology specified under paragraph (c)(1) of this section.

(B) *Ceiling.* If the hospital's per resident amount is greater than 140 percent of the locality-adjusted national average per resident amount, the per resident amount is adjusted as follows for FY 2001 through FY 2013:

(*1*) *FY 2001.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2001, if the hospital's FY 2000 per resident amount exceeds 140 percent of the FY 2001 locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident

amount is frozen at the FY 2000 per resident amount and is not updated for FY 2001 by the CPI-U factor.

(*2*) *FY 2002*. For cost reporting periods beginning on or after October 1, 2001, and on or before September 30, 2002, if the hospital's FY 2001 per resident amount exceeds 140 percent of the FY 2002 locality-adjusted national average per resident amount, subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident amount is frozen at the FY 2001 per resident amount and is not updated for FY 2002 by the CPI-U factor.

(*3*) *FY 2003*. For cost reporting periods beginning on or after October 1, 2002, and on or before September 30, 2003, if the hospital's per resident amount for the previous cost reporting period is greater than 140 percent of the locality-adjusted national average per resident amount for that same previous cost reporting period (for example, for cost reporting periods beginning in FY 2003, compare the hospital's per resident amount from the FY 2002 cost report to the hospital's locality-adjusted national average per resident amount from FY 2002), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital's per resident amount is adjusted using the methodology specified in paragraph (c)(1) of this section, except that the CPI-U applied for a 12-month period is reduced (but not below zero) by 2 percentage points.

(*4*) *FY 2004 through FY 2013*. For cost reporting periods beginning on or after October 1, 2003, and on or before September 30, 2013, if the hospital's preceding year per resident amount exceeds 140 percent of the current year's locality-adjusted national average per resident amount (as calculated under paragraph (d)(2)(ii) of this section), subject to the provision stated in paragraph (d)(2)(iii)(B)(*5*) of this section, the hospital-specific per resident amount is frozen for the current year at the preceding year's hospital-specific per resident amount and is not updated by the CPI-U factor.

(*5*) *General rule for hospitals that exceed the ceiling*. For cost reporting periods beginning on or after October 1, 2000, and on or before September 30, 2013, if a hospital's per resident amount exceeds 140 percent of the hospital's locality-adjusted national average per resident amount and it is adjusted under any of the criteria under paragraphs (d)(2)(iii)(B)(*1*) through (d)(2)(iii)(B)(*3*) of this section, the current year per resident amount cannot be reduced below 140 percent of the locality-adjusted national average per resident amount.

(C) *Per resident amounts greater than or equal to the floor and less than or equal to the ceiling*. For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2013, if a hospital's per resident amount is greater than or equal to 70 percent and less than or equal to 140 percent of the hospital's locality-adjusted national average per resident amount for each respective fiscal year, the hospital's per resident amount is updated using the methodology specified in paragraph (c)(1) of this section.

(e) *Exceptions*—(1) *Base period for certain hospitals*. If a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after July 1, 1985, the contractor establishes a per resident amount for the hospital using the information from the first cost reporting period during which the hospital participates in Medicare and the residents are on duty during the first month of that period. Effective for cost reporting periods beginning on or after October 1, 2006, if a hospital did not have any approved medical residency training programs or did not participate in Medicare during the base period, but either condition changes in a cost reporting period beginning on or after October 1, 2006, and the residents are not on duty during the first month of that period, the contractor establishes a per resident amount for the hospital using the information from the first cost reporting period immediately following the cost reporting period during which the hospital participates in Medicare and residents began training at the hospital. The per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or paragraph (e)(1)(ii) of this

section, subject to the provisions of paragraph (e)(1)(iii) of this section. Any GME costs incurred by the hospital during the cost reporting period prior to the base period used for calculating the PRA are reimbursed on a reasonable cost basis.

(i) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period as established in paragraph (e)(1) of this section.

(ii) Except as specified in paragraph (e)(1)(iii)of this section—

(A) For base periods that begin before October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area, as that term is used in the prospective payment system under Part 412 of this chapter.

(B) For base periods beginning on or after October 1, 2002, the updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(iii) If, under paragraph (e)(1)(ii)(A) or (B) or (e)(1)(iv)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(iv) A hospital that, as of December 27, 2020, has a per resident amount based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997, may choose to receive a recalculated per resident amount either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after December 27, 2021. A hospital that, as of December 27, 2020, has a per resident amount based on no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, may choose to receive a recalculated per resident amount either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning after December 27, 2021. In either case, residents need not be on duty during the first month of the cost reporting period. The recalculated per resident amount is based on the lower of—

(A) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period, which is, for hospitals with a per resident amount previously based on less than 1.0 FTE, either when it trains at least 1.0 FTE in the earliest cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, or when it trains at least 1.0 FTE in the first cost reporting period beginning after December 27, 2021; and for hospitals with a per resident amount previously based on not more than 3.0 FTEs, either when it trains more than 3.0 FTEs in the earliest cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, or when it trains more than 3.0 FTE in the first cost reporting period beginning or after December 27, 2021; or

(B) The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(v) Effective for a cost reporting periods beginning on or after December 27, 2020, a per resident amount must be established if a hospital trains less than 1.0 FTE resident and this training results from the hospital's participation

in a Medicare GME affiliation agreement under § 413.79(f). Effective for a cost reporting period beginning on or after December 27, 2020, a per resident amount must only be established when the hospital trains at least 1.0 FTE and does not participate in a Medicare GME affiliation agreement under § 413.79(f) for that training. Residents need not be on duty during the first month of the cost reporting period from which the per resident amount is established.

(2) *Short or long base-period cost reporting periods.* If a hospital's base-period cost reporting period reflects GME costs for a period that is shorter than 50 weeks or longer than 54 weeks, the contractor converts the allowable costs for the base period into a daily figure. The daily figure is then multiplied by 365 or 366, as appropriate, to derive the approved per resident amount for a 12-month base-period cost reporting period. If a hospital has two cost reporting periods beginning in the base period, the later period serves as the base-period cost reporting period.

(3) *Short or long cost reporting periods beginning on or after July 1, 1985.* If a hospital's cost reporting period is shorter than 50 weeks or longer than 54 weeks, the hospital's contractor should contact CMS Central Office to receive a special CPI-U adjustment factor.

(f) *Residency match.* Effective for portions of cost reporting periods beginning on or after October 1, 2004, with respect to a resident who matches simultaneously for a first year of training in a primary care specialty, and for an additional year(s) of training in a nonprimary care specialty, the per resident amount that is used to determine direct GME payment with respect to that resident is the nonprimary care per resident amount for the first year of training in the primary care specialty and for the duration of the resident's training in the nonprimary care specialty.

(g) *Special use of locality-adjusted national average per resident amount.* Effective for portions of cost reporting periods beginning on or after July 1, 2005, for a hospital that counts additional residents as a result of an increase in its FTE resident cap under § 413.79(c)(4) direct GME payments attributable to those additional FTE residents are calculated using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section. The hospital will receive direct GME payments based on the sum of the following two direct GME calculations:

(1) A calculation using the per resident amount(s) as determined under paragraph (d) of this section and the hospital's number of FTE residents that is not attributable to an FTE resident cap increase under § 413.79(c)(4); and

(2) A calculation using the locality-adjusted national average per resident amount, as determined under paragraph (d)(2)(ii) of this section, inflated to the hospital's current cost reporting period, and the hospital's number of FTE residents that is attributable to the increase in the hospital's FTE resident cap under § 413.79(c)(4).

(h) *Hospital mergers.* Effective for cost reporting periods beginning on or after October 1, 2006, when multiple hospitals merge, a primary care and obstetrics and gynecology weighted average per resident amount and a nonprimary care weighted average per resident amount is calculated, if applicable, for the surviving hospital, using FTE resident data and per resident amount data from the most recently settled cost reports of the respective hospitals prior to the merger.

[69 FR 49254, Aug. 11, 2004, as amended at 69 FR 60252, Oct. 7, 2004; 70 FR 47489, Aug. 12, 2005; 71 FR 48142, Aug. 18, 2006; 86 FR 73512, Dec. 27, 2021; 87 FR 4167, Jan. 27, 2022]

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

Subject to the weighting factors in §§ 413.79 and 413.80, and subject to the provisions of § 413.81, the count of FTE residents is determined as follows:

(a) Residents in an approved program working in all areas of the hospital complex may be counted.

(b) (1) No individual resident may be counted as more than one FTE based on the total time spent in training at all sites. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as

provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(2) Effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if it does not participate in a Medicare GME affiliation agreement (as defined under § 413.75(b)), and the hospital trains at least 1.0 FTE in an approved program or programs, or, if the hospital trains less than 1.0 FTE residents in an approved program or programs and this training results from the hospital's participation in a Medicare GME affiliation agreement (as defined under § 413.75(b)).

(c) On or after July 1, 1987, and for portions of cost reporting periods occurring before January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs is not excluded in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) There is a written agreement between the hospital and the outside entity that states that the resident's compensation for training time spent outside of the hospital setting is to be paid by the hospital.

(d) For portions of cost reporting periods occurring on or after January 1, 1999, and before October 1, 2004, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) The written agreement between the hospital and the nonhospital site must indicate that the hospital will incur the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(3) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting in accordance with the definition in § 413.75(b).

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(e) For portions of cost reporting periods occurring on or after October 1, 2004, and for cost reporting periods beginning before July 1, 2007, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met:

(1) The resident spends his or her time in patient care activities, as defined in § 413.75(b).

(2) The hospital must incur all or substantially all of the costs of the training program in a nonhospital setting(s) (in accordance with the definition under § 413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred.

(ii) There is a written agreement between the hospital and the nonhospital site that states that the hospital will incur the cost of the resident's salary

and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities.

(iii) If the hospital has in place an emergency Medicare GME affiliation agreement in accordance with §413.79(f)(7), during the period covered by the emergency Medicare GME affiliation agreement—

(A) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the sixth month following the month in which the training in the nonhospital site occurred. For the costs that would otherwise be required to be paid by the hospital during the period of August 29, 2005 through November 1, 2007, the participating hospital must pay the costs by April 29, 2008; or

(B) There is a written agreement that specifies that the hospital is incurring the cost of the resident's salary and fringe benefits while the resident is training in the nonhospital site and the hospital is providing reasonable compensation to the nonhospital site for supervisory teaching activities. The agreement must indicate the compensation the hospital is providing to the nonhospital site for supervisory teaching activities. The written agreement must be submitted to the contractor by 180 days after the training at the nonhospital site begins. For written agreements that would otherwise be required to be submitted prior to the date the resident(s) begin training at the nonhospital site during the period of August 29, 2005 through November 1, 2007, the written agreement must be submitted to the CMS contractor by April 29, 2008.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in §413.81.

(f) For cost reporting periods beginning on or after July 1, 2007, and before July 1, 2010, the time residents spend in nonprovider settings such as free-standing clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time in patient care activities as defined at §413.75(b), except that for cost reporting periods beginning on or after July 1, 2009, the time spent training in nonpatient care activities, such as didactic conferences and seminars, but excluding research not associated with the treatment or diagnosis of a particular patient, in a nonprovider setting that is primarily engaged in furnishing patient care activities, as defined at §413.75(b), also may be counted.

(2) The hospital must incur all or substantially all of the costs for the training program in the nonhospital setting(s) (in accordance with the definition under §413.75(b)).

(3) The hospital must comply with one of the following:

(i) The hospital must pay for all or substantially all of the costs for the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the third month following the month in which the training in the nonhospital site occurred.

(ii) There is a written agreement in place between the hospital and the nonhospital site before the training begins that states that the hospital will incur at least 90 percent of the total of the costs of the resident's salary and fringe benefits (and travel and lodging where applicable) while the resident is training in the nonhospital site and the portion of the cost of the teaching physician's salary attributable to nonpatient care direct GME activities. The written agreement must specify the total cost of the training program at the nonhospital site, and the amount the hospital will incur (at least 90 percent of the total), and must indicate the portion of the amount the hospital will incur that reflects residents' salaries and fringe benefits (and travel and lodging where applicable), and the portion of this amount that reflects teaching physician compensation. Hospitals

may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that at least 90 percent of the costs of the training program in the nonhospital site has been incurred.

(iii) If the hospital has in place an emergency Medicare GME affiliation agreement in accordance with § 413.79(f)(7), during the period covered by the emergency Medicare GME affiliation agreement—

(A) The hospital must pay all or substantially all of the costs of the training program in a nonhospital setting(s) attributable to training that occurs during a month by the end of the sixth month after the month in which the training in the nonhospital site occurs. For the costs that would otherwise be required to be incurred by the hospital during the period of August 29, 2005 through November 1, 2007, the participating hospital must incur the costs by April 29, 2008; or

(B) There is a written agreement that specifies that the hospital will incur at least 90 percent of the total of the costs of the resident's salary and fringe benefits (and travel and lodging where applicable) while the resident is training in the nonhospital site and the portion of the cost of the teaching physician's salary attributable to nonpatient care direct GME activities. The written agreement must specify the total cost of the training program at the nonhospital site, and the amount the hospital will incur (at least 90 percent of the total), and must indicate the portion of the amount the hospital will incur that reflects residents' salaries and fringe benefits (and travel and lodging where applicable), and the portion of this amount that reflects teaching physician compensation. The written agreement must be submitted to the contractor by 180 days after the training at the nonhospital site begins. Hospitals may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that at least 90 percent of the costs of the training program in the nonhospital site has been incurred. For written agreements that would otherwise be required to be submitted prior to the date the training begins in the nonhospital site during the period of August 29, 2005 through November 1, 2007, the hospital must submit the written agreement to its contractor by April 29, 2008.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(g) For cost reporting periods beginning on or after July 1, 2010, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physicians' offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met—

(1) The resident spends his or her time—

(i) In patient care activities as defined at § 413.75(b); or

(ii) In nonpatient care activities, such as didactic conferences and seminars, but excluding research not associated with the treatment or diagnosis of a particular patient, in a nonprovider setting that is primarily engaged in furnishing patient care activities, as defined at § 413.75(b).

(2) The hospital or hospitals must incur the costs of the salaries and fringe benefits of the resident during the time the resident spends in the nonprovider setting. If more than one hospital incurs these costs, either directly or through a third party, the hospitals must count a proportional share of the time that residents train at the nonprovider setting(s) as recorded in a written agreement between the hospitals.

(i) Hospitals must have a reasonable basis for establishing that proportion of the cost and the FTE time that each will incur and count.

(ii) If hospitals already arrange payment to the nonprovider site via a written agreement as described in paragraph (g)(3)(ii) of this section, the proportion may be recorded in that agreement.

(iii) If hospitals choose to pay the nonprovider site concurrently as described in paragraph (g)(3)(i) of this section, the hospitals must record the proportion of cost and FTE time they are incurring and counting in a written agreement between the hospitals.

(3) The hospital or hospitals must comply with one of the following:

(i) The hospital or hospitals must incur the costs of the salaries and fringe benefits of the resident during the time the resident spends in the nonprovider setting by the end of the third month following the month in which the training in the nonprovider site occurred.

(ii) There is a written agreement between the hospital or hospitals and the outside entity that states that the residents' salaries and fringe benefits (including travel and lodging where applicable) during the time the resident spends in the nonprovider setting is to be paid by the hospital(s). Hospitals may modify the amounts specified in the written agreement by the end of the academic year (that is, June 30) to reflect that the costs of the training program in the nonprovider site have been incurred.

(4) The hospital is subject to the principles of community support and redistribution of costs as specified in § 413.81.

(5) For cost reporting periods beginning on or after July 1, 2010, a hospital must maintain and make available records of the FTE count determined for direct GME purposes under this section that its residents spend in nonprovider sites, in order to compare that time to the time spent by its residents in nonprovider sites in the base year of cost reporting periods beginning on or after July 1, 2009, and before June 30, 2010. The hospital must supply the CMS contractor with the data for each of its primary care programs on a program-specific basis, and with data for its nonprimary care programs on an overall basis.

(6) The provisions of paragraphs (g)(1)(ii), (g)(2), (g)(3), and (g)(5) of this section shall not be applied in a manner that requires reopening of any settled cost reports as to which there is not a jurisdictionally proper appeal pending as of March 23, 2010, on direct GME or IME payments. Cost reporting periods beginning before July 1, 2010 are not governed by paragraph (g) of this section.

(h) Effective for cost reporting periods beginning on or after January 1, 1983, the time spent by a resident in an approved medical residency program on vacation, sick leave, or other approved leave that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program is countable. This provision cannot be applied in a manner that would require the reopening of settled cost reports, except those cost reports on which there is a jurisdictionally proper appeal pending on direct GME or IME payments as of March 23, 2010.

(i) For the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID–19 was in effect, a sending hospital can include FTE residents training at another hospital in its FTE count if all of the following conditions are met.

(1) The sending hospital sends the resident to the other hospital in response to the COVID–19 pandemic.

(2) The time spent by the resident training at the other hospital is in lieu of time that would have been spent in approved training at the sending hospital.

(3) The time that the resident spent training immediately prior to and/or subsequent to the time frame that the Public Health Emergency (as defined in § 400.200 of this chapter) associated with COVID–19 was in effect is included in the FTE count for the sending hospital.

[69 FR 49254, Aug. 11, 2004, as amended at 71 FR 48142, Aug. 18, 2006; 72 FR 26995, May 11, 2007; 72 FR 66931, Nov. 27, 2007; 75 FR 72262, Nov. 24, 2010; 78 FR 50968, Aug. 19, 2013; 79 FR 50357, Aug. 22, 2014; 85 FR 27623, May 8, 2020; 86 FR 73513, Dec. 27, 2021; 89 FR 69912, Aug. 28, 2024]

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

Subject to the provisions in § 413.80, CMS determines a hospital's number of FTE residents by applying a weighting factor to each resident and then summing the resulting numbers that represent each resident. The weighting factor is determined as follows:

(a) *Initial residency period.* Generally, for purposes of this section, effective July 1, 1995, an initial residency period is defined as the minimum number of years required for board eligibility.

(1) Prior to July 1, 1995, the initial residency period equals the minimum number of years required for board eligibility in a specialty or subspecialty plus 1 year. An initial residency period may not exceed 5 years in order to be counted toward determining FTE status except in the case of a resident in an approved geriatric program whose initial residency period may last up to 2 additional years.

(2) Effective October 1, 2003, for a resident who trains in an approved geriatric program that requires the residents to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatrics program are treated as part of the resident's initial residency period.

(3) Effective July 1, 2000, for residency programs that began before, on, or after November 29, 1999, the period of board eligibility and the initial residency period for a resident in an approved child neurology program is the period of board eligibility for pediatrics plus 2 years.

(4) Effective August 10, 1993, residents or fellows in an approved preventive medicine residency or fellowship program also may be counted as a full FTE resident for up to 2 additional years beyond the initial residency period limitations.

(5) For combined residency programs, an initial residency period is defined as the time required for individual certification in the longer of the programs. If the resident is enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training primary care residents (as defined in § 413.75(b)) or obstetrics and gynecology residents, the initial residency period is the time required for individual certification in the longer of the programs plus 1 year.

(6) For residency programs other than those specified in paragraphs (a)(2) through (a)(4) of this section, the initial residency period is the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training, as specified in the most recently published edition of the Graduate Medical Education Directory.

(7) For residency programs in osteopathy, dentistry, and podiatry, the minimum requirement for certification in a specialty or subspecialty is the minimum number of years of formal training necessary to satisfy the requirements of the appropriate approving body listed in § 415.152 of this chapter.

(8) For residency programs in geriatric medicine, accredited by the appropriate approving body listed in § 415.152 of this chapter, these programs are considered approved programs on the later of—

(i) The starting date of the program within a hospital; or

(ii) The hospital's cost reporting periods beginning on or after July 1, 1985.

(9) The time spent in residency programs that do not lead to certification in a specialty or subspecialty, but that otherwise meet the definition of approved programs, as described in § 413.75(b), is counted toward the initial residency period limitation.

(10) Effective for portions of cost reporting periods beginning on or after October 1, 2004, if a hospital can document that a resident simultaneously matched for one year of training in a particular specialty program, and for a subsequent year(s) of training in a different specialty program, the resident's initial residency period will be determined based on the period of board eligibility for the specialty associated with the program for which the resident matched for the subsequent year(s) of training. Effective for portions of cost reporting periods beginning on or after October 1, 2005, if a hospital can document that a particular resident, prior to beginning the first year of residency training, matched in a specialty program for which training would begin at the conclusion of the first year of training, that resident's initial residency period will be determined in the resident's first year of training based on the period of board eligibility associated with the specialty program for which the resident matched for subsequent training year(s).

(b) *Weighting factor.* (1) If the resident is in an initial residency period, the weighting factor is one.

(2) If the resident is not in an initial residency period, the weighting factor is 1.00 during the period beginning on or after July 1, 1985 and before July 1, 1986, .75 during the period beginning on or after July 1, 1986 and before July 1, 1987, and .50 thereafter without regard to the hospital's cost reporting period.

(c) *Unweighted FTE counts*—(1) *Definitions.* As used in this paragraph (c):

(i) *Otherwise applicable resident cap* refers to a hospital's FTE resident cap that is determined for a particular cost reporting period under paragraph (c)(2) of this section.

(ii)(A) For purposes of paragraph (c)(3) of this section, *reference resident level* refers to a hospital's resident level in the applicable reference period specified under paragraph (c)(3) of this section.

(B) For purposes of paragraph (m) of this section, *reference resident level* means with respect to a hospital, the highest resident level for any of the three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010.

(iii) *Resident level* refers to the number of unweighted allopathic and osteopathic FTE residents who are training in a hospital in a particular cost reporting period.

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) through (6) and (m) through (p) of this section and §413.81, for purposes of determining direct GME payment—

(i) For cost reporting periods beginning on or after October 1, 1997, a hospital's resident level may not exceed the hospital's unweighted FTE count (or, effective for cost reporting periods beginning on or after April 1, 2000, 130 percent of the unweighted FTE count for a hospital located in a rural area) for these residents for the most recent cost reporting period ending on or before December 31, 1996.

(ii) If a hospital's number of FTE residents in a cost reporting period beginning on or after October 1, 1997, and before October 1, 2001, exceeds the limit described in this section, the hospital's total weighted FTE count (before application of the limit) will be reduced in the same proportion that the number of FTE residents for that cost reporting period exceeds the number of FTE residents for the most recent cost reporting period ending on or before December 31, 1996.

(iii) Effective for cost reporting periods beginning on or after October 1, 2001, if the hospital's unweighted number of FTE residents exceeds the limit described in this section, and the number of weighted FTE residents in accordance with paragraph (b) of this section also exceeds that limit, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the limit. If the number of FTE residents weighted in accordance with paragraph (b) of this section does not exceed that limit, then the allowable weighted FTE count is the actual weighted FTE count.

(iv) Hospitals that are part of the same Medicare GME affiliated group or the same emergency Medicare GME affiliated group (as described under §413.75(b)) may elect to apply the limit on an aggregate basis as described under paragraph (f) of this section.

(v) The contractor may make appropriate modifications to apply the provisions of this paragraph (c) of this section based on the equivalent of a 12-month cost reporting period.

(3) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots under section 422 of Public Law 108–173.* If a hospital's reference resident level is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (c)(3)(ii) of this section), for portions of cost reporting periods beginning on or after July 1, 2005, the hospital's otherwise applicable FTE resident cap is reduced by 75 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. Under this provision—

(i) *Exemption for certain rural hospitals.* A rural hospital, as defined at

subpart D of part 412 of this subchapter, with less than 250 beds (as determined at §412.105(b)) in its most recent cost reporting period ending on or before September 30, 2002, is exempt from any reduction to the otherwise applicable FTE resident cap limit under paragraph (c)(3) of this section.

(ii) *Reference cost reporting periods.*

(A) To determine a hospital's reference resident level, CMS uses one of the following periods:

(*1*) A hospital's most recent cost reporting period ending on or before September 30, 2002, for which a cost report has been settled or if the cost report has not been settled, the as-submitted cost report (subject to audit); or

(*2*) A hospital's cost reporting period that includes July 1, 2003 if the hospital submits a timely request to CMS to increase its resident level due to an expansion of an existing program and that expansion is not reflected on the hospital's most recent settled cost report. An expansion of an existing program means that, except for expansions due to newly approved programs under paragraph (c)(3)(ii)(A)(*3*) of this section, the number of unweighted allopathic and osteopathic FTE residents in any cost reporting period after the hospital's most recent settled cost report, up to and including the hospital's cost report that includes July 1, 2003, is greater than the number of unweighted allopathic and osteopathic FTE residents in programs that were existing at that hospital during the hospital's most recent settled cost report.

(*3*) A hospital may submit a timely request that CMS adjust the resident level for purposes of determining any reduction under paragraph (c)(3) of this section for the following purposes:

(*i*) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under §415.152 of this chapter) before January 1, 2002, if the program was not in operation during the reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*); or

(*ii*) In the hospital's reference cost reporting period under paragraph (c)(3)(ii)(A)(*2*) of this section, to include the number of FTE residents for which a new program was accredited by the appropriate allopathic or osteopathic accrediting body (listed under §415.152 of this chapter) before January 1, 2002, if the program was not in operation during the cost reporting period that includes July 1, 2003, and if the hospital also qualifies to use its cost report under paragraph (c)(3)(ii)(A)(*2*) of this section due to an expansion of an existing program.

(B) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the contractor may make appropriate modifications to apply the provisions of paragraph (c)(3)(i)(A) of this section based on the equivalent of a 12-month cost reporting period.

(iii) If the new program described in paragraph (c)(3)(ii)(A)(3)(i) or paragraph (c)(3)(ii)(A)(ii) was accredited for a range of residents, the hospital may request that its reference resident level in its applicable reference cost reporting period under paragraph (c)(3)(ii)(A)(*1*) or (c)(3)(ii)(A)(*2*) of this section be adjusted to reflect the maximum number of accredited slots applicable to that hospital.

(iv) *Consideration of Medicare GME affiliated group agreements.* For hospitals that are members of the same affiliated group for the program year July 1, 2003 through June 30, 2004, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph (c)(3) of this section, CMS treats these hospitals as a group. Using information from the hospitals' cost reports that include July 1, 2003, if the hospitals' aggregate FTE resident counts are equal to or greater than the aggregate otherwise applicable FTE resident cap for the affiliated group, then no reductions are made under paragraph (c)(3) of this section to the hospitals' otherwise applicable FTE resident caps. If the hospitals' aggregate FTE resident count is below the aggregate otherwise applicable FTE resident cap, then CMS determines on a hospital-specific basis whether the individual hospital's FTE

resident count is less than its otherwise applicable resident cap (as adjusted by affiliation agreement(s)) in the hospital's cost report that includes July 1, 2003. If the hospital's FTE resident count is in excess of its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (c)(3) of this section. Hospitals in the affiliated group that have FTE resident counts below their individual otherwise applicable FTE resident caps are subject to a pro rata reduction in their otherwise applicable FTE resident caps that is equal, in total, to 75 percent of the difference between the aggregate FTE cap and the aggregate FTE count for the affiliated group. The pro rata reduction to the individual hospital's otherwise applicable resident cap is calculated by dividing the difference between the hospital's individual otherwise applicable FTE resident cap and the hospital's FTE resident count by the total amount by which all of the hospitals' individual FTE resident counts are below their otherwise affiliated FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the affiliated group, and multiplying that result by 75 percent.

(4) *Determination of an increase in the otherwise applicable resident cap under section 422 of Public Law 108–173.* For portions of cost reporting periods beginning on or after July 1, 2005, a hospital may receive an increase in its otherwise applicable FTE resident cap up to an additional 25 FTEs (as determined by CMS) if the hospital meets the requirements and qualifying criteria of section 1886(h)(7) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the timeframe specified by CMS.

(5) *Special rules for hospitals that participate in demonstration projects or voluntary resident reduction plans for purposes of section 422 of Public Law 108–173.* (i) If a hospital was participating in a demonstration project under section 402 of Public Law 90–248 or the voluntary reduction plan under § 413.88 for a greater period of time than the time period that elapsed since it withdrew from participation (or if it completed its participation) in the demonstration program or the voluntary reduction plan, for purposes of determining a possible reduction to the FTE resident caps under paragraph (c)(3) of this section, CMS compares the higher of the hospital's base number of residents (after subtracting any dental and podiatric FTE residents) or the hospital's reference resident level to the hospital's otherwise applicable resident cap determined under paragraph (c)(2) of this section.

(ii) If a hospital participated in the demonstration project or the voluntary resident reduction plan for a period of time that is less than the time that elapsed since it withdraw from participation in the demonstration project or the voluntary reduction plan, the special rules in paragraph (c)(5)(i) do not apply, and the hospital is subject to the procedures applicable to all other hospitals for determining possible reductions to the FTE resident caps under paragraph (c)(3) of this section.

(iii) CMS will not redistribute residency positions that are attributable to a hospital's participation in a demonstration project or a voluntary resident reduction plan to other hospitals that seek to increase their FTE resident caps under paragraph (c)(4) of this section.

(6) *FTE resident caps for rural hospitals that are redesignated as urban.* A rural hospital redesignated as urban after September 30, 2004, as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003, may retain the increases to its FTE resident cap that it received under paragraphs (c)(2)(i), (e)(1)(iii), and (e)(3) of this section while it was located in a rural area. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical areas adopted by CMS, the redesignated urban hospital may retain any existing increases to its FTE resident cap that it had received prior to when the redesignation became effective. Effective October 1, 2014, if a rural hospital is redesignated as urban due to the most recent OMB standards for delineating statistical

areas adopted by CMS, the redesignated urban hospital may receive an increase to its FTE resident cap for a new program, in accordance with paragraph (e) of this section, if it received a letter of accreditation for the new program and/or started training residents in the new program prior to the redesignation becoming effective.

(d) *Weighted FTE counts.* Subject to the provisions of §413.81, for purposes of determining direct GME payment—

(1) For the hospital's first cost reporting period beginning on or after October 1, 1997, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding cost reporting period.

(2) For cost reporting periods beginning on or after October 1, 1998, and before October 1, 2001, the hospital's weighted FTE count is equal to the average of the weighted FTE count for the payment year cost reporting period and the preceding two cost reporting periods.

(3) For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE count for primary care and obstetrics and gynecology residents is equal to the average of the weighted primary care and obstetrics and gynecology counts for the payment year cost reporting period and the preceding two cost reporting periods, and the hospital's weighted FTE count for nonprimary care residents is equal to the average of the weighted nonprimary care FTE counts for the payment year cost reporting period and the preceding two cost reporting periods. For cost reporting periods beginning on or after October 1, 2001, the hospital's weighted FTE counts for the preceding two cost reporting periods are calculated in accordance with the payment formula in paragraph (c)(2)(iii) of this section.

(4) The contractor may make appropriate modifications to apply the provisions of this paragraph (d) based on the equivalent of 12-month cost reporting periods.

(5) (i) For new programs started prior to October 1, 2012, if a hospital qualifies for an adjustment to the limit established under paragraph (c)(2) of this section for new medical residency programs created under paragraph (e) of this section, the count of the residents participating in new medical residency training programs above the number included in the hospital's FTE count for the cost reporting period ending during calendar year 1996 is added after applying the averaging rules in this paragraph (d), for a period of years. Residents participating in new medical residency training programs are included in the hospital's FTE count before applying the averaging rules after the period of years has expired. For purposes of this paragraph (d), for each new program started, the period of years equals the minimum accredited length for each new program. The period of years begins when the first resident begins training in each new program.

(ii) For new programs started on or after October 1, 2012, for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e), FTE residents participating in new medical residency training programs are excluded from the hospital's FTE count before applying the averaging rules during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, for hospitals for which the FTE may be adjusted in accordance with §413.79(e)(1), and prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started, for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(3). Beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the each individual new program started for hospitals for which the FTE cap may be adjusted in accordance with §413.79(e)(3), FTE residents participating in new medical

residency training programs are included in the hospital's FTE count before applying the averaging rules.

(6) Subject to the provisions of paragraph (h) of this section, FTE residents who are displaced by the closure of either another hospital or another hospital's program are added to the FTE count after applying the averaging rules in this paragraph (d), for the receiving hospital for the duration of the time that the displaced residents are training at the receiving hospital.

(7) (i) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000 and before cost reporting periods beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(ii) Subject to the provisions under paragraph (k) of this section, effective for rural track programs started in a cost reporting period beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital or rural hospital are excluded from rolling average calculation described in this paragraph (d) during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(e) *New medical residency training programs.* If a hospital establishes a new medical residency training program as defined in paragraph (l) of this section on or after January 1, 1995, the hospital's FTE cap described under paragraph (c) of this section may be adjusted as follows:

(1) If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of FTE residents in any program year during the third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program. If a hospital had no allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, the hospital's unweighted FTE resident cap under paragraph (c) of this section may be adjusted for new residency training programs based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to the cap may not exceed the number of accredited slots available to the hospital for the new program.

(i) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, and if the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for a new medical residency training program(s) is equal to the sum of the products of the highest number of FTE residents in any program year during the third year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, and if the residents are spending portions of a program (or

years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each qualifying hospital's cap for new residency training program (s) is equal to the sum of the products of three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

(ii) If a hospital begins training residents in a new medical residency training program(s) for the first time on or after January 1, 1995, but before October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's first new residency program(s), the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's first new residency program using the actual number of residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year. If a hospital begins training residents in a new medical residency training program(s) for the first time on or after October 1, 2012, prior to the implementation of the hospital's adjustment to its FTE cap beginning with the sixth year of the hospital's first new residency program(s), the hospital's cap may be adjusted temporarily during each of the first 5 years of the hospital's first new residency program using the actual number of FTE residents participating in the new program. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(iii) If a hospital begins training residents in a new medical residency training program for the first time on or after January 1, 1995, but before October 1, 2012, the cap will not be adjusted for new programs established more than 3 years after residents begin training in the first new program, or if a hospital begins training residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program.

(iv)(A) Effective for Medicare GME affiliation agreements entered into on or after October 1, 2005, exceptas provided in paragraph (e)(1)(iv)(B) of this section, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap only if the adjustment that results from the affiliation is an increase to the urban hospital's FTE cap.

(B) Effective for Medicare GME affiliation agreements entered into on or after July 1, 2019, an urban hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap and receive an adjustment that is a decrease to the urban hospital's FTE cap, provided the Medicare GME affiliated group meets one of the following conditions:

(*1*) The Medicare GME affiliated group consists solely of two or more urban hospitals that qualify for adjustments to their FTE caps under paragraph (e)(1) of this section.

(*2*) The Medicare GME affiliated group includes an urban hospital(s) that received FTE cap(s) under paragraph (c)(2)(i) of this section or § 412.105(f)(1)(iv)(A) of this subchapter, or both. This Medicare GME affiliated group must be established effective with a July 1 date (the residency training year) that is at least 5 years after the start of the cost reporting period that coincides with or follows the start of the sixth program year of the first new program for which the hospital's

FTE cap was adjusted in accordance with paragraph (e)(1) of this section or § 412.105(f)(1)(v)(C) or (D) of this subchapter, or both.

(v) A rural hospital that qualifies for an adjustment to its FTE cap under paragraph (e)(1) of this section is permitted to be part of a Medicare GME affiliated group for purposes of establishing an aggregate FTE cap.

(vi) In the case of a hospital that, as of December 27, 2020, has a FTE cap based on the training of less than 1.0 FTE in any cost reporting period beginning before October 1, 1997; or based on the training of no more than 3.0 FTEs in on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, if such a hospital begins training residents in a new approved program (as defined under § 413.79(l)) in a program year beginning on or after December 27, 2020 and before December 26, 2025, the hospital with a previous FTE cap of less than 1.0 FTE may receive an adjusted FTE cap when it begins to train at least 1.0 FTE in a new program(s); and the hospital with a previous FTE cap of no more than 3.0 FTEs may receive an adjusted FTE cap when it begins to train more than 3.0 FTEs in a new program(s). The adjusted FTE cap is equal to the sum of the original FTE cap and the products of the following three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence started in a program year beginning on or after December 27, 2020 and before December 26, 2025, at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

(2) If a hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted for a new medical residency training program(s) established on or after January 1, 1995, and on or before August 5, 1997. The adjustment to the hospital's FTE resident cap for new residency training programs is based on the sum of the product of the highest number of FTE residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete each program based on the minimum accredited length for the type of program.

(i) If the residents are spending portions of a program year (or years) at one hospital and the remainder of the program at another hospital(s), the adjustment to each respective hospital's cap for each program is equal to the product of the highest number of FTE residents in any program year during the third year of each program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program and the number of years the residents are training at each respective hospital.

(ii) Prior to the implementation of the hospital's adjustment to its FTE cap beginning with the fourth year of the hospital's residency program, the hospital's cap may be temporarily adjusted during each of the first 3 years of the hospital's new residency program, using the actual number of FTE residents in the new programs. The adjustment may not exceed the number of accredited slots available to the hospital for each program year.

(3) If a rural hospital participates in new medical residency training programs, regardless of whether the rural hospital had allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, the hospital's unweighted FTE cap may be adjusted in the same manner described in paragraph (e)(2) of this section to reflect the increase for residents training in a new medical residency training program(s) established after August 5, 1997 and before October 1, 2012. If a rural hospital participates in new medical

residency training programs on or after October 1, 2012, the hospital's unweighted FTE cap is adjusted in accordance with paragraph (e)(1) of this section, except that the adjustment is based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of each new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program.

(4) A hospital seeking an adjustment to its FTE cap must provide documentation to its fiscal contractor justifying the adjustment.

(5) The cap will not be adjusted for expansion of existing or previously existing programs.

(6) Effective for a cost reporting period beginning on or after December 27, 2020, FTE resident caps must be established when the hospital trains 1.0 or more FTE residents in a new medical residency program (as defined under paragraph (l) of this section).

(f) *Medicare GME affiliated group.* A hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under paragraph (d) of this section, to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group (as defined under § 413.75(b)). Under this provision—

(1) Except as provided in paragraph (f)(6) of this section, each hospital in the Medicare GME affiliated group must submit the Medicare GME affiliation agreement, as defined under § 413.75(b) of this section, to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

(2) Each hospital in the Medicare GME affiliated group must have a shared rotational arrangement, as defined in § 413.75(b), with at least one other hospital within the Medicare GME affiliated group, and all of the hospitals within the Medicare GME affiliated group must be connected by a series of such shared rotational arrangements.

(3) During the shared rotational arrangements under a Medicare GME affiliation agreement, as defined in § 413.75(b), more than one of the hospitals in the Medicare GME affiliated group must count the proportionate amount of the time spent by the resident(s) in its FTE resident counts. No resident may be counted in the aggregate as more than one FTE.

(4) The net effect of the adjustments (positive or negative) on the Medicare GME affiliated hospitals' aggregate FTE cap for each Medicare GME affiliation agreement must not exceed zero.

(5) If the Medicare GME affiliation agreement terminates for any reason, the FTE cap of each hospital in the Medicare GME affiliated group will revert to the individual hospital's pre-affiliation FTE cap that is determined under the provisions of paragraph (c) of this section.

(6) Effective October 1, 2009, a hospital that is new after July 1 and begins training residents for the first time after the July 1 start date of an academic year may receive a temporary adjustment to its FTE resident cap to reflect its participation in an existing Medicare GME affiliated group by submitting the Medicare GME affiliation agreement, as defined under § 413.75(b), to the CMS contractor or MAC servicing the hospital and sending a copy to the CMS Central Office by the earlier of June 30 of the residency program year during which the Medicare GME affiliation agreement will be in effect or the end of the first cost reporting period during which the hospital begins training residents. The Medicare GME affiliation agreement must specify the effective period for the agreement, which may begin no earlier than the date the affiliation agreement is submitted to CMS. Each of the other hospitals participating in the Medicare GME affiliated group must submit an amended Medicare GME affiliation agreement that reflects the participation of the new hospital to the CMS contractor or MAC servicing the hospital and send a copy to the CMS Central Office no later than June 30 of the residency program year during which the Medicare GME affiliation agreement will be in effect. For

purposes of this paragraph, a new hospital is one for which a new Medicare provider agreement takes effect in accordance with § 489.13 of this chapter.

(7) *Emergency Medicare GME affiliated group.* Effective on or after August 29, 2005, home and host hospitals as defined in § 413.75(b) may form an emergency Medicare GME affiliated group by meeting the requirements provided in this section. The emergency Medicare GME affiliation agreements may be made effective beginning on or after the first day of a section 1135 emergency period, and must terminate no later than at the conclusion of 4 academic years following the academic year during which the section 1135 emergency period began.

(i) *Requirements for submission of emergency Medicare GME affiliation agreements.* Each hospital in the emergency Medicare GME affiliated group must submit an emergency Medicare GME affiliation agreement that is written, signed, and dated by responsible representatives of each participating hospital in the manner specified in paragraph (ii) and includes the following information:

(A) List each participating hospital and its provider number; and indicate whether each hospital is a home or host hospital.

(B) Specify the effective period of the emergency Medicare GME affiliation agreement (which must, in any event, terminate at the conclusion of four academic years following the academic year in which the section 1135 emergency period began).

(C) List each participating hospital's IME and direct GME FTE caps in effect before the emergency Medicare GME affiliation agreement (including any adjustments to those caps in effect as a result of other Medicare GME affiliation agreements but not including any slots gained under § 413.79(c)(4)).

(D) Specify the total adjustment to each participating hospital's FTE caps in each academic year that the emergency Medicare GME affiliation agreement is in effect, for both direct GME and IME, that reflects a positive adjustment to the host hospital's direct and indirect FTE caps that is offset by a negative adjustment to the home hospital's (or hospitals') direct and indirect FTE caps of at least the same amount subject to the following—

(*1*) The sum total of adjustments to all the participating hospitals' FTE caps under the emergency Medicare GME affiliation agreement may not exceed the aggregate adjusted FTE caps of the hospitals participating in the emergency Medicare GME affiliated group.

(*2*) A home hospital's IME and direct GME FTE cap reductions in an emergency Medicare GME affiliation agreement are limited to the home hospital's IME and direct GME FTE resident caps at § 413.79(c) or § 413.79(f)(1) through (f)(5), that is, as adjusted by any and all existing affiliation agreements as applicable.

(*3*) For emergency Medicare GME affiliation agreements for the third or fourth academic years subsequent to the year in which the section 1135 emergency period began and involving an out-of-State host hospital, the positive adjustment to the out-of-State host hospital's direct and indirect FTE caps pursuant to the agreement shall reflect only FTE residents that were actually displaced from a home hospital immediately following the emergency.

(E) Attach copies of all existing Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements in which the hospital is participating at the time the emergency Medicare GME affiliation agreement is executed.

(ii) *Deadline for submission of the emergency Medicare GME affiliation agreement.* Each participating home and host hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to the CMS contractor/MAC by the applicable due date.

(A) For emergency Medicare GME affiliation agreements that would otherwise be required to be submitted by June 30, 2006, or July 1, 2006, each participating host and home hospital must submit an emergency Medicare GME affiliation agreement to CMS and submit a copy to its CMS contractor/MAC on or before October 9, 2006.

(B) Except for emergency Medicare GME affiliation agreements specified in paragraph (f)(6)(ii)(A) of this section,

for emergency Medicare GME affiliation agreements that would otherwise be required to be submitted prior to October 1, 2008, the following due dates are applicable:

(*1*) *First year*. The later of 180 days after the section 1135 emergency period begins or by June 30 of the academic year in which the section 1135 emergency was declared; or

(*2*) *Subsequent academic years*. The later of 180 days after the section 1135 emergency period begins, or by July 1 of each academic year.

(C) For emergency Medicare GME affiliation agreements that would otherwise be required to be submitted after October 1, 2008, the following due dates are applicable:

(*1*) *First year*. By 180 days after the end of the academic year in which the section 1135 emergency was declared;

(*2*) *Second academic year*. By 180 days after the end of the next academic year following the academic year in which the section 1135 emergency was declared; or

(*3*) *Subsequent academic years*. By July 1 of each academic year.

(iii) *Exemption from the Shared Rotational Arrangement Requirement*. During the effective period of the emergency Medicare GME affiliation agreement, hospitals in the emergency Medicare GME affiliated group are not required to participate in a shared rotational arrangement as defined at § 413.75(b).

(iv) *Host Hospital Exception from the Rolling Average for the Period from August 29, 2005 to June 30, 2006*. To determine the FTE resident count for a host hospital that is training residents in excess of its cap, a two step process will be applied. First, subject to the limit at paragraph (f)(6)(i)(D) of this section, a host hospital is to exclude the displaced FTE residents that are counted by a host hospital in excess of the hospital's cap pursuant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, from the current year's FTE resident count before applying the three-year rolling averaging rules under paragraph (d) of this section to calculate the average FTE resident count. Second, the displaced FTE residents that are counted by the host hospital in excess of the host hospital's cap pursuant to an emergency Medicare GME affiliation agreement from August 29, 2005, to June 30, 2006, are added to the hospital's 3-year rolling average FTE resident count to determine the host hospital's FTE resident count for payment purposes.

(8) FTE resident cap slots added under section 126 of Public Law 116–260 and section 4122 of Public Law 117–328 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

(g) *Newly constructed hospitals*. A hospital that began construction of its facility prior to August 5, 1997, and sponsored new medical residency training programs on or after January 1, 1995, and on or before August 5, 1997, that either received initial accreditation by the appropriate accrediting body or temporarily trained residents at another hospital(s) until the facility was completed, may receive an adjustment to its FTE cap.

(1) The newly constructed hospital's FTE cap is equal to the lesser of—

(i) The product of the highest number of residents in any program year during the third year of the newly established program and the number of years in which residents are expected to complete the programs based on the minimum accredited length for each type of program; or

(ii) The number of accredited slots available to the hospital for each year of the programs.

(2) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for 3 years or more by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents training in the third year of the programs begun at the temporary training site.

(3) If the new medical residency training programs sponsored by the newly constructed hospital have been in existence for less than 3 years by the time the residents begin training at the newly constructed hospital, the newly constructed hospital's cap will be based on the number of residents

training at the newly constructed hospital in the third year of the programs (including the years at the temporary training site).

(4) A hospital that qualifies for an adjustment to its FTE cap under this paragraph (g) may be part of an affiliated group for purposes of establishing an aggregate FTE cap.

(5) The provisions of this paragraph (g) are applicable during portions of cost reporting periods occurring on or after October 1, 1999.

(h) *Closure of hospital or hospital residency program*—(1) *Definitions.* For purposes of this section—

(i) *Closure of a hospital* means the hospital terminates its Medicare agreement under the provisions of §489.52 of this chapter.

(ii) *Closure of a hospital residency training program* means the hospital ceases to offer training for residents in a particular approved medical residency training program.

(iii) *Displaced resident* means a resident who—

(A) Leaves a program after the hospital or program closure is publicly announced, but before the actual hospital or program closure;

(B) Is assigned to and training at planned rotations at another hospital who will be unable to return to his/her rotation at the closing hospital or program;

(C) Is accepted into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program;

(D) Is physically training in the hospital on the day prior to or day of program or hospital closure; or

(E) Is on approved leave at the time of the announcement of closure or actual closure, and therefore, cannot return to his/her rotation at the closing hospital or program.

(2) *Closure of a hospital.* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following criteria:

(i) The hospital is training additional residents from a hospital that closed on or after July 1, 1996.

(ii) No later than 60 days after the hospital begins to train the residents, the hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

(3) *Closure of a hospital's residency training program.* If a hospital that closes its residency training program voluntarily agrees to temporarily reduce its FTE cap according to the criteria specified in paragraph (h)(3)(ii) of this section, another hospital(s) may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of the residency training program if the criteria specified in paragraph (h)(3)(i) of this section are met.

(i) *Receiving hospital(s).* A hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of the closure of another hospital's residency training program if—

(A) The hospital is training additional residents from the residency training program of a hospital that closed a program; and

(B) No later than 60 days after the hospital begins to train the residents, the hospital submits to its contractor a request for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from another hospital's closed program and have caused the hospital to exceed its cap, specifies the length of time the adjustment is needed, and submits to its contractor a copy of the FTE reduction statement by the hospital that closed its program, as specified in paragraph (h)(3)(ii)(B) of this section.

(ii) *Hospital that closed its program(s).* A hospital that agrees to train residents who have been displaced by the closure of another hospital's program may receive a temporary FTE cap adjustment only if the hospital with the closed program—

(A) Temporarily reduces its FTE cap based on the FTE residents in each program year training in the program at

the time of the program's closure. This yearly reduction in the FTE cap will be determined based on the number of those residents who would have been training in the program during that year had the program not closed; and

(B) No later than 60 days after the residents who were in the closed program begin training at another hospital, submit to its contractor a statement signed and dated by its representative that specifies that it agrees to the temporary reduction in its FTE cap to allow the hospital training the displaced residents to obtain a temporary adjustment to its cap; identifies the residents who were in training at the time of the program's closure; identifies the hospitals to which the residents are transferring once the program closes; and specifies the reduction for the applicable program years.

(i) *Additional FTEs for residents on maternity or disability leave or other approved leave of absence.* Effective for cost reporting periods beginning on or after November 29, 1999, a hospital may receive an adjustment to its FTE cap of up to three additional resident FTEs, if the hospital meets the following criteria:

(1) The additional residents are residents of a primary care program that would have been counted by the hospital as residents for purposes of the hospital's FTE cap but for the fact that the additional residents were on maternity or disability leave or a similar approved leave of absence during the hospital's most recent cost reporting period ending on or before December 31, 1996;

(2) The leave of absence was approved by the residency program director to allow the residents to be absent from the program and return to the program after the leave of absence; and

(3) No later than 6 months after August 1, 2000, the hospital submits to the contractor a request for an adjustment to its FTE cap, and provides contemporaneous documentation of the approval of the leave of absence by the residency director, specific to each additional resident that is to be counted for purposes of the adjustment.

(j) *Residents previously trained at VA hospitals.* For cost reporting periods beginning on or after October 1, 1997, a non-Veterans Affairs (VA) hospital may receive a temporary adjustment to its FTE cap to reflect residents who had previously trained at a VA hospital and were subsequently transferred to the non-VA hospital, if that hospital meets the following criteria:

(1) The transferred residents had been training previously at a VA hospital in a program that would have lost its accreditation by the ACGME if the residents continued to train at the VA hospital;

(2) The residents were transferred to the hospital from the VA hospital on or after January 1, 1997, and before July 31, 1998; and

(3) The hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that it is eligible for this temporary adjustment by identifying the residents who have come from the VA hospital, and specifies the length of time those residents will be trained at the hospital.

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may add the rotations of the residents in those rural tracks to its FTE cap specified under paragraph (c) of this section. An urban hospital (or, effective for a cost reporting period beginning on or after October 1, 2022, a rural hospital) with a Rural Track Program (as defined at section 413.75(b) of this subchapter) may count residents in those Rural Track Programs up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and before October 1, 2022, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital, not

to exceed its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if an urban hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural hospital(s) for more than one-half of the duration of the program, both the urban and the rural hospital may include those residents in their FTE counts for the time the rural track residents spend at the urban and rural hospital, respectively, not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012 and before October 1, 2022, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section. For Rural Track Programs started on or after October 1, 2022, beginning with the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). For cost reporting periods beginning on or after October 1, 2022, if an urban or rural hospital rotates residents to a Rural Track Program (as defined at section 413.75(b) of this subchapter) at a rural nonprovider site for more than one-half of the duration of the program, the urban or rural hospital may include those residents in its FTE count, subject to which hospital meets the requirements under § 413.78(g), not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i)(A) For rural track programs started before October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each

urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(B) For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s).

(C) For cost reporting periods beginning on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the Rural Track Program's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the Rural Track Program at the urban or rural hospital and subject to the requirements under § 413.78(g), at the rural nonprovider site(s).

(ii)(A) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(*i*) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonprovider site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*ii*) The rural nonprovider site(s); and

(*2*) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(B) For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under paragraph (e)(3) of this section, or the rural hospital's FTE count does not exceed that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(4)(i) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after

April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g), as applicable. The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*2*) The length of time in which the residents are training at the rural nonprovider site(s) only.

(C) For programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(ii) For rural track programs started on or after October 1, 2012 and prior to October 1, 2022, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) Prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonprovider site(s).

(B) Beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at the rural nonprovider site(s) or are designated at the beginning of their training to be rotated to the rural nonprovider site(s) for a period that is for one-half or less than one-half of the duration of the program; and

(*2*) The ratio of the length of time in which the residents are training at the rural nonprovider site(s) only to the total duration of the program.

(C) For cost reporting periods beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(5) All urban hospitals that wish to count FTE residents in rural tracks, not to exceed their respective rural track FTE limitation, must also comply with all of the following conditions:

(i) A hospital may not include in its rural track FTE limitation or (assuming the hospital's FTE count exceeds its FTE cap) FTE count residents who are training in a rural track residency program that were already included as part of the hospital's FTE cap.

(ii) Each hospital must base its count of residents in a rural track on written contemporaneous documentation that

each resident enrolled in a rural track program at the hospital intends to rotate for a portion of the residency program to a rural area.

(iii) All residents that are included by the hospital as part of its rural track FTE count (not to exceed its rural track FTE limitation) must train in the rural area. However, where a resident begins to train in the rural track program at the urban hospital but leaves the program before completing the total required portion of training in the rural area, the urban hospital may count the time the resident trained in the urban hospital if another resident fills the vacated FTE slot and completes the training in the rural portion of the rural track program. An urban hospital may not receive GME payment for the time the resident trained at the urban hospital if another resident fills the vacated FTE slot and first begins to train at the urban hospital.

(iv) Effective for cost reporting periods beginning on or after October 1, 2022, in order for an urban or rural hospital to receive a rural track FTE limitation, greater than 50 percent of the program must occur in a rural area.

(6) If CMS finds that residents who are included by the urban hospital as part of its FTE count did not actually complete the training in the rural area, CMS will reopen the urban hospital's cost report within the 3-year reopening period as specified in § 405.1885 of this chapter and adjust the hospital's Medicare GME payments (and, where applicable, the hospital's rural track FTE limitation).

(7)(i) Effective prior to October 1, 2014, if an urban hospital had established a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent census data and implementation of the new labor market area definitions announced by OMB on June 6, 2003, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) for the rural track programs established prior to the adoption of such new labor market area definitions. In order to receive an adjustment to its FTE resident cap for a new rural track residency program, the urban hospital must establish a rural track program with hospitals that are designated rural based on the most recent geographical location delineations adopted by CMS.

(ii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(7)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(iii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by

CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 5-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(l) For purposes of this section, a new medical residency training program means a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.

(m) *Determination of the reduction to the FTE resident cap due to unused FTE resident slots under section 5503 of Public Law 111–148.* If a hospital's reference resident level, as defined under paragraph (c)(1)(ii)(B) of this section is less than its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section or paragraph (e) of this section in the reference cost reporting period (as described under paragraph (m)(6) of this section), for

portions of cost reporting periods beginning on or after July 1, 2011, the hospital's otherwise applicable FTE resident cap is reduced by 65 percent of the difference between the otherwise applicable FTE resident cap and the reference resident level. The reduction shall take into account the hospital's FTE resident cap as reduced under paragraph (c)(3) of this section. Under this provision—

(1) *Exemption for certain rural hospitals.* A rural hospital, as defined at subpart D of part 412 of this subchapter, with fewer than 250 beds (as determined at § 412.105(b)) in its most recent cost reporting period ending on or before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(2) *Exemption for certain hospitals that participate in demonstration projects or voluntary residency reduction plans.* A hospital that was participating in a demonstration project under section 402 of Public Law 90–248 or the voluntary reduction plan under § 413.88, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section if, by January 21, 2011, it submits a plan to CMS for filling all of its unused FTE resident slots by not later than March 23, 2012.

(3) *Exemption for a hospital described at section 1886(h)(4)(H)(v) of the Act.* A hospital described at section 1886(h)(4)(H)(v) of the Act, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(4) *Exemptions for certain other hospitals.* A hospital training at or above its otherwise applicable FTE resident cap as determined under paragraph (c)(2) of this section for all three most recent cost reporting periods ending prior to March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(5) *New teaching hospital.* A new teaching hospital that does not have an otherwise applicable FTE resident cap as determined under paragraph (e)(1) of this section for all three most recent cost reporting periods ending prior to March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, is exempt from any reduction to its otherwise applicable FTE resident cap under paragraph (m) of this section.

(6) *Reference cost reporting period.* (i) To determine a hospital's reference resident level, CMS determines, for a hospital's three most recent cost reporting periods ending before March 23, 2010, for which a cost report has been either settled or submitted (subject to audit) to the Medicare contractor by March 23, 2010, the cost reporting period with the highest resident level.

(ii) If the cost report that is used to determine a hospital's otherwise applicable FTE resident cap in the reference period is not equal to 12 months, the Medicare contractor may make appropriate modifications to apply the provisions of paragraph (m) of this section based on the equivalent of a 12-month cost reporting period.

(7) *Consideration for members of Medicare GME affiliated groups.* For a hospital that is a member of a Medicare GME affiliated group at any point during any of the hospital's three most recent cost reporting periods ending before March 23, 2010 for which a cost report has been settled or has been submitted to Medicare contractor by March 23, 2010, in determining whether a hospital's otherwise applicable resident FTE resident cap is reduced under paragraph (m) of this section, the Medicare contractor determines a hospital's reference cost reporting period by finding the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(i) If the reference resident level is less than the otherwise applicable resident limit in that reference cost reporting period, the Medicare contractor must then determine if the hospital was a member of a Medicare GME affiliated group as of the July 1 that

occurs during that reference cost reporting period.

(ii) If the hospital was a member of a Medicare GME affiliated group as of the July 1 that occurs during that reference cost report, the Medicare contractor does all of the following:

(A) Treat the members of the Medicare GME affiliated group as a group for that reference cost reporting period, for the purpose of determining a reduction to the particular hospital's FTE resident cap.

(B) Determine for each hospital in the Medicare GME affiliated group respectively the FTE resident cap and FTE resident count (IME and direct GME separately).

(C) Add each hospital's FTE resident caps (IME and direct GME separately) to determine the aggregate FTE resident cap.

(D) Add each hospital's FTE resident count (IME and direct GME separately) to determine the aggregate FTE resident count.

(iii) If the aggregate FTE resident count is equal to or exceeds the aggregate FTE resident cap, then the Medicare contractor would make no reduction to the particular hospital's otherwise applicable FTE resident cap under paragraph (m) of this section, and no further steps are necessary for that hospital.

(iv) If the hospitals' aggregate FTE resident count is less than the aggregate FTE resident cap, then the Medicare contractor would determine on a hospital-specific basis whether the particular hospital's FTE resident count is less than its otherwise applicable FTE resident cap (as adjusted by affiliation agreement(s)) in the hospital's reference cost report.

(v) If the hospital's FTE resident count exceeds its otherwise applicable FTE resident cap, the hospital will not have its otherwise applicable FTE resident cap reduced under paragraph (m) of this section.

(vi) If the particular hospital's FTE resident count is less than its otherwise applicable FTE resident cap, the Medicare contractor determines a pro rata cap reduction amount that is equal, in total, to 65 percent of the difference between the aggregate FTE resident cap and the aggregate FTE resident count for the Medicare GME affiliated group.

(A) The pro rata cap reduction to the particular hospital's otherwise applicable FTE resident cap is calculated by dividing the difference between the hospital's otherwise applicable FTE resident cap and the hospital's FTE resident count, by the total amount by which all of the hospitals' individual FTE resident counts are below their affiliated FTE resident caps, multiplying the quotient by the difference between the aggregate FTE resident cap and the aggregate FTE resident counts for the Medicare GME affiliated group, and multiplying that result by 65 percent.

(B) The final reduction takes into account the hospital's FTE resident cap as reduced under the provisions of paragraph (c)(3) of this section.

(n) *Determination of an increase in the otherwise applicable resident cap under section 5503 of Public Law 111–148.* (1) For portions of cost reporting periods beginning on or after July 1, 2011, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) of not more than 75 additional FTEs if the hospital meets the requirements and qualifying criteria of section 1886(h)(8) of the Act and implementing instructions issued by CMS and if the hospital submits an application to CMS within the timeframe specified by CMS.

(2) A hospital that receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section must ensure, during the 5-year period beginning on July 1, 2011 and ending on June 30, 2016, that—

(i) The number of FTE primary care residents, as defined in § 413.75(b), excluding any additional positions under this paragraph, is not less than the average number of FTE primary care residents (as so determined) during the three most recent cost reporting periods ending prior to March 23, 2010 (and submitted to the Medicare contractor by March 23, 2010); and not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency programs.

(ii) If a hospital receives an increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this

section, and does not use all of that increase in its final (12-month or partial) cost report of the 5-year period beginning July 1, 2011 and ending June 30, 2016, the Medicare contractor will remove the applicable unused slots, and the hospital's increase in the otherwise applicable FTE resident cap received under paragraph (n)(1) of this section will be reduced for portions of cost reporting periods on or after July 1, 2016. The number of applicable unused slots is equal to the difference between the increase in the otherwise applicable FTE resident cap and the applicable slots used. In determining the applicable slots used, the following amounts are added, as relevant:

(A) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to expand an existing program(s), the used slots are equal to the lesser of the number of slots used for an expansion(s) in the fourth 12-month cost report or the final cost report.

(B) If a hospital uses the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section to start a new program(s), the used slots are equal to the number of slots used for a new program(s) in the final cost report.

(C) The portion, if any, of the increase in the otherwise applicable FTE resident cap under paragraph (n)(1) of this section used for cap relief, subject to the requirements in paragraph (n)(2)(i) of this section.

(iii) CMS may determine whether a hospital has met the requirements under paragraphs (n)(2)(i) and (n)(2)(ii) of this section during the 5-year period of July 1, 2011, through June 30, 2016, in such manner and at such time as CMS determines appropriate, including at the end of such 5-year period.

(iv) In a case where the Medicare contractor determines that a hospital did not meet the requirements under paragraphs (n)(2)(i), (n)(2)(ii), and (n)(2)(iii) of this section in a cost reporting period within the 5-year time period, the Medicare contractor will reduce the otherwise applicable FTE resident cap of the hospital by the amount by which such limit was increased under paragraph (n)(1) of this section from the earliest cost reporting period that is reopenable in which it would be determined that the hospital did not meet the requirements.

(o) *Determination of an increase in the FTE resident cap due to slots redistributed from a closed hospital.* (1) Except in the case of the closure of the hospital with Medicare Provider Number 05–0578, in the instance of a hospital closure, as defined at paragraph (h)(1)(i) of this section, the FTE resident cap of the closed hospital would be redistributed, and a hospital that meets the requirements and qualifying criteria of section 1886(h)(4)(H)(vi) of the Act and implementing instructions issued by CMS, including submission of a timely application to CMS, may receive an increase in its FTE resident cap, as determined by CMS.

(2)(i) Except in the case of the closure of the hospital with Medicare Provider Number 05–0578, in redistributing the FTE resident cap of a closed hospital, consideration shall be given to ensure that there is no duplication of FTE slots between FTE slots redistributed under this paragraph and temporary adjustments to FTE resident caps provider under paragraph (h)(2) of this section.

(ii) The provisions of this paragraph (o) will not be applied in a manner that will require the reopening of settled cost reports, except where the provider has a jurisdictionally proper appeal pending on direct GME or IME payments as of March 23, 2010.

(p) *Determination of an increase in the otherwise applicable resident cap under section 126 of the Consolidated Appropriations Act (Pub. L. 116–260).* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

(q) *Determination of an increase in the otherwise applicable resident cap under section 4122 of the Consolidated Appropriations Act (Pub. L. 117–328).* For portions of cost reporting periods beginning on or after July 1, 2026, a hospital

may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(10) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

[69 FR 49254, Aug. 11, 2004]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 413.79, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 413.80 Direct GME payments: Determination of weighting factors for foreign medical graduates.

(a) The weighting factor for a foreign medical graduate is determined under the provisions of § 413.79 if the foreign medical graduate—

(1) Has passed FMGEMS; or

(2) Before July 1, 1986, received certification from, or passed an examination of, the Educational Committee for Foreign Medical Graduates.

(b) Before July 1, 1986, the weighting factor for a foreign medical graduate is 1.0 times the weight determined under the provisions of § 413.79. On or after July 1, 1986, and before July 1, 1987, the weighting factor for a graduate of a foreign medical school who was in a residency program both before and after July 1, 1986 but who does not meet the requirements set forth in paragraph (a) of this section is .50 times the weight determined under the provisions of § 413.79.

(c) On or after July 1, 1987, these foreign medical graduates are not counted in determining the number of FTE residents.

(d) During the cost reporting period in which a foreign medical graduate passes FMGEMS, the weighting factor for that resident is determined under the provisions of § 413.79 for the part of the cost reporting period beginning with the month the resident passes the test.

(e) On or after September 1, 1989, the National Board of Medical Examiners Examination, Parts I and II, may be substituted for FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section.

(f) On or after June 1, 1992, the United States Medical Licensing Examination may be substituted for the FMGEMS for purposes of the determination made under paragraphs (a) and (d) of this section. On or after July 1, 1993, only the results of steps I and II of the United States Medical Licensing Examination will be accepted for purposes of making this determination.

[69 FR 49254, Aug. 11, 2004]

§ 413.81 Direct GME payments: Application of community support and redistribution of costs in determining FTE resident counts.

(a) For purposes of determining direct GME payments, the following principles apply:

(1) *Community support.* If the community has undertaken to bear the costs of medical education through community support, the costs are not considered GME costs to the hospital for purposes of Medicare payment.

(2) *Redistribution of costs.* The costs of training residents that constitute a redistribution of costs from an educational institution to the hospital are not considered GME costs to the hospital for purposes of Medicare payment.

(b) *Application.* A hospital must continuously incur costs of direct GME of residents training in a particular program at a training site since the date the residents first began training in that program in order for the hospital to count the FTE residents in accordance with the provisions of §§ 413.78, 413.79 (c) through (e), and 413.79(k). This rule also applies to providers that are paid for direct GME in accordance with § 405.2468 of this chapter, § 422.270 of this subchapter, and § 413.70.

(c)(1) *Effective date.* Subject to the provisions of paragraph (c)(2) of this section, payments made in accordance with determinations made under the provisions of paragraphs (a) and (b) of this section will be effective for portions of cost reporting periods occurring on or after October 1, 2003.

(2) *Applicability for certain hospitals.* With respect to an FTE resident who begins training in a residency program on or before October 1, 2003, and with

respect to whom there has been a redistribution of costs or community support determined under the provisions of paragraphs (a) and (b) of this section, the hospital may continue to count the FTE resident until the resident has completed training in that program, or until 3 years after the date the resident began training in that program, whichever comes first.

[69 FR 49254, Aug. 11, 2004]

§ 413.82 Direct GME payments: Special rules for States that formerly had a waiver from Medicare reimbursement principles.

(a) Effective for cost reporting periods beginning on or after January 1, 1986, hospitals in States that, prior to becoming subject to the prospective payment system, had a waiver for the operation of a State reimbursement control system under section 1886(c) of the Act, section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1 or section 222(a) of the Social Security Amendment of 1972 (42 U.S.C. 1395b–1 (note)) are permitted to change the order in which they allocate administrative and general costs to the order specified in the instructions for the Medicare cost report.

(b) For hospitals making this election, the base-period costs for the purpose of determining the per resident amount are adjusted to take into account the change in the order by which they allocate administrative and general costs to interns and residents in approved program cost centers.

(c) Per resident amounts are determined for the base period and updated as described in § 413.77. For cost reporting periods beginning on or after January 1, 1986, payment is made based on the methodology described in § 413.76.

[69 FR 49254, Aug. 11, 2004]

§ 413.83 Direct GME payments: Adjustment of a hospital's target amount or prospective payment hospital-specific rate.

(a) *Misclassified operating costs*—(1) *General rule.* If a hospital has its base-period GME costs reduced under § 413.77(a) of this section because those costs included misclassified operating costs, the hospital may request that the contractor review the classification of the affected costs in its rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its rate-of-increase ceiling or prospective payment base year costs no later than 180 days after the date of the notice by the contractor of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the contractor that adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of contractor's review.* If the contractor, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate or the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

(b) *Misclassification of GME costs*—(1) *General rule.* If costs that should have been classified as GME costs were treated as operating costs during both the GME base period and the rate-of-increase ceiling base year or prospective payment base year and the hospital wishes to receive benefit for the appropriate classification of these costs as GME costs in the GME base period, the hospital must request that the contractor review the classification of the affected costs in the rate-of-increase ceiling or prospective payment base year for purposes of adjusting the hospital's target amount or hospital-specific rate. For those cost reports that are not subject to reopening under § 405.1885 of this chapter, the hospital's reopening request must explicitly state that the review is limited to this one issue.

(2) *Request for review.* The hospital must request review of the classification of its costs no later than 180 days after the date of the contractor's notice of the hospital's base-period average per resident amount. A hospital's request for review must include sufficient documentation to demonstrate to the contractor that modification of the adjustment of the hospital's hospital-specific rate or target amount is warranted.

(3) *Effect of contractor's review.* If the contractor, upon review of the hospital's costs, determines that the hospital's hospital-specific rate or target amount should be adjusted, the adjustment of the hospital-specific rate and the adjustment of the target amount is effective for the hospital's cost reporting periods subject to the prospective payment system or the rate-of-increase ceiling that are still subject to reopening under § 405.1885 of this chapter.

[69 FR 49254, Aug. 11, 2004]

§ 413.85 Cost of approved nursing and allied health education activities.

(a) *Statutory basis.* This section implements section 1861(v)(1)(A) of the Act and section 4004(b) of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508) by establishing the methodology for Medicare payment of the costs of approved nursing and allied health education activities.

(b) *Scope.* (1) This section sets forth the rules for determining Medicare payments to hospitals for the costs of nursing and allied health education activities.

(2) This section does not address Medicare payments for the direct and indirect costs of graduate medical education (that is, approved residency programs in medicine, osteopathy, dentistry, and podiatry). Medicare payment for these costs is determined as provided in § 412.105 of this subchapter and §§ 413.75 through 413.83.

(3) The rules under this section do not apply to activities that are specified in paragraph (h) of this section and identified as normal operating costs.

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

Approved educational activities means formally organized or planned programs of study of the type that:

(1) Are operated by providers as specified in paragraph (f) of this section;

(2) Enhance the quality of health care at the provider; and

(3) Meet the requirements of paragraph (e) of this section for State licensure or accreditation.

Classroom instruction costs are those costs associated with formal, didactic instruction on a specific topic or subject in a class that meets at regular, scheduled intervals over a specific time period (for example, semester or quarter), and for which a student receives a grade.

Clinical training costs means costs of training for the acquisition and use of the skills of a nursing or allied health profession or trade in the actual environment in which these skills will be used by the student upon graduation. Clinical training may involve occasional or periodic meetings to discuss or analyze cases, critique performance, or discuss specific skills or techniques; it involves no classroom instruction.

Community support means funding that is provided by the community and generally includes all non-Medicare sources of funding (other than payments made for furnishing services to individual patients), including State and local government appropriations. Community support does not include grants, gifts, and endowments of the kind that are not to be offset in accordance with section 1134 of the Act.

Redistribution of costs means an attempt by a provider to increase the amount, or to expand the types, of the costs of educational activities that are allowed for Medicare payment purposes by claiming costs that previously were not claimed by the provider and were considered costs of an educational institution. For example, costs for a school of nursing or allied health education or a medical school that were incurred by an educational institution and were not allowable to the provider in its prospective payment or rate-of-increase limit base year cost report, or graduate medical education per resident amount calculated under §§ 413.75 through 413.83, are not allowable costs in subsequent fiscal years.

(d) *General payment rules.* (1) Payment for a provider's net cost of nursing and allied health education activities is determined on a reasonable cost basis, subject to the following conditions and limitations:

(i) An approved educational activity—

(A) Is recognized by a national approving body or State licensing authority as specified in paragraph (e) of this section;

(B) Meets the criteria specified in paragraph (f) of this section for identification as an operator of an approved education program.

(C) Enhance the quality of health care at the provider.

(ii) The cost for certain nonprovider-operated programs are reimbursable on a reasonable cost basis if the programs meet the criteria specified in paragraph (g)(2) of this section.

(iii) The costs of certain nonprovider-operated programs at wholly owned subsidiary educational institutions are reimbursable on a reasonable cost basis if the provisions of paragraph (g)(3) of this section are met.

(2) *Determination of net cost.* (i) Subject to the provisions of paragraph (d)(2)(iii) of this section, the net cost of approved educational activities is determined by deducting the revenues that a provider receives from tuition and student fees from the provider's total allowable educational costs that are directly related to approved educational activities.

(ii) A provider's total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24. These costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

(iii) The net costs of approved certified registered nurse anesthetist (CRNA) education programs that are determined on a reasonable cost basis are subject to the additional condition that allowable compensation costs for faculty members who are CRNAs are limited to the compensation costs for administrative activities related to the educational program, the compensation costs directly related to hours spent in classroom instruction, and the costs related to the clinical training of students for which the CRNA may not receive payment under the CRNA fee schedule. No pass-through compensation costs are allowable for the time a CRNA spends in the clinical training of a student anesthetist during a surgical procedure in the operating room for which the CRNA may receive payment under the CRNA fee schedule. As specified at § 414.46 of this chapter, if the CRNA continuously supervises the services of a single student nurse anesthetist, or where the medical direction rules allow a CRNA to bill for the service, payment can be made under the CRNA fee schedule.

(iv) Net costs are subject to apportionment for Medicare utilization as described in § 413.50.

(e) *Approved nursing and allied health education programs.* CMS will consider an activity an approved nursing and allied health education program if the program is a planned program of study that is licensed by State law, or if licensing is not required, is accredited by the recognized national professional organization for the particular activity. Such national accrediting bodies include, but are not limited to, the Commission on Accreditation of Allied Health Education Programs, the National League of Nursing Accrediting Commission, the Association for Clinical Pastoral Education Inc., and the American Dietetic Association.

(f) *Criteria for identifying programs operated by a provider.* (1) Except as provided in paragraph (f)(2) of this section, for cost reporting periods beginning on or after October 1, 1983, in order to be considered the operator of an approved nursing or allied health education program, a provider must meet all of the following requirements:

(i) Directly incur the training costs.

(ii) Have direct control of the program curriculum. (A provider may enter into an agreement with an educational institution to furnish basic academic courses required for completion of the program, but the provider

must provide all of the courses relating to the theory and practice of the nursing or allied health profession involved that are required for the degree, diploma, or certificate awarded at the completion of the program.)

(iii) Control the administration of the program, including collection of tuition (where applicable), control the maintenance of payroll records of teaching staff or students, or both (where applicable), and be responsible for day-to-day program operation. (A provider may contract with another entity to perform some administrative functions, but the provider must maintain control over all aspects of the contracted functions.)

(iv) Employ the teaching staff.

(v) Provide and control both classroom instruction and clinical training (where classroom instruction is a requirement for program completion), subject to the parenthetical sentence in paragraph (f)(1)(ii) of this section.

(2) Absent evidence to the contrary, the provider that issues the degree, diploma, or other certificate upon successful completion of an approved education program is assumed to meet all of the criteria set forth in paragraph (f)(1) of this section and to be the operator of the program.

(g) *Payment for certain nonprovider-operated programs*—(1) *Payment rule.* Costs incurred by a provider, or by an educational institution that is related to the provider by common ownership or control (that is, a related organization as defined in § 413.17(b)), for the clinical training of students enrolled in an approved nursing or allied health education program that is not operated by the provider, are paid on a reasonable cost basis if the conditions specified in paragraph (g)(2) of this section are met.

(2) *Criteria for identification of nonprovider-operated education programs.* Payment for the incurred costs of educational activities identified in paragraph (g)(1) of this section will be made if the following conditions are met:

(i) The clinical training must occur on the premises of the provider, that is, in the hospital itself or in the physical area immediately adjacent to the provider's main buildings, or in other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.

(ii) The provider must have claimed and been paid for clinical training costs on a reasonable cost basis during the most recent cost reporting period that ended on or before October 1, 1989. This condition is met if a notice of program reimbursement (NPR) was issued for that cost reporting period by November 5, 1990, and the clinical training costs were included as pass-through costs. If an NPR was not issued by that date, or an NPR was issued but did not treat the clinical training costs as pass-through costs, the condition is met if—

(A) The contractor included the clinical training costs in the allowable costs used to determine the interim rate for the most recent cost reporting period ending on or before October 1, 1989; or

(B) The provider claimed the clinical training costs as pass-through costs when the cost report for the most recent cost reporting period ending on or before October 1, 1989, was initially submitted.

(iii) In any cost reporting period, the percentage of total allowable provider cost attributable to allowable clinical training cost does not exceed the percentage of total cost for clinical training in the provider's most recent cost reporting period ending on or before October 1, 1989.

(iv) The students in the educational program must provide a benefit to the provider through the provision of clinical services to patients of the provider.

(v) The clinical training costs must be incurred by the provider or by an educational institution related to the provider by common control or ownership as defined in § 413.17(b) (''*Cost to related organizations.*'') Costs incurred by a third-party, regardless of its relationship to either the provider or the educational institution, are not allowed.

(vi) The costs incurred by a provider does not exceed the costs the provider would have incurred if it was the sole operator of the program.

(3) *Special rule: Payment for certain nonprovider-operated programs at wholly owned subsidiary educational institutions.* (i) Effective for portions of cost

reporting periods occurring on or after October 1, 2003, a provider that incurs costs for a nursing or allied health education program(s) where those program(s) had originally been provider-operated according to the criteria at paragraph (f) of this section, and then operation of the program(s) was transferred to a wholly owned subsidiary educational institution in order to meet accreditation standards prior to October 1, 2003, and where the provider has continuously incurred the costs of both the classroom and clinical training portions of the program(s) at the educational institution, may receive reasonable cost payment for such a program(s) according to the specifications under paragraphs (g)(3)(ii) and (g)(3)(iii) of this section.

(ii) Payment for the incurred costs of educational activities identified in paragraph (g)(3)(i) of this section will be made on a reasonable cost basis if a provider, as described in paragraph (g)(3)(i) of this section, received Medicare reasonable cost payment for those nursing and allied health education program(s) both prior and subsequent to the date the provider transferred operation of the program(s) to its wholly owned subsidiary educational institution (and ceased to be a provider-operated program(s) according to the criteria under paragraph (f) of this section).

(iii) The provider that meets the requirements in paragraphs (g)(3)(i) and (g)(3)(ii) of this section will be eligible to receive payment under this paragraph for: (A) the clinical training costs incurred for the program(s) as described in paragraph (g)(3)(i) of this section; and (B) classroom costs, but only those costs incurred by the provider for the courses that were included in the programs.

(h) *Cost of educational activities treated as normal operating costs.* The costs of the following educational activities incurred by a provider but not operated by that provider are recognized only as normal operating costs and paid in accordance with the reimbursement principles specified in Part 412 of this subchapter. They include:

(1) Orientation and on-the-job training.

(2) Part-time education for bona fide full-time employees at properly accredited academic or technical institutions (including other providers) devoted to undergraduate or graduate work.

(3) Educational seminars, workshops, and continuing education programs in which the employees or trainees participate that enhance the quality of medical care or operating efficiency of the provider and, effective October 1, 2003, do not lead to the ability to practice and begin employment in a nursing or allied health specialty.

(4) Maintenance of a medical library.

(5) Training of a patient or patient's family in the use of medical appliances or other treatments.

(6) Except as provided in paragraph (g) of this section, clinical training and classroom instruction of students enrolled in an educational program that is not operated by the provider. The following are clinical training and classroom instruction costs that are allowable as normal operating costs:

(i) Costs incurred in the clinical training of students, including the clinical training or clerkship of undergraduate medical school students that takes place in a provider.

(ii) Classroom instruction costs incurred by a provider that meet the following criteria:

(A) The provider's support does not constitute a redistribution of nonprovider costs to the provider. The support must be in addition to the costs already being incurred by the nonprovider-operated program. If the nonprovider entity reduces its costs due to receiving provider support, this reduction constitutes a redistribution of costs from an educational institution to a patient care institution and is a nonallowable provider cost.

(B) The provider receives a benefit for the support it furnishes.

(C) The cost of the provider's support is less than the cost the provider would incur were it to operate the program.

(7) Other activities that do not involve the actual operation of an approved educational program.

[66 FR 3374, Jan. 12, 2001, as amended at 66 FR 14342, Mar. 12, 2001; 68 FR 45471, Aug. 1, 2003; 69 FR 49254, Aug. 11, 2004; 71 FR 48142, Aug. 18, 2006; 75 FR 50418, Aug. 16, 2010]

§ 413.87 Payments for Medicare + Choice nursing and allied health education programs.

(a) *Statutory basis.* This section implements section 1886(l) of the Act, which provides for additional payments to hospitals that operate and receive Medicare reasonable cost reimbursement for approved nursing and allied health education programs and the methodology for determining the additional payments.

(b) *Scope.* This section sets forth the rules for determining an additional payment amount to hospitals that receive payments for the costs of operating approved nursing or allied health education programs under § 413.85.

(c) *Qualifying conditions for payment.* (1) For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, a hospital that operates and receives payment for a nursing or allied health education program under § 413.85 may receive an additional payment amount associated with Medicare + Choice utilization. The hospital may receive the additional payment amount, which is calculated in accordance with the provisions of paragraph (d) of this section, if both of the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section are met.

(i) The hospital must have received Medicare reasonable cost payment for an approved nursing or allied health education program under § 413.85 in its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year. (For example, if the current year is calendar year 2000, the fiscal year that is 2 years prior to calendar year 2000 is FY 1998.) For a hospital that first establishes a nursing or allied health education program after FY 1998 and receives reasonable cost payment for the program as specified under § 413.85 after FY 1998, the hospital is eligible to receive an additional payment amount in a calendar year that is 2 years after the respective fiscal year so long as the hospital also meets the condition under paragraph (c)(1(ii) of this section.

(ii) The hospital must be receiving reasonable cost payment for an approved nursing or allied health education program under § 413.85 in the current calendar year.

(2) For portions of cost reporting periods occurring on or after January 1, 2001, in addition to meeting the conditions specified in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, the hospital must have had a Medicare + Choice utilization greater than zero in its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year.

(d) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2000 and before January 1, 2001, subject to the provisions of § 413.76(d)(4) relating to calculating a proportional reduction in Medicare + Choice direct GME payments, the additional payment amount specified in paragraph (c) of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine the hospital's total nursing and allied health education program payments from its cost reporting period(s) ending in the fiscal year that is 2 years prior to the current calendar year.

(2) *Step two.* Determine the ratio of the hospital's payments from step one to the total of all nursing and allied health education program payments across all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year.

(3) *Step three.* Multiply the ratio calculated in step two by the Medicare + Choice nursing and allied health payment ''pool'' determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(e) *Calculating the additional payment amount for portions of cost reporting periods occurring on or after January 1, 2001.* For portions of cost reporting periods occurring on or after January 1, 2001, subject to the provisions of § 413.76(d) relating to calculating a proportional reduction in Medicare + Choice direct GME payments, the additional payment amount specified in paragraph (c)

of this section is calculated according to the following steps:

(1) *Step one.* Each calendar year, determine for each eligible hospital the total—

(i) Medicare payments received for approved nursing or allied health education programs based on data from the settled cost reports for the period(s) ending in the fiscal year that is 2 years prior to the current calendar year; and

(ii) Inpatient days for that same cost reporting period.

(iii) Medicare + Choice inpatient days for that same cost reporting period.

(2) *Step two.* Using the data from step one, determine the ratio of the individual hospital's total nursing or allied health payments, to its total inpatient days. Multiply this ratio by the hospital's total Medicare + Choice inpatient days.

(3) *Step three.* CMS will determine, using the best available data, for all eligible hospitals the total of all—

(i) Nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year;

(ii) Inpatient days from those same cost reporting periods; and

(iii) Medicare + Choice inpatient days for those same cost reporting periods.

(4) *Step four.* Using the data from step three, CMS will determine the ratio of the total of all nursing and allied health education program payments made to all hospitals for all cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year, to the total of all inpatient days from those same cost reporting periods. CMS will multiply this ratio by the total of all Medicare + Choice inpatient days for those same cost reporting periods.

(5) *Step 5.* Calculate the ratio of the product determined in step two to the product determined in step four.

(6) *Step 6.* Multiply the ratio calculated in step five by the amount determined in accordance with paragraph (f) of this section for the current calendar year. The resulting product is each respective hospital's additional payment amount.

(f) *Calculation of the payment ''pool.''* (1) Subject to paragraph (f)(3) of this section, each calendar year, CMS will calculate a Medicare + Choice nursing and allied health payment ''pool'' according to the following steps:

(i) Determine the ratio of projected total Medicare + Choice direct GME payments made in accordance with the provisions of § 413.76(c) across all hospitals in the current calendar year to projected total direct GME payments made across all hospitals in the current calendar year.

(ii) Multiply the ratio calculated in paragraph (f)(1)(i) of this section by projected total Medicare nursing and allied health education reasonable cost payments made to all hospitals in the current calendar year.

(2) The resulting product of the steps under paragraphs (f)(1)(i) and (f)(1)(ii) of this section is the Medicare + Choice nursing and allied health payment ''pool'' for the current calendar year.

(3) The payment pool may not exceed $60 million in any calendar year.

[65 FR 47051, Aug. 1, 2000, as amended at 66 FR 32195, June 13, 2001; 69 FR 49265, Aug. 11, 2004; 70 FR 47489, Aug. 12, 2005]

§ 413.88 Incentive payments under plans for voluntary reduction in number of medical residents.

(a) *Statutory basis.* This section implements section 1886(h)(6) of the Act, which establishes a program under which incentive payments may be made to qualifying entities that develop and implement approved plans to voluntarily reduce the number of residents in medical residency training.

(b) *Qualifying entity defined.* ''Qualifying entity'' means:

(1) An individual hospital that is operating one or more approved medical residency training programs as defined in § 413.75(b) of this chapter; or

(2) Two or more hospitals that are operating approved medical residency training programs as defined in § 413.75(b) of this chapter and that submit a residency reduction application as a single entity.

(c) *Conditions for payments.* (1) A qualifying entity must submit an application for a voluntary residency reduction plan that meets the requirements and conditions of this section in

order to receive incentive payments for reducing the number of residents in its medical residency training programs.

(2) The incentive payments will be determined as specified under paragraph (g) of this section.

(d) *Requirements for voluntary plans.* In order for a qualifying entity to receive incentive payments under a voluntary residency reduction plan, the qualifying entity must submit an application that contains the following information, documents, and agreements—

(1) A description of the operation of a plan for reducing the full-time equivalent (FTE) residents in its approved medical residency training programs, consistent with the percentage reduction requirements specified in paragraphs (g)(2) and (g)(3) of this section;

(2) An election of the period of residency training years during which the reductions will occur. The reductions must be fully implemented by not later than the fifth residency training year in which the plan is effective;

(3) FTE counts for the base number of residents, as defined in paragraph (g)(1) of this section, with a breakdown of the number of primary care residents compared to the total number of residents; and the direct and indirect FTE counts of the entity on June 30, 1997. For joint applicants, these counts must be provided individually and collectively;

(4) Data on the annual and cumulative targets for reducing the number of FTE residents and the ratios of the number of primary care residents to the total number of residents for the base year and for each year in the 5-year reduction period. For joint applicants, these data must be provided individually and collectively;

(5) An agreement to not reduce the proportion of its primary care residents to its total number of residents below the proportion that exists in the base year, as specified in paragraph (g)(1) of this section;

(6) An agreement to comply with data submission requirements deemed necessary by CMS to make annual incentive payments during the 5-year residency reduction plan, and to fully cooperate with additional audit and monitoring activities deemed necessary by CMS;

(7) For a qualifying entity that is a member of an affiliated group as defined in § 413.75(b), a statement that all members of the group agree to an aggregate FTE cap that reflects—

(i) The reduction in the qualifying entity's FTE count as specified in the plan during each year of the plan; and

(ii) The 1996 FTE count of the other hospital(s) in the affiliated group.

(8) A statement indicating voluntary participation in the plan under the terms of this section, signed by each hospital that is part of the applying entity.

(e) *Deadline for applications.* A qualifying entity must submit an application that meets the requirements of paragraph (d) of this section at least one day prior to the first day of the period to which the plan would be effective but no later than November 1, 1999. The application must be submitted to the contractor, with a copy to CMS.

(f) *Effective dates of plans.* Residency reduction plans that are submitted to the contractor on or after September 17, 1999 but on or before November 1, 1999, may be effective for portions of cost reporting periods beginning no earlier than the day after the date of the application.

(g) *Residency reduction requirements*—(1) *Base number of residents defined.* (i) ''Base number of residents'' means the lesser of—

(A) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for the most recent residency training year ending June 30, 1996; or

(B) The number of FTE residents in all approved medical residency training programs of the qualifying entity (before application of weighting factors under § 413.79) for any subsequent residency training year that ends before the date the entity submits its plan to the contractor and CMS.

(ii) The residency training year used to determine the base number of residents is the ''base year'' for determining reduction requirements.

(iii) The qualifying entity's base number of residents may not be adjusted to reflect adjustments that may otherwise be made to the entity's FTE caps for new medical residency training programs.

(2) *Qualifying entity consisting of individual hospital.* The base number of FTE residents in all the approved medical residency training programs operated by or through a qualifying entity consisting of an individual hospital must be reduced as follows:

(i) If the base number of residents exceeds 750, residents, by at least 20 percent of the base number.

(ii) If the base number of residents exceeds 600 but is less than or equal to 750 residents—

(A) By 150 residents; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number by at least 20 percent.

(iii) If the base number of residents is 600 or less residents—

(A) By 25 percent; or

(B) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(3) *Qualifying entity consisting of two or more hospitals.* The base number of FTE residents in the aggregate for all the approved medical residency training programs operated by or through a qualifying entity consisting of two or more hospitals must be reduced—

(i) By 25 percent; or

(ii) By 20 percent, if the qualifying entity increases the number of primary care residents included in the base number of residents by at least 20 percent.

(4) *Treatment of rotating residents.* A qualifying entity will not be eligible for incentive payments for a reduction in the base number of residents if the reduction is a result of the entity rotating residents to another hospital that is not a part of its voluntary residency reduction plan.

(5) *Updates to annual and cumulative targets* (i) Except as provided in paragraph (g)(5)(ii) of this section an entity with an approved voluntary residency reduction plan may not change the annual and cumulative reduction targets that are specified in its plan in accordance with paragraphs (g)(2) and (g)(3) of this section.

(ii) An entity may update annual reduction targets specified in its plan only if—

(A) It has failed to meet a specified annual target for a plan year in the 5-year period; and

(B) It wishes to adjust future annual targets for the remaining years of the plan in order to comply with its cumulative target.

(iii) An updated plan allowed under paragraph (g)(5)(ii) of this section must be submitted prior to the beginning of each July 1 medical residency training year during the plan years.

(h) *Computation of incentive payment amount.* (1) Incentive payments to qualifying entities that meets the requirements and conditions of paragraphs (d) and (g) of this section will be computed as follows:

(i) *Step 1.* Determine the amount (if any) by which the payment amount that would have been made under § 413.76 if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the amount of payment that would have been made under § 413.76 in each year under the voluntary residency reduction plan, taking into account the reduction in the number of FTE residents under the plan.

(ii) *Step 2.* Determine the amount (if any) by which the payment amount that would have been made under § 412.105 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.105 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iii) *Step 3.* Determine the amount (if any) by which the payment amount that would have been made under § 412.322 of this chapter if there had been a 5-percent reduction in the number of FTE residents in the approved medical education training programs

of the hospital as of June 30, 1997, exceeds the payment amount made under § 412.322 of this chapter in each year under the voluntary residency reduction plan, taking into account the actual reduction in the number of FTE residents.

(iv) *Step 4.* Multiply the sum of the amounts determined under paragraph (h)(i), (ii), and (iii) of this section by the applicable hold harmless percentages specified in paragraph (i) of this section.

(2) The determination of the amounts under paragraph (h)(1) of this section for any year is based on the applicable Medicare statutory provisions in effect on the application deadline date for the voluntary reduction plan specified under paragraph (e) of this section.

(i) *Applicable hold-harmless percentage.* The applicable hold-harmless percentages for each year in which the residency reduction plan is in effect are as follows:

(1) 100 percent for the first and second residency training years;

(2) 75 percent for the third year;

(3) 50 percent for the fourth year; and

(4) 25 percent for the fifth year.

(j) *Payments to qualifying entities.* Annual incentive payments through cost reports will be made to each hospital that is or is part of a qualifying entity over the 5-year reduction period if the qualifying entity meets the annual and cumulative reduction targets specified in its voluntary reduction plan.

(k) *Penalty for noncompliance*—(1) *Nonpayment.* No incentive payment may be made to a qualifying entity for a residency training year if the qualifying entity has failed to reduce the number of FTE residents according to its voluntary residency reduction plan.

(2) *Repayment of incentive amounts.* The qualifying entity is liable for repayment of the total amount of incentive payments it has received if the qualifying entity—

(i) Fails to reduce the base number of residents by the percentages specified in paragraphs (g)(2) and (g)(3) of this section by the end of the fifth residency training year; or

(ii) Increases the number of FTE residents above the number of residents permitted under the voluntary residency reduction plan as of the completion date of the plan.

(l) *Postplan determination of FTE caps for qualifying entities*—(1) *No penalty imposed.* Upon completion of a voluntary residency reduction plan, if no penalty is imposed, the qualifying entity's 1996 FTE count is permanently adjusted to equal the unweighted FTE count used for direct GME payments for the last residency training year in which a qualifying entity participates.

(2) *Penalty imposed.* Upon completion of the voluntary residency reduction plan—

(i) *During repayment period.* If a penalty is imposed under paragraph (k)(2) of this section, during the period of repayment, the qualifying entity's FTE count is as specified in paragraph (l)(1) of this section.

(ii) *After repayment period.* Once the penalty repayment is completed, the qualifying entity's FTE reverts back to its original 1996 FTE cap.

[64 FR 44855, Aug. 18, 1999, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.89 Bad debts, charity, and courtesy allowances.

(a) *Principle.* Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost. However, subject to the limitations described under paragraph (h) of this section and the exception for services described under paragraph (i) of this section, bad debts attributable to the deductibles and coinsurance amounts are reimbursable under the program.

(b) *Definitions*—(1) *Bad debts.* (i) For cost reporting periods beginning before October 1, 2020:

(A) ''Bad debts'' are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.

(B) ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(ii) For cost reporting periods beginning on or after October 1, 2020, ''bad debts'' are amounts considered to be uncollectible from patient accounts that were created or acquired in providing services and are categorized as

implicit price concessions for cost reporting purposes and are recorded in the provider's accounting records as a component of net patient revenue.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill-Burton obligation are considered as charity allowances.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

(c) *Normal accounting treatment: Reduction in revenue.* (1) For cost reporting periods beginning before October 1, 2020:

(i) Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts.

(2) For cost reporting periods beginning on or after October 1, 2020:

(i) Bad debts, also known as ''implicit price concessions,'' charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services as these costs have already been incurred in the production of the services.

(ii) Medicare bad debts must not be written off to a contractual allowance account but must be recorded as an implicit price concession that results in a reduction in revenue.

(d) *Requirements for Medicare.* Under Medicare, costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the Medicare program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the Medicare program. Uncollected revenue related to services furnished to beneficiaries of the program generally means the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts could result in the related costs of covered services being borne by other than Medicare beneficiaries. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts that remain unpaid are added to the Medicare share of allowable costs. Bad debts arising from other sources are not allowable costs.

(e) *Criteria for allowable bad debt.* A bad debt must meet the following criteria to be allowable:

(1) The debt must be related to covered services and derived from deductible and coinsurance amounts.

(2) The provider must be able to establish that reasonable collection efforts were made.

(i) *Non-indigent beneficiary.* A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes. To be considered a reasonable collection effort for non-indigent beneficiaries, all of the following are applicable:

(A) A provider's collection effort or the effort of a collection agency acting on the provider's behalf, or both, to collect Medicare deductible or coinsurance amounts must consist of all of the following:

(*1*) Be similar to the collection effort put forth to collect comparable amounts from non-Medicare patients.

(*2*) For cost reporting periods beginning before October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.

(*3*) For cost reporting periods beginning on or after October 1, 2020, involve the issuance of a bill to the beneficiary

or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:

(*i*) The date of the Medicare remittance advice that results from processing the claim for services furnished to the beneficiary and generates the beneficiary's cost sharing amounts.

(*ii*) The date of the remittance advice from the beneficiary's secondary payer, if any.

(*iii*) The date of the notification that the beneficiary's secondary payer does not cover the service furnished to the beneficiary.

(*4*) Include other actions such as subsequent billings, collection letters, and telephone calls, emails, text messages, or personal contacts with this party.

(*5*)(*i*) Last at least 120 days after paragraph (e)(2)(i)(A)(*2*) or (*3*) of this section is met before being written off as uncollectible under paragraph (e)(3) of this section.

(*ii*) Start a new 120-day collection period each time a payment is received within a 120-day collection period.

(*6*) Maintaining and, upon request, furnishing verifiable documentation to its contractor that includes all of the following:

(*i*) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients.

(*ii*) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.

(*iii*) The beneficiary's file with copies of the bill(s) and follow-up notices.

(B) A provider that uses a collection agency to perform its collection effort must do all of the following:

(*1*) Reduce the beneficiary's account receivable by the gross amount collected.

(*2*) Include any fee charged by the collection agency as an administrative cost.

(*3*) Before claiming the unpaid amounts as a Medicare bad debt, cease all collection efforts, including the collection agency efforts, and ensure that the collection accounts have been returned to the provider from the agency.

(ii) *Indigent non-dual eligible beneficiary*. An indigent non-dual eligible beneficiary is a beneficiary who is determined to be indigent or medically indigent by the provider and is not eligible for Medicaid as categorically or medically needy.

(A) To determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider—

(*1*) Must not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence;

(*2*) Must take into account the analysis of both the beneficiary's assets (only those convertible to cash and unnecessary for the beneficiary's daily living) and income;

(*3*) May consider extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence which may include an analysis of both the beneficiary's liabilities and expenses, if indigence is unable to be determined under paragraph (e)(ii)(A)(*2*) of this section;

(*4*) Must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program; and

(*5*) Must maintain and, upon request, furnish its contractor its indigence policy describing the method by which indigence or medical indigence is determined and all the verifiable beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence.

(B) Once indigence is determined the bad debt may be deemed uncollectible without applying a collection effort under paragraph (e)(2)(i)(A) or (B) of this section.

(iii) *Indigent dual-eligible beneficiaries (including qualified Medicare beneficiaries)*. Providers may deem Medicare beneficiaries indigent or medically indigent when such individuals have also been determined eligible for Medicaid

under a State's Title XIX Medicaid program as either categorically needy individuals or medically needy individuals. To be considered a reasonable collection effort for dual-eligible beneficiaries:

(A) When a State permits a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, to determine the State's liability for the beneficiary's Medicare cost sharing, the provider—

(*1*) Must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible or coinsurance amounts;

(*2*) Must submit a bill to its Medicaid/Title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance;

(*3*) Must submit the Medicaid remittance advice received from the State to its Medicare contractor;

(*4*) Must reduce allowable Medicare bad debt by any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, regardless of whether the State actually pays its obligated amount to the provider; and

(*5*) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(B) When, through no fault of the provider, a provider does not receive a Medicaid remittance advice because the State does not permit a Medicare provider's Medicaid enrollment for the purposes of processing a beneficiary's claim, or because the State does not generate a Medicaid remittance advice, the provider—

(*1*) Must submit to its contractor, all of the following auditable and verifiable documentation:

(*i*) The State's Medicaid notification stating that the State has no legal obligation to pay the provider for the beneficiary's Medicare cost sharing.

(*ii*) A calculation of the amount the State owes the provider for Medicare cost sharing.

(*iii*) Verification of the beneficiary's eligibility for Medicaid for the date of service;

(*2*) Must reduce allowable Medicare bad debt by any amount the State is obligated to pay, regardless of whether the State actually pays its obligated amount to the provider; and

(*3*) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(3) The debt was actually uncollectible when claimed as worthless.

(4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

(f) *Reporting period for writing off bad debts and reporting of recoveries of bad debts reimbursed in prior periods.* For cost reporting periods beginning before, on, or after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless.

(1) Any payment on the account made by the beneficiary or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

(2) In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent period.

(i) In situations described in this paragraph (f)(2), the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered.

(ii) The amount of reduction in the period of recovery (as specified in paragraph (f)(2)(i) of this section) must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period.

(g) *Charity allowances.* Charity allowances have no relationship to beneficiaries of the Medicare program and are not allowable costs. These charity

allowances include the costs of uncompensated services furnished under a Hill-Burton obligation. (Note: In accordance with section 106(b) of Pub. L. 97–248 (enacted September 3, 1982), this sentence is effective with respect to any costs incurred under Medicare except that it does not apply to costs which have been allowed prior to September 3, 1982, pursuant to a final court order affirmed by a United States Court of Appeals.) The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

(h) *Limitations on bad debts*—(1) *Hospitals.* In determining reasonable costs for hospitals, the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

(i) For cost reporting periods beginning during fiscal year 1998, by 25 percent;

(ii) For cost reporting periods beginning during fiscal year 1999, by 40 percent;

(iii) For cost reporting periods beginning during fiscal year 2000, by 45 percent; and

(iv) For cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(2) *Skilled nursing facilities and swing bed hospitals.* For the purposes of this paragraph (h)(2), a dual eligible individual is defined as an individual that is entitled to benefits under Part A of Medicare and is determined eligible by the State for medical assistance under Title XIX of the Act as described under paragraph (2) of the definition of a ''full-benefit dual eligible individual'' at §423.772 of this chapter. In determining reasonable costs for a skilled nursing facility and for post-hospital SNF care furnished in a swing bed hospital, as defined in §413.114(b), the amount of allowable bad debt (as defined in paragraph (e) of this section) is reduced:

(i) *For non-dual eligible individuals*—(A) For cost reporting periods beginning during fiscal years 2006 through 2012, by 30 percent, for a patient in a skilled nursing facility.

(B) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or receiving post-hospital SNF care in a swing bed hospital.

(ii) *For dual eligible individuals*—(A) For cost reporting periods beginning during fiscal year 2013, by 12 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(B) For cost reporting periods beginning during fiscal year 2014, by 24 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(C) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent, for a patient in a skilled nursing facility or a patient receiving post-hospital SNF care in a swing bed hospital.

(3) *End-stage renal dialysis facilities.* In determining reasonable costs for an end-stage renal dialysis facility, the amount of allowable bad debt (as defined in paragraph (e) of this section) is:

(i) For cost reporting periods beginning before October 1, 2012, reimbursed up to the facility's costs.

(ii) For cost reporting periods beginning on or after October 1, 2012 and before January 1, 2013, reduced by 12 percent with the resulting amount reimbursed up to the facility's costs.

(iii) For cost reporting periods beginning on or after January 1, 2013 and before October 1, 2013, reduced by 12 percent.

(iv) For cost reporting periods beginning during fiscal year 2014, reduced by 24 percent.

(v) For cost reporting periods beginning during a subsequent fiscal year, reduced by 35 percent.

(4) *All other providers.* In determining reasonable costs for all other providers, suppliers and other entities not described elsewhere in paragraph (h) of this section that are eligible to receive reimbursement for bad debts under this section, the amount of allowable bad debts (as defined in paragraph (e) of this section) is reduced:

(i) For cost reporting periods beginning during fiscal year 2013, by 12 percent.

(ii) For cost reporting periods beginning during fiscal year 2014, by 24 percent.

(iii) For cost reporting periods beginning during a subsequent fiscal year, by 35 percent.

(i) *Exceptions applicable to bad debt reimbursement.* (1) Bad debts arising from covered services paid under a reasonable charge-based methodology or a fee schedule are not reimbursable under the program.

(2) For end-stage renal dialysis services furnished on or after January 1, 2011 and paid for under the end-stage renal dialysis prospective payment system described in §413.215, bad debts arising from covered items or services that, prior to January 1, 2011 were paid under a reasonable charge-based methodology or a fee schedule, including but not limited to drugs, laboratory tests, and supplies are not reimbursable under the program.

[51 FR 34793, Sept. 30, 1986, as amended at 57 FR 33898, July 31, 1992; 60 FR 63189, Dec. 8, 1995; 63 FR 41005, July 31, 1998; 66 FR 32195, June 13, 2001. Redesignated at 69 FR 49254, Aug. 11, 2004, and amended at 71 FR 48142, Aug. 18, 2006; 71 FR 69785, Dec. 1, 2006; 75 FR 49198, Aug. 12, 2010; 77 FR 67350, Nov. 9, 2012; 85 FR 59023, Sept. 18, 2020]

§ 413.90 Research costs.

(a) *Principle.* Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

(b) *Application.* (1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the Medicare programs.

(2) If research is conducted in conjunction with, and as a part of, the care of patients, the costs of usual patient care and studies, analyses, surveys, and related activities to serve the provider's administrative and program needs are allowable costs in the determination of payment under Medicare.

[51 FR 34793, Sept. 30, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

§ 413.92 Costs of surety bonds.

Costs incurred by a provider to obtain a surety bond required by part 489, subpart F of this chapter are not included as allowable costs.

[63 FR 310, Jan. 5, 1998]

§ 413.94 Value of services of nonpaid workers.

(a) *Principle.* The value of services in positions customarily held by full-time employees performed on a regular, scheduled basis by individuals as nonpaid members of organizations under arrangements between such organizations and a provider for the performance of such services without direct remuneration from the provider to such individuals is allowable as an operating expense for the determination of allowable cost subject to the limitation contained in paragraph (b) of this section. The amounts allowed are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institutions as a legal obligation for operating expenses.

(b) *Limitations: Services of nonpaid workers.* The services must be performed on a regular, scheduled basis in positions customarily held by full-time employees and necessary to enable the provider to carry out the functions of normal patient care and operation of the institution. The value of services of a type for which providers generally do not remunerate individuals performing such services is not allowable as a reimbursable cost under the Medicare program. For example, donated services of individuals in distributing books and magazines to patients, or in serving in a provider canteen or cafeteria or in a provider gift shop, would not be reimbursable.

(c) *Application.* The following illustrates how a provider would determine an amount to be allowed under this

principle: The prevailing salary for a lay nurse working in Hospital A is $5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital $2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional $3,000 to bring the value of the services rendered to $5,000. The amount of $3,000 would be allowable if the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

§ 413.98 Purchase discounts and allowances, and refunds of expenses.

(a) *Principle.* Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

(b) *Definitions*—(1) *Discounts.* Discounts, in general, are reductions granted for the settlement of debts.

(2) *Allowances.* Allowances are deductions granted for damage, delay, shortage, imperfection, or other causes, excluding discounts and returns.

(3) *Refunds.* Refunds are amounts paid back or a credit allowed on account of an overcollection.

(c) *Normal accounting treatment—Reduction of costs.* All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. If they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, if they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

(d) *Application.* (1) Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required. In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

(2) As with discounts, allowances, and rebates received from purchases of goods or services, refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

§ 413.99 Qualified and Non-Qualified Deferred Compensation Plans.

(a) *Statutory basis, scope, and definitions*—(1) *Basis.* All payments to providers of services must be based on the reasonable cost of services covered under Title XVIII in accordance with section 1861(v) of the Act and the regulations in this part.

(2) *Scope.* This section and § 413.100(c)(2)(vii) apply to Medicare's treatment of the costs incurred for Qualified and Non-Qualified Deferred Compensation Plans.

(3) *Definitions.* As used in this section the following definitions apply:

Deferred Compensation means remuneration currently earned by an employee that is not received until a subsequent period, usually after retirement.

Employee Retirement Income Security Act of 1974 (ERISA) is a Federal law that sets standards of protection for individuals in most voluntarily established, private-sector retirement plans.

The law is set forth in Title 29, Chapter 18 of the U.S. Code.

Funded Plan means a plan in which assets have been irrevocably and unconditionally set aside with a third party for the payment of plan benefits (for example, in a trust or escrow account), and those assets are beyond the reach of the employer or its general creditors.

Non-Qualified Deferred Compensation Plan (NQDC) means an elective or nonelective plan, agreement, method, or arrangement between an employer and an employee to pay the employee compensation in the future. In comparison with qualified plans, nonqualified plans do not provide employers and employees with the tax benefits associated with qualified plans because NQDC plans do not satisfy all the requirements of 26 U.S.C. 401(a).

Non-Qualified Defined Benefit Plan (NQDB) means a type of NQDC that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees.

Pension Benefit Guaranty Corporation (PBGC) is a Federal agency created by ERISA to protect benefits in private-sector QDBP plans described in section 3(35) of ERISA.

Qualified Defined Benefit Plan (QDBP) means a type of Qualified Deferred Compensation Plan that is established and maintained by the employer primarily to provide definitely determinable benefits to its employees usually over a period of years, or for life, after retirement. Such benefits are generally measured by, and based on, such factors as age of employees, years of service, and compensation received by the employees. A QDBP meets the applicable requirements of ERISA, as amended, and the requirements for a QDBP under 26 U.S.C. 401(a). Under a qualified plan, employers are entitled to deduct expenses in the year the employer makes contributions even though employees will not recognize income until the receipt of distributions.

Qualified Defined Contribution or Individual Account Plan (QDCP) means a type of Deferred Compensation Plan in which the employee, the employer, or both, contribute to an employee's individual account under the plan. The amount in the account at distribution includes the contributions and investment gains or losses, minus any investment and administrative fees. The value of the account changes based on contributions and the value and performance of the investments. A QDCP meets the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and, if applicable 26 U.S.C. 401(k).

Unfunded Plan means a plan in which benefits are supported by assets that have not been set aside (that is, a ''pay as you go'' plan), or by assets that have been set aside, but remain subject to the claims of the employer's general creditors.

(b) *Principle requirements*—(1) *General.* Deferred Compensation contributions or payments must be made by a provider of services, or an employee of the provider of services, to a Qualified or Non-Qualified Deferred Compensation Plan, established and maintained by the provider of services to provide retirement income to employees or to result in the deferral of income by employees for periods extending to the termination of covered employment or beyond. Contributions or payments made by a provider of services for the benefit of its employees to a Qualified or Non-Qualified Deferred Compensation Plan are allowable, when, and to the extent that, such costs are actually incurred by the provider of services and found to be reasonable and necessary under the principles of reasonable cost.

(2) *Deferred Compensation for provider-based physicians services in a hospital or SNF.* Costs incurred by a hospital or SNF to fund a Qualified or Non-Qualified Deferred Compensation Plan for a provider-based physician must meet the following requirements to be allowable under the program:

(i) The allocation of physician compensation costs required under § 415.60 of this chapter does not attribute the provider-based physician's Deferred Compensation entirely to one category

of service and his current compensation to another.

(ii) Contributions or payments toward the Qualified or Non-Qualified Deferred Compensation Plan do not include any cost excluded from the definition of physician compensation at §415.60(a) of this chapter.

(iii) The amount of Deferred Compensation does not exceed the amount specified in the agreement required by §415.60(g) of this chapter.

(iv) An arrangement between a physician and a provider of services under which the physician is reimbursed for patient charges, but the provider of services does the billing as a Deferred Compensation agreement, is not allowed.

(v) The costs incurred for physician guaranteed arrangements for hospital emergency room availability services, must meet the following additional requirements:

(A) The terms of both the guarantee arrangements and the Deferred Compensation Plan establish the amounts to be included at the beginning of the hospital's cost reporting period.

(B) The amount of Deferred Compensation is included in the guaranteed amount.

(C) The hospital contributes to the Deferred Compensation Plan from its own funds.

(D) The amount of Deferred Compensation that is allowable is limited to the amount by which the guarantee, including Deferred Compensation, exceeds the total billed by the hospital to all patients for the physician's patient care services.

(E) When the physician's charges to all patients equal or exceed the amount guaranteed by the hospital, the program does not recognize a Deferred Compensation contribution/payment.

(c) *Requirements for Non-Qualified and Qualified Deferred Compensation Plans*—(1) *NQDC requirements.* In order for contributions or payments by a provider of services to an NQDC as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDC must meet the general requirements at paragraph (c)(1)(i) of this section, and it must either meet the requirements for a funded NQDC at paragraph (c)(1)(ii) of this section or the requirements for an unfunded NQDC at paragraph (c)(1)(iii) of this section, as applicable.

(i) *General requirements.* An NQDC must satisfy the requirements for document compliance and operational compliance set forth in 26 U.S.C. 409A.

(ii) *Funded NQDCs.* A funded NQDC must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDCs.* An NQDC that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDC as a result of contributions made by a provider of services.

(2) *QDCP requirements.* A QDCP must meet the applicable requirements of ERISA, as amended, and the requirements set forth in 26 U.S.C. 401(a), and if applicable 26 U.S.C. 401(k). A QDCP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(3) *QDBP requirements.* A QDBP must meet the applicable requirements of ERISA, as amended, and the requirements for a defined benefit plan under 26 U.S.C. 401(a). A QDBP must meet the definition of a Funded Plan in paragraph (a)(3) of this section and comply with the requirements in paragraph (c)(5) of this section.

(4) *NQDB requirements.* In order for contributions or payments by a provider of services to an NQDB as defined at paragraph (a)(3) of this section to be allowable under the program, the NQDB must meet the general requirements at paragraph (c)(4)(i) of this section, and it must either meet the requirements for a funded NQDB at paragraph (c)(4)(ii) of this section or the requirements for an unfunded NQDB at paragraph (c)(4)(iii) of this section, as applicable.

(i) *General requirements.* An NQDB must satisfy the requirements for document compliance set forth in 26 U.S.C. 409A and operational compliance set forth in 26 U.S.C. 409A(a).

(ii) *Funded NQDBs.* An NQDB that is funded must meet the definition of a Funded Plan in paragraph (a)(3) of this

section and comply with the requirements in paragraph (c)(5) of this section.

(iii) *Unfunded NQDBs.* An NQDB that is unfunded must meet the definition of an Unfunded Plan in paragraph (a)(3) of this section, and there must be no constructive receipt of income for employees from a NQDB as a result of contributions made by a provider of services.

(5) *Funded Plan requirements*—(i) *Acceptable funding mechanism.* Both provider of services contributions and employee contributions must be used either to purchase an insured plan with a commercial insurance company, to establish a custodial bank account, or to establish a trust fund administered by a trustee.

(ii) *Life insurance contracts.* The purchase of an ordinary life insurance contract (for example, whole life, straight life, or other) is not a deferral of compensation and is not recognized as a funding mechanism, even where it is convertible at the normal retirement date specified in the policy to an annuity payable over the remaining life of the employee.

(iii) *Sole benefit of participating employees.* Regardless of the funding mechanism utilized, all provider of services and employee contributions to the fund established under the Deferred Compensation Plan and income therefrom must be used for the sole benefit of the participating employees.

(d) *Recognition of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plans*—(1) *General rule.* Except as provided for in paragraph (c)(1)(iii) of this section with respect to QDBPs and funded NQDBs, contributions to Qualified Deferred Compensation Plans or payments to plan participants from Non-Qualified Deferred Compensation Plans are recognized as allowable costs in accordance with paragraph (c)(1)(i) of this section (in the case of Unfunded Plans) and paragraph (c)(1)(ii) of this section (in the case of Funded Plans).

(i) *Unfunded Plans.* Contributions or payments made to an unfunded Deferred Compensation Plans (including unfunded NQDBs) by a provider of services on behalf of its employees are included in allowable costs only during the cost reporting period in which an actual payment is made to the participating employees (or their beneficiaries) and only to the extent considered reasonable, in accordance with § 413.100(c)(2)(vii)(A).

(ii) *Funded Plans.* Reasonable provider of services payments made under funded Deferred Compensation Plans (specifically, funded Defined Contribution Plans, but excluding QDBPs and funded NQDBs) are included in allowable costs in accordance with § 413.100(c)(2)(vii)(B).

(iii) *Exception for QDBPs and funded NQDBs.* (A) QDBP and NQDB contributions are found to have been incurred only if paid directly to participants or beneficiaries under the terms of the plan or to the QDBP or NQDB.

(B) Payments to a QDBP or funded NQDB for a cost reporting period must be measured on a cash basis. A contribution or payment is deemed to occur on the date it is credited to the fund established for the QDBP or funded NQDB, or for provider of services payments made directly to a plan participant or beneficiary, on the date the provider of services account is debited.

(C) Payments or contributions made to fully fund a terminating QDBP or funded NQDB are to be included as funding on the date they are paid. Excess assets withdrawn from a QDBP or funded NQDB are to be treated as negative contributions on the date that they are withdrawn.

(D) QDBP and funded NQDB annual allowable costs are computed as follows:

(*1*) QDBP and funded NQDB costs and limits are computed in accordance with § 413.100(c)(2)(vii)(D).

(*2*) For purposes of determining the QDBP or funded NQDB cost limit under § 413.100(c)(2)(vii)(D)(*2*), provider of services contribution payments for each applicable cost reporting period must be determined on a cash basis without regard to any limit determined for the period during which the contributions were made, and excluding any contributions deposited in a prior period and treated as carry forward contributions.

(*3*) The averaging period used to determine the QDBP or funded NQDB cost limit must be determined without

regard to a provider of services period of participation in the Medicare program. Periods that are not Medicare cost reporting periods (for example, periods prior to the hospital's participation in the Medicare program) must be defined as consecutive 12-month periods ending immediately prior to the provider of services initial Medicare cost reporting period.

(*4*) The averaging period used to determine the QDBP or funded NQDB cost limit must exclude all periods ending prior to the initial effective date of the plan (or a predecessor plan in the case of a merger).

(*5*) In general, the current period defined benefit cost and limit is computed and applied separately for each QDBP or funded NQDB offered by a provider of services. In the case of a plan merger, the contributions or payments made by a provider of services to a predecessor QDBP or funded NQDB and reflected in the assets subsequently transferred to a successor plan are treated as contribution payments made to the successor plan.

(2) [Reserved]

(e) *Documentation requirements.* Documentation must be maintained by the provider of services in accordance with § 413.20 to substantiate the allowability of contributions or payments to Qualified and Non-Qualified Deferred Compensation Plan(s) that it has included in its cost reports.

(1) *Required documentation.* The provider of services must maintain and make available, upon request by the contractor or CMS, certain specified documentation, to substantiate the allowability of the contributions or payments to its Qualified or Non-Qualified Deferred Compensation Plan(s), or both:

(i) Documentation that demonstrates that the provider of services is in compliance with 26 U.S.C. 409A and 409A(a), and, if applicable, 26 U.S.C. 457.

(ii) Ledger accounts/account statements for each plan participant noting current year deferrals, distributions and loans, including any deferral election forms completed by employees, any change requests, and the approval of such requests.

(iii) Documentation that demonstrates the amount(s) and date(s) of actual contributions or payments made to the Qualified or Non-Qualified Deferred Compensation Plan during the current cost reporting period.

(iv) Schedule SB of Form 5500 (triagency form (Department of Labor (DOL), Internal Revenue Service (IRS), and PBGC) that plans file with the DOL's ''EFAST'' electronic filing system) for a QDBP for the current cost reporting period, or any applicable prior periods.

(v) In the case of a system-wide (multiple employer) plan, the home office shall identify the contributions attributed to each participating provider of services. If the costs included in the cost report for a period differ from the contributions made during the reporting period (that is, as a result of carry forward contributions), the provider of services must also have data available to track and reconcile the difference.

(2) *Additional documentation.* The following additional documentation must be made available, upon request by the contractor or CMS, to substantiate the allowability of the payments/contributions by a provider of services to a Qualified or Non-Qualified Deferred Compensation Plan:

(i) The plan document, the trust document and all amendments related to the current cost reporting period.

(ii) If applicable, any Form 5330, Return of Excise Taxes Related to Employee Benefit Plans, for the cost reporting period.

(iii)(A) Supporting documents for all plan assets and liabilities, such as broker's statements, bank statements, insurance contracts, loan documents, deeds, etc.

(B) Verification of how assets are valued.

(iv)(A) Trustee or administrator reports.

(B) Ledgers.

(C) Journals.

(D) Trustee, administrator, and investment committee minutes.

(E) Certified audit report and other financial reports for the trust.

(F) Any other financial reports, including receipt and disbursement statements, a detailed income statement, and a detailed balance sheet.

(v) For each covered QDBP, documentation of the certified premium information and payments to the PBGC.

(f) *Administrative and other costs associated with Deferred Compensation Plans.* The provider of services shall file a cost report required under §§ 413.20 and 413.24(f) that is consistent with the policies set forth in this section.

(1) *Trustee and custodial fees.* Reasonable trustee or custodial fees, including PBGC premiums, paid by the provider of services are allowed as an administrative cost except where the plan provides that such fees are paid out of the corpus or earnings of the fund.

(2) *Vested benefits.* The forfeiture of an employee's benefits for cause (as defined in the plan) is recognized as an allowable cost provided that such forfeited amounts are used to reduce the provider of services contributions or payments to the plan during the cost reporting period in which the forfeiture occurs.

(3) *Benefits to be paid.* If an employee terminates participation in the Deferred Compensation Plan before their rights are vested, the applicable nonvested contributions/payments cannot be applied to increase the benefits of the surviving participants. Instead the non-vested contributions or payments should be used to reduce the provider of services contributions or payments to the Deferred Compensation Plan, in the cost reporting period in which the employee terminated participation in the Deferred Compensation Plan. Otherwise, the contributions/payments made by the provider of services must be applied to reduce the subsequent contributions or payments to the Deferred Compensation Plan in the next cost reporting period. If subsequent provider of services contributions/payments to the Deferred Compensation Plan are not made, then the provider of services costs are reduced by the contractor to the extent of such non-vested funds.

(4) *DOL, IRS, or PBGC penalties.* If the provider of services is assessed an excise tax or other remedy by the DOL, IRS, or PBGC for failure to follow DOL, IRS, or PBGC requirements under ERISA or any other penalty fee or penalty interest applicable to its Deferred Compensation Plan, the cost is unallowable in accordance with section 1861(v)(8) of the Act.

(5) *Loans made from a Deferred Compensation Plan.* A provider of services cannot make a loan to itself from a Deferred Compensation Plan where ERISA or IRS rules prohibit such a transaction, except where specifically excepted.

(6) *Termination/discontinuation of a Deferred Compensation Plan.* If the provider of services declines to vest its outstanding required contributions or payments (that is, matching or nonelective) to a Deferred Compensation Plan as a result of a termination in full or in part or a discontinuation of contributions or payments to a Deferred Compensation Plan, then the provider of services total outstanding required contributions or payments to the Deferred Compensation Plan during the cost reporting period wherein such termination is initiated cannot be included in the provider of services allowable cost for the cost reporting period in which the termination is initiated, nor any future period.

(7) *Required offset against interest expense.* Investment income earned on a Deferred Compensation Plan after its termination but prior to liquidation of the plan's assets and distribution to the provider of services must be offset against the provider of services allowable interest expense under § 413.153.

(8) *Treatment of residual assets following termination of a Funded Plan.* (i) Residual assets arising from the termination of a funded Deferred Compensation Plan must be recouped in the year of the plan termination only against the cost center(s) in which the provider of services reported its plan contributions or payments, usually the administrative and general cost center.

(ii) Residual assets exceeding the amount in the administrative and general (or other) cost center are not further offset in the current or subsequent years.

(iii) The Medicare share of the reversion is based on the Medicare utilization rate in the year the reversion occurs (or the year the actuarial surplus is determined), and not Medicare's utilization in the years the contributions to the plan were made.

(g) *Treatment of costs associated with the PBGC.* Costs associated with the requirements set forth in ERISA and by the PBGC and incurred by a provider of services who sponsors a QDBP are allowable or unallowable under the program as provided for in this paragraph (g).

(1) *Costs paid out of the plan trust.* PBGC premiums and costs paid out of the corpus or earnings of the trust are included in the contributions allowed under paragraph (d)(1)(iii)(A) of this section, and are not allowable as separate costs.

(2) *Premium payments for single- and multi-employer plans.* The amount of PBGC premiums paid for basic benefits (flat rate or variable, excluding amounts paid out of the corpus or earnings of the trust) by a provider of services who sponsors a QDBP are allowable under the program.

(3) *Liability for missing participants or beneficiaries.* The total amount paid to the PBGC by a provider of services who sponsors a QDBP (excluding amounts paid out of the corpus or earnings of the trust) of the benefit transfer amount (as described in 29 CFR 4050.103(d)) for all missing participants or beneficiaries of the QDBP, is allowable under the program.

(4) *Plan termination due to distress.* For a defined benefit plan that terminated with insufficient assets to pay all of the plan benefits, which resulted in the PBGC making payment of vested benefits up to limits defined by law in accordance with 29 CFR part 4022, such amounts contributed to the QDBP by the provider of services who sponsors the QDBP are allowable. Benefits paid to the participants and beneficiaries of the QDBP by the PBGC are unallowable.

(5) *Restored plan payments.* If the PBGC issues or has issued a plan restoration order as described in 29 CFR part 4047, the amounts that the provider of services repays to the PBGC for guaranteed benefits and related expenses under the plan while the plan was in terminated status, and any administrative costs assessed by the PBGC, excluding penalties, are allowable.

[87 FR 49406, Aug. 10, 2022]

§ 413.100 Special treatment of certain accrued costs.

(a) *Principle.* As described in § 413.24(b)(2), under the accrual basis of accounting, revenue is reported in the period in which it is earned and expenses are reported in the period in which they are incurred. In the case of accrued costs described in this section, for Medicare payment purposes the costs are allowable in the year in which the costs are accrued and claimed for Medicare payment only under the conditions set forth in paragraph (c) of this section.

(b) *Definitions*—(1) *All-inclusive paid days off benefit.* An all-inclusive paid days off benefit replaces other vacation and sick pay plans. It is a formal plan under which, based on actual hours worked, all employees accrue vested leave or payment in lieu of vested leave for any combination of types of leave, such as illness, medical appointments, holidays, and vacations.

(2) *Self-insurance.* Self-insurance is a means by which a provider independently or as part of a group undertakes the risk of protecting itself against anticipated liabilities by providing funds in an amount equal to anticipated liabilities, rather than by purchasing insurance coverage.

(c) *Recognition of accrued costs*—(1) *General.* Although Medicare recognizes, in the year of accrual, the accrual of costs for which a provider has not actually expended funds during the current cost reporting period, for purposes of payment Medicare does not recognize the accrual of costs unless the related liabilities are liquidated timely.

(2) *Requirements for liquidation of liabilities.* For accrued costs to be recognized for Medicare payment in the year of the accrual, the requirements set forth below must be met with respect to the liquidation of related liabilities. If liquidation does not meet these requirements, the cost is disallowed, generally in the year of accrual, except as specified in paragraph (c)(2)(ii) of this section.

(i) *A short-term liability.* (A) Except as provided in paragraph (c)(2)(i)(B) of this section, a short-term liability, including the current portion of a long-term liability (for example, mortgage interest payments due to be paid in the

current year), must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred.

(B) If, within the 1-year time limit, the provider furnishes to the contractor sufficient written justification (based upon documented evidence) for nonpayment of the liability , the contractor may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred.

(ii) *Vacation pay and all-inclusive paid days off.* (A) If the provider's vacation policy, or its policy for all-inclusive paid days off, is consistent for all employees, liquidation of the liability must be made within the period provided for by that policy.

(B) If the provider's vacation policy, or its policy for all-inclusive paid days off, is not consistent for all employees, liquidation of the liability must be made within 2 years after the close of the cost reporting period in which the liability is accrued.

(C) If payment is not made within the required time period or if benefits are forfeited by the employee, an adjustment to disallow the accrued cost is made in the current period (that is, the latest year in which payment should have been made or the year in which the benefits are forfeited) rather than in the period in which the cost was accrued and claimed for Medicare payment. However, an contractor may choose to require the adjustment in the period in which the cost was accrued and claimed for Medicare payment if the cost report for that period is open or can be reopened as provided in §405.1885 of this chapter, and if the contractor believes the adjustment is more appropriate in that period.

(iii) *Sick pay.* (A) If sick leave is vested and funded in a deferred compensation plan, liabilities related to the contributions to the fund must be liquidated, generally within 1 year after the end of the cost reporting period in which the liability is incurred. If, within the 1-year time limit, the provider furnishes to the contractor sufficient written justification (based upon documented evidence) for nonpayment of the liability, the contractor may grant an extension for good cause. The extension may not exceed 3 years beyond the end of the cost reporting year in which the liability was incurred. Contributions to the deferred compensation plan must be reduced to reflect estimated forfeitures. Actual forfeitures above or below estimated forfeitures must be used to adjust annual contributions to the fund.

(B) If the sick leave plan grants employees the nonforfeitable right to demand cash payment for unused sick leave at the end of each year, sick pay is includable in allowable costs, without funding, in the cost reporting period in which it is earned.

(C) Sick pay paid on any basis other than that specified in paragraphs (c)(2)(iii) (A) or (B) of this section can be claimed for Medicare payment only on a cash basis for the year in which the benefits are paid.

(iv) *Compensation of owners.* Accrued liability related to compensation of owners other than sole proprietors and partners must be liquidated within 75 days after the close of the cost reporting period in which the liability occurs.

(v) *Nonpaid workers.* Obligations incurred under a legally-enforceable agreement to remunerate an organization of nonpaid workers must be discharged no later than the end of the provider's cost reporting period following the period in which the services were furnished.

(vi) *FICA and other payroll taxes—(A) General rule.* The provider's share of FICA and other payroll taxes that the provider becomes obligated to remit to governmental agencies is included in allowable costs only during the cost reporting period in which payment (upon which the payroll taxes are based) is actually made to the employee. For example, payroll taxes applicable to vacation benefits are not to be accrued in the period in which the vacation benefits themselves are accrued but rather are allowable only in the period in which the employee takes the vacation.

(B) *Exception.* If payment would be made to an employee during a cost reporting period but for the fact the regularly scheduled payment date is after the end of the period, costs of accrued payroll taxes related to the portion of

payroll accrued through the end of the period, but paid to the employee after the beginning of the new period, are allowable costs in the year of accrual, subject to the liquidation requirements specified in paragraph (c)(2)(i) of this section.

(vii) *Deferred compensation.* (A) Reasonable provider payments made under unfunded deferred compensation plans are included in allowable costs only during the cost reporting period in which actual payment is made to the participating employee.

(B) Accrued liability related to contributions to a funded deferred compensation plan must be liquidated within 1 year after the end of the cost reporting period in which the liability is incurred. An extension, not to exceed 3 years beyond the end of the cost reporting year in which the liability was incurred, may be granted by the contractor for good cause if the provider, within the 1-year time limit, furnishes to the contractor sufficient written justification for non-payment of the liability.

(C) Postretirement benefit plans (including those addressed in Statement of Financial Accounting Standards No. 106 (December 1990)) are deferred compensation arrangements and thus are subject to the provisions of this section regarding deferred compensation and to applicable program instructions for determining Medicare payment for deferred compensation.

(D) Exception: Qualified defined benefit pension plans, which are funded deferred compensation arrangements, shall be reported on a cash accounting basis as follows:

(*1*) The allowable pension cost shall be equal to the amount of actual pension contributions funded during the hospital's current Medicare cost reporting period, plus any contributions funded in a prior period and carried forward, subject to the limit under paragraph (c)(2)(vii)(D)*(2)* of this section.

(*2*) Except as provided in paragraph (c)(2)(vii)(D)*(3)* of this section, the allowable pension cost shall not exceed 150 percent of the average contribution(s) funded during the three consecutive Medicare cost reporting periods that produce the highest average contribution(s), out of the five most recent Medicare cost reporting periods (ending with the current cost reporting period). Contributions in excess of the limit may be carried forward to future period(s). In the case of a newly adopted pension plan, the 5-year look-back period and/or the 3-year averaging period will be limited to the number of cost reporting periods the provider sponsored a qualified defined benefit pension plan.

(*3*) A waiver of the limit imposed under paragraph (c)(2)(vii)(D)(*2*) of this section may be granted for a specific Medicare cost reporting period for all or a portion of the contributions in excess of the limit imposed under paragraph (c)(2)(vii)(D)(*2*) of this section if it is determined that such excess costs are reasonable and necessary for that period.

(viii) *Self-insurance.* Accrued liability related to contributions to a self-insurance program that are systematically made to a funding agency and that cover malpractice and comprehensive general liability, unemployment compensation, workers' compensation insurance losses, or employee health benefits, must be liquidated within 75 days after the close of the cost reporting period.

[60 FR 33136, June 27, 1995, as amended at 64 FR 51909, Sept. 27, 1999; 77 FR 53682, Aug. 31, 2012]

§ 413.102 Compensation of owners.

(a) *Principle.* A reasonable allowance of compensation for services of owners is an allowable cost provided that the services are actually performed in a necessary function.

(b) *Definitions*—(1) *Compensation.* Compensation means the total benefit received by the owner for the services he furnishes to the institution. It includes the following items:

(i) Salary amounts paid for managerial, administrative, professional, and other services.

(ii) Amounts paid by the institution for the personal benefit of the proprietor.

(iii) The cost of assets and services that the proprietor receives from the institution.

(iv) Deferred compensation.

(2) *Reasonableness.* Reasonableness requires that the compensation allowance—

(i) Be such an amount as would ordinarily be paid for comparable services by comparable institutions; and

(ii) Depend upon the facts and circumstances of each case.

(3) *Necessary.* Necessary requires that the function be—

(i) Such that had the owner not furnished the services, the institution would have had to employ another person to perform the services; and

(ii) Pertinent to the operation and sound conduct of the institution.

(c) *Application.* (1) Owners of provider organizations often furnish services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services furnished to be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

(2) Ordinarily, compensation paid to proprietors is a distribution of profits. However, if a proprietor furnishes necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. If the services are furnished on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be determined by other appropriate means.

§413.106 Reasonable cost of physical and other therapy services furnished under arrangements.

(a) *Principle.* The reasonable cost of the services of physical, occupational, speech, and other therapists, and services of other health specialists (other than physicians), furnished under arrangements (as defined in section 1861(w) of the Act) with a provider of services, a clinic, a rehabilitation agency or a public health agency, may not exceed an amount equivalent to the prevailing salary and additional costs that would reasonably have been incurred by the provider or other organization had such services been performed by such person in an employment relationship, plus the cost of other reasonable expenses incurred by such person in furnishing services under such an arrangement. However, if the services of a therapist are required on a limited part-time basis, or to perform intermittent services, payment may be made on the basis of a reasonable rate per unit of service, even though this rate may be greater per unit of time than salary-related amounts, if the greater payment is, in the aggregate, less than the amount that would have been paid had a therapist been employed on a full-time or regular part-time salaried basis. Pursuant to section 17(a) of Public Law 93–233 (87 Stat. 967), the provisions of this section are effective for cost reporting periods beginning after March, 1975.

(b) *Definitions*—(1) *Prevailing salary.* The prevailing salary is the hourly salary rate based on the 75th percentile of salary ranges paid by providers in the geographical area, by type of therapy, to therapists working full time in an employment relationship.

(2) *Fringe benefit and expense factor.* The standard fringe benefit and expense factor is an amount that takes account of fringe benefits, such as vacation pay, insurance premiums, pension payments, allowances for job-related training, meals, etc., generally received by an employee therapist, as well as expenses, such as maintaining an office, appropriate insurance, etc., an individual not working as an employee might incur in furnishing services under arrangements.

(3) *Adjusted hourly salary equivalency amount.* The adjusted hourly salary equivalency amount is the prevailing hourly salary rate plus the standard fringe benefit and expense factor. This amount is determined on a periodic basis for appropriate geographical areas.

(4) *Travel allowance.* A standard travel allowance is an amount that is recognized, in addition to the adjusted hourly salary equivalency amount.

(5) *Limited part-time or intermittent services.* Therapy services are considered to be on a limited part-time or intermittent basis if the provider or other organization furnishing the services under arrangements requires the services of a therapist or therapists on an average of less than 15 hours per week. This determination is made by dividing the total hours of services furnished during the cost reporting period by the number of weeks in which the services were furnished in the cost reporting period regardless of the number of days in each week in which services were performed.

(6) *Guidelines.* Guidelines are the amounts published by CMS reflecting the application of paragraphs (b) (1) through (4) of this section to an individual therapy service and a geographical area. Other statistically valid data may be used to establish guidelines for a geographical area, provided that the study designs, questionnaires and instructions, as well as the resultant survey data for determining the guidelines are submitted to and approved in advance by CMS. Such data must be arrayed so as to permit the determination of the 75th percentile of the range of salaries paid to full-time employee therapists.

(7) *Administrative responsibility.* Administrative responsibility is the performance of those duties that normally fall within the purview of a department head or other supervisor. This term does not apply to directing aides or other assistants in furnishing direct patient care.

(c) *Application.* (1) Under this provision, CMS will establish criteria for use in determining the reasonable cost of physical, occupational, speech, and other therapy services and the services of other health specialists (other than physicians) furnished by individuals under arrangements with a provider of services, a clinic, a rehabilitation agency, or public health agency. It is recognized that providers have a wide variety of arrangements with such individuals. These individuals may be independent practitioners or employees of organizations furnishing various health care specialists. This provision does not require change in the substance of these arrangements.

(2) If therapy services are performed under arrangements at a provider site on a full-time or regular part-time basis, the reasonable cost of such services may not exceed the amount determined by taking into account the total number of hours of services furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished and a standard travel allowance.

(3) If therapy services are performed under arrangements on a limited part-time or intermittent basis at the provider site, the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis, except that payment for these services, in the aggregate, during the cost reporting period, may not exceed the amount that would be determined to be reasonable under paragraph (c)(2) of this section, had a therapist furnished the provider or other organization furnishing the services under arrangements 15 hours of service per week on a regular part-time basis for the weeks in which services were furnished by the non-employee therapist.

(4) If an HHA furnishes services under arrangements at the patient's residence or in other situations in which therapy services are not performed at the provider's site, the reasonable cost of such services is evaluated as follows:

(i) *Time records available.* If time records of HHA visits are maintained by the provider, the reasonable cost of such services is evaluated on a unit-of-time basis, by taking into account the total number of hours of service furnished by the therapist, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance for each visit. However, if the travel time of the therapist is accurately recorded by the therapist, and approved and maintained by the provider, the reasonable cost of such

services may be evaluated, at the option of the provider, by taking into account the total number of hours of service furnished by the therapist, including travel time, and the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished. This option does not apply to services furnished by HHAs under arrangements with providers other than HHAs.

(ii) *No time records available.* If time records are unavailable or found to be inaccurate, each HHA visit is considered the equivalent of one hour of service. In such cases, the reasonable cost of such services is determined by taking into account the number of visits made by the therapist under arrangements with such agency, the adjusted hourly salary equivalency amount appropriate for the particular therapy in the geographical area in which the services are furnished, and a standard travel allowance.

(iii) *Limited part-time or intermittent services.* If under paragraph (c)(4) (i) or (ii) of this section, the provider required therapy services on an average of less than 15 hours per week, the services are considered limited part-time or intermittent services, and the reasonable cost of such services is evaluated on a reasonable rate per unit of service basis as described in paragraph (c)(3) of this section.

(5) If therapy services are performed in situations where compensation to a therapist employed by the provider is based, at least in part, on a fee-for-service or on a percentage of income (or commission), the guidelines will apply. The entire compensation will be subject to the guidelines in cases where the nature of the arrangements is most like an under ''arrangement'' situation, although technically the provider may treat the therapists as employees. The intent of this section is to prevent an employment relationship from being used to circumvent the guidelines.

(6) These provisions are applicable to individual therapy services or disciplines by means of separate guidelines by geographical area and apply to costs incurred after issuance of the guidelines but no earlier than the beginning of the provider's cost reporting period described in paragraph (a) of this section. Until a guideline is issued for a specific therapy or discipline, costs are evaluated so that such costs do not exceed what a prudent and cost-conscious buyer would pay for the given service.

(d) *Notice of guidelines to be imposed.* Prior to the beginning of a period to which a guideline will be applied, a notice will be published in the FEDERAL REGISTER establishing the guideline amounts to be applied to each geographical area by type of therapy.

(e) *Additional allowances.* (1) If a therapist supervises other therapists or has administrative responsibility for operating a provider's therapy department, a reasonable allowance may be added to the adjusted hourly salary equivalency amount by the contractor based on its knowledge of the differential between therapy supervisors' and therapists' salaries in similar provider settings in the area.

(2) If a therapist performing services under arrangements furnishes equipment and supplies used in furnishing therapy services, the guideline amount may be supplemented by the cost of the equipment and supplies, provided the cost does not exceed the amount the provider, as a prudent and cost-conscious buyer, would have been able to include as allowable cost.

(f) *Exceptions.* The following exceptions may be granted but only upon the provider's demonstration that the conditions indicated are present:

(1) *Exception because of unique circumstances or special labor market conditions.* An exception may be granted under this section by the contractor if a provider demonstrates that the costs for therapy services established by the guideline amounts are inappropriate to a particular provider because of some unique circumstances or special labor market conditions in the area.

(2) *Exception for services furnished by risk-basis HMO providers.* For special rules concerning services furnished to an HMO's enrollees who are Medicare beneficiaries by a provider owned or operated by a risk-basis HMO (see §417.201(b) of this chapter) or related to

a risk-basis HMO by common ownership or control (see § 417.250(c) of this chapter).

(3) *Exception for inpatient hospital services.* Effective with cost reporting periods beginning on or after October 1, 1983, the costs of therapy services furnished under arrangements to a hospital inpatient are excepted from the guidelines issued under this section if such costs are subject to the provisions of § 413.40 or part 412 of this chapter. The contractor will grant the exception without request from the provider.

(g) *Appeals.* A request by a provider for a hearing on the determination of an contractor concerning the therapy costs determined to be allowable based on the provisions of this section, including a determination with respect to an exception under paragraph (f) of this section, is made to the contractor only after submission of its cost report and receipt of the notice of amount of program reimbursement reflecting such determination, in accordance with the provisions of subpart R of part 405 of this chapter.

[51 FR 34793, Sept. 30, 1986, as amended at 63 FR 5139, Jan. 30, 1998]

§ 413.114 Payment for posthospital SNF care furnished by a swing-bed hospital.

(a) *Purpose and basis.* This section implements section 1883 of the Act, which provides for payment for posthospital SNF care furnished by rural hospitals and CAHs having a swing-bed approval.

(1) *Services furnished in cost reporting periods beginning prior to July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals and CAHs is paid in accordance with the special rules in paragraph (c) of this section for determining the reasonable cost of this care. When furnished by rural and CAH swing-bed hospitals approved after March 31, 1988 with more than 49 beds (but fewer than 100), these services must also meet the additional payment requirements set forth in paragraph (d) of this section.

(2) *Services furnished in cost reporting periods beginning on and after July 1, 2002.* Posthospital SNF care furnished in general routine inpatient beds in rural hospitals (other than CAHs) is paid in accordance with the provisions of the prospective payment system for SNFs described in subpart J of this part, except that for purposes of this paragraph, the requirements of § 413.343(a) must be met using the specific assessment instrument and data designated by CMS for this purpose. Posthospital SNF care furnished in general routine inpatient beds in CAHs is paid based on reasonable cost for cost reporting periods beginning on and after July 1, 2002 and before January 1, 2004, and is paid based on 101 percent of reasonable cost for cost reporting periods beginning on and after January 1, 2004, in accordance with the provisions of subparts A through G of this part (other than paragraphs (c) and (d) of this section).

(b) *Definitions.* For purposes of this section—

Availability date means with respect to a posthospital SNF care patient in a swing-bed hospital, the later of—

(i) Any date on which a bed is available for the patient in a Medicare-participating SNF located within the hospital's geographic region;

(ii) The date that a hospital learns that a bed is available in a Medicare-participating SNF; or

(iii) If the notice is prospective, the date that a bed will become available in a Medicare-participating SNF.

Geographic region means an area that includes the SNFs with which a hospital has traditionally arranged transfers and all other SNFs within the same proximity to the hospital. In the case of a hospital without existing transfer practices upon which to base a determination, the geographic region is an area that includes all the SNFs within 50 miles (as defined in § 412.92(c)(1) of this chapter) of the hospital unless the hospital can demonstrate that the SNFs are inaccessible to its patients. In the event of a dispute as to whether an SNF is within a hospital's geographic region or the SNF is inaccessible to hospital patients, the CMS Regional Office makes a determination.

Swing-bed hospital means a hospital or CAH participating in Medicare that has an approval from CMS to provide posthospital SNF care as defined in § 409.20 of this chapter, and meets the

requirements specified in §482.58 or §485.645 of this chapter, respectively.

(c) *Special rules for determining the reasonable cost of posthospital SNF care furnished in cost reporting periods beginning prior to July 1, 2002.* The reasonable cost of posthospital SNF care furnished by a swing-bed hospital is determined as follows:

(1) The reasonable cost of routine SNF services is based on the average Medicare rate per patient day for routine services provided in freestanding SNFs in the region where the swing-bed hospital is located. The rates are calculated using the regions as defined in section 1886(d)(2)(D) of the Social Security Act. The rates are based on the most recent year for which settled cost reporting period data are available, increased in a compounded manner, using the increase applicable to the SNF routine cost limits, up to and including the calendar year for which the rates are in effect. If the current Medicare swing-bed rate for routine extended care services furnished by a swing-bed hospital during a calendar year is less than the rate for the prior calendar year, payment is made based on the prior calendar year's rate.

(2) The reasonable cost of ancillary services furnished as posthospital SNF care is determined in the same manner as the reasonable cost of other ancillary services furnished by the hospital in accordance with §413.53(a)(1).

(d) *Additional requirements*—(1) *General rule.* For services furnished in cost reporting periods beginning prior to July 1, 2002, in order for Medicare payment to be made to a swing-bed hospital with more than 49 beds (but fewer than 100), the following payment requirements must be met:

(i) If there is an available SNF bed in the geographic region, a posthospital SNF care patient must be transferred within 5 days (excluding weekends and holidays) of the availability date, unless the patient's physician certifies within the 5-day period that transfer is not medically appropriate.

(ii) The number of patient days for posthospital SNF care in a cost reporting period does not exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the hospital in the period. In those States that do not license their hospital beds, the hospitals must use the total number of hospital beds reported on their most recent Certificate of Need (CON), excluding bassinets. If during the cost reporting period, there is an increase or decrease in the number of ''licensed'' beds, the number of ''licensed'' beds for each part of the period is to be multiplied by the number of days for which that number of ''licensed'' beds was available. After totalling the results, compute 15 percent of the total available ''licensed'' bed days to determine the payment limitation.

(2) *Payment restrictions.* (i) The hospital must not seek payment for posthospital SNF care after the end of the 5 day period (excluding weekends and holidays) beginning on the availability date of a SNF bed unless the patient's physician has certified, within that 5 day period, that the transfer of the patient to the SNF was not medically appropriate.

(ii) The hospital must not seek payment for posthospital SNF care in a cost reporting period to the extent that they exceed 15 percent of the product of the number of days in the period and the average number of licensed beds in the period. In those States that do not license hospital beds, the hospital must use the average number of hospital beds reported on its most recent CON, excluding bassinets.

(3) *Payment exception.* Payment will continue to be made during the cost reporting period in which the 15 percent limit specified in paragraph (d)(1)(ii) of this section is reached for those patients who are receiving posthospital SNF care at the time the hospital reaches the limit.

[51 FR 34793, Sept. 30, 1986, as amended at 54 FR 37274, Sept. 7, 1989; 56 FR 54545, Oct. 22, 1991; 58 FR 30671, May 26, 1993; 61 FR 51616, Oct. 3, 1996; 62 FR 46037, Aug. 29, 1997; 66 FR 39600, July 31, 2001; 69 FR 49265, Aug. 11, 2004; 79 FR 27153, May 12, 2014; 85 FR 47633, Aug. 5, 2020]

§413.118 Payment for facility services related to covered ASC surgical procedures performed in hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1833(a)(4) and (i)(3) of the Act and establishes the method for

determining Medicare payments for services related to covered ambulatory surgical center (ASC) procedures performed in a hospital on an outpatient basis. It does not apply to services furnished by an ASC operated by a hospital that has an agreement with CMS to be paid in accordance with § 416.30 of this chapter. (For regulations governing ASCs see part 416 of this chapter.)

(b) *Definitions.* For purposes of this section—

Facility services are those items and services, as specified in § 416.61 of this chapter, that are furnished by a hospital on an outpatient basis in connection with covered ASC surgical procedures, as described in § 416.65 of this chapter.

Standard overhead amount means an amount equal to the prospectively determined payment rate that would be paid for the procedure if it had been furnished by an ASC in the same geographic area.

(c) *Payment principle.* The aggregate amount of payments for facility services, furnished in a hospital on an outpatient basis, that are related to covered ASC surgical procedures (covered under § 416.65 of this chapter) is equal to the lesser of—

(1) The hospital's reasonable cost or customary charges, as determined in accordance with § 413.13, reduced by deductibles and coinsurance; or

(2) The blended payment amount as described in paragraph (d) of this section, which is based on hospital-specific cost and charge data and rates paid to free-standing ASCs.

(d) *Blended payment amount.* (1) For cost reporting periods beginning on or after October 1, 1987 but before October 1, 1988, the blended payment amount is equal to the sum of—

(i) 75 percent of the hospital-specific amount (the lesser of the hospital's reasonable cost or customary charges, reduced by deductibles and coinsurance); and

(ii) 25 percent of the ASC payment amount (that is, 80 percent of the result obtained by subtracting the deductibles from the sum of the standard overhead amounts.)

(2) For the period of time beginning with the first day of a hospital's cost reporting period that begins on or after October 1, 1988 and ends on December 31, 1990, the blended payment amount is equal to 50 percent of the hospital-specific amount and 50 percent of the ASC payment amount.

(3) For portions of cost reporting periods beginning on or after January 1, 1991, the blended payment amount is equal to 42 percent of the hospital-specific amount and 58 percent of the ASC payment amount.

(4) For cost reporting periods beginning on or after October 1, 1988 and before January 1, 1995, the blended payment amount is equal to the sum of 75 percent of the hospital-specific amount and 25 percent of the ASC payment amount for a hospital that makes an application to its contractor and meets the following requirements.

(i) More than 60 percent of the hospital's inpatient hospital discharges, as described in § 412.60 of this chapter, occurring during its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, are classified in diagnosis related groups 36 through 74.

(ii) During its cost reporting period beginning on or after October 1, 1986 and before October 1, 1987, more than 30 percent of the hospital's total revenues is derived from outpatient services.

(5) For portions of cost reporting periods beginning on or after October 1, 1997, for purposes of calculating the blended payment amount under paragraph (d)(4) of this section, the ASC payment amount is the sum of the standard overhead amounts reduced by deductibles and coinsurance as defined in section 1866(a)(2)(ii) of the Act.

(e) *Aggregation of cost, charges, and the blended amount.* For purposes of determining the correct payment amount under paragraphs (c) and (d) of this section, all reasonable costs and customary charges attributable to facility services furnished during a cost reporting period are aggregated and treated separately from the reasonable costs and customary charges attributable to

all other services furnished in the hospital.

[52 FR 36773, Oct. 1, 1987; 52 FR 37715, Oct. 8, 1987, as amended at 55 FR 33699, Aug. 17, 1990; 55 FR 34797, Aug. 24, 1990; 57 FR 36017, Aug. 12, 1992; 57 FR 45113, Sept. 30, 1992; 65 FR 18541, Apr. 7, 2000]

§413.122 Payment for hospital outpatient radiology services and other diagnostic procedures.

(a) *Basis and purpose.* (1) This section implements section 1833(n) of the Act and establishes the method for determining Medicare payments for radiology services and other diagnostic procedures performed by a hospital on an outpatient basis.

(2) For purposes of this section—

(i) Radiology services include diagnostic and therapeutic radiology, nuclear medicine, CAT scan procedures, magnetic resonance imaging, ultrasound and other imaging services; and

(ii) Other diagnostic procedures are those identified by CMS, and do not include diagnostic radiology procedures or diagnostic laboratory tests.

(b) *Payment for hospital outpatient radiology services.* (1) The aggregate payment for hospital outpatient radiology services furnished on or after October 1, 1988 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with §413.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment amount described in paragraph (b)(2) of this section.

(2) The blended payment amount for hospital outpatient radiology services furnished on or after October 1, 1988, but before October 1, 1989, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge or fee schedule amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual deductible from 62 percent of the prevailing charges (or for services furnished on or after January 1, 1989, the fee schedule amount established) for the same services when furnished by participating physicians in their offices in the same locality.

(3) For hospital outpatient radiology services furnished on or after October 1, 1989, the blended payment amount is equal to the sum of 50 percent of the hospital-specific amount and 50 percent of the fee schedule amount.

(4) For hospital outpatient radiology services furnished on or after January 1, 1991, the blended payment amount is equal to the sum of 42 percent of the hospital-specific amount and 58 percent of the fee schedule amount.

(5) For hospital outpatient radiology services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 42 percent of the hospital-specific amount; and

(ii) 58 percent of the fee schedule amount calculated as 62 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality, less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

(c) *Payment for other diagnostic procedures.* (1) The aggregate payment for other diagnostic procedures performed by a hospital on an outpatient basis on or after October 1, 1989 is equal to the lesser of the following:

(i) The hospital's reasonable cost or customary charges, as determined in accordance with §414.13, reduced by the applicable Part B annual deductible and coinsurance amounts.

(ii) The blended payment described in paragraph (c)(2) of this section.

(2) The blended payment amount for other diagnostic procedures furnished on or after October 1, 1989, but before October 1, 1990, is equal to the sum of—

(i) 65 percent of the hospital-specific amount (the hospital's reasonable cost or customary charges, whichever is less, reduced by the applicable Part B annual deductible and coinsurance amounts); and

(ii) 35 percent of a prevailing charge amount that is calculated as 80 percent of the amount determined by subtracting the applicable Part B annual

deductible from 42 percent of the prevailing charges for the same services furnished by participating physicians in their offices in the same locality.

(3) For other diagnostic procedures performed by a hospital on or after October 1, 1990, the blended payment is equal to 50 percent of the hospital-specific amount and 50 percent of the prevailing charge amount.

(4) For other diagnostic services furnished on or after October 1, 1997, the blended payment amount is equal to the sum of—

(i) 50 percent of the hospital-specific amount; and

(ii) 50 percent of the fee schedule amount calculated as 42 percent of the sum of the fee schedule amounts payable for the same services when furnished by participating physicians in their offices in the same locality less deductible and coinsurance as defined in section 1866(a)(2)(A)(ii) of the Act.

[56 FR 8842, Mar. 1, 1991, as amended at 57 FR 36017, Aug. 12, 1992; 65 FR 18542, Apr. 7, 2000]

§ 413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1834(c)(1)(C) of the Act and establishes the method for determining Medicare payment for screening mammographies performed by hospitals.

(b) *Payment to hospitals for outpatient services.* Payment to hospitals for screening mammography services performed on an outpatient basis is determined in accordance with the technical component billing requirements in § 405.534(d) of this chapter.

[55 FR 53522, Dec. 31, 1990, as amended at 59 FR 49834, Sept. 30, 1994]

§ 413.124 Reduction to hospital outpatient operating costs.

(a) Except for sole community hospitals, as defined in § 412.92 of this chapter, and critical access hospitals, the reasonable costs of outpatient hospital services (other than capital-related costs of these services) are reduced by 5.8 percent for services furnished during portions of cost reporting periods occurring on or after October 1, 1990 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

(b) For purposes of determining the blended payment amounts of ambulatory surgical center approved surgical procedures performed in the hospital outpatient setting under § 413.118 and hospital outpatient radiology services and other diagnostic procedures under § 413.122, the reduction is applicable only to the hospital-specific portion of the blended payment amounts.

[57 FR 36017, Aug. 12, 1992, as amended at 59 FR 26960, May 25, 1994; 62 FR 46037, Aug. 29, 1997; 65 FR 18542, Apr. 07, 2000]

§ 413.125 Payment for home health agency services.

(a) For additional rules on the allowability of certain costs incurred by home health agencies, see §§ 409.46 and 409.49(b) of this chapter.

(b) The reasonable cost of outpatient rehabilitation services furnished by a home health agency to homebound patients who are not entitled to home health benefits may not exceed the amounts payable under the physician fee schedule for comparable services effective January 1, 1999.

[59 FR 65497, Dec. 20, 1994, as amended at 63 FR 58910, Nov. 2, 1998]

Subpart G—Capital-Related Costs

§ 413.130 Introduction to capital-related costs.

(a) *General rule.* Capital-related costs and an allowance for return on equity are limited to the following:

(1) Net depreciation expense as determined under §§ 413.134, 413.144, and 413.149, adjusted by gains and losses realized from the disposal of depreciable assets under § 413.134(f).

(2) Taxes on land or depreciable assets used for patient care.

(3) Leases and rentals, including license and royalty fees, for the use of depreciable assets or land, as described in paragraph (b) of this section.

(4) The costs of betterments and improvements as described in paragraph (c) of this section.

(5) The costs of minor equipment that are capitalized, rather than expensed, as described in paragraph (d) of this section.

(6) Insurance expense on depreciable assets, as described in paragraph (e) of this section.

(7) Interest expense as determined under §413.153, subject to the qualifications of paragraph (f) of this section.

(8) For certain proprietary providers, return on equity capital, as determined under §413.157.

(9) The capital-related costs of related organizations (as described in §413.17), as determined in accordance with paragraph (g) of this section.

(10) Debt issuance costs, debt discounts, and debt redemption costs, if the associated debt was incurred to acquire land or depreciable assets used for patient care or to refinance existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(11) The apportionment of the capital-related costs of jointly owned assets among the owners must be on a basis that reflects the relative use by each owner, rather than the ownership share or the amount of time the asset is located at each owners site.

(b) *Leases and rentals.* (1) Subject to the qualifications of paragraphs (b) (2), (4), (5), and (8) of this section, leases and rentals, including licenses and royalty fees, are includable in capital-related costs if they relate to the use of assets that would be depreciable if the provider owned them outright or they relate to land, which is neither depreciable nor amortizable if owned outright. The terms ''*leases*'' and ''*rentals of assets*'' signify that a provider has possession, use, and enjoyment of the assets.

(2) For sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992 and for sale and leaseback agreements for other providers entered into at any time, a provider may include incurred rental charges in its capital-related costs, as specified in a sale and leaseback agreement with a nonrelated purchaser (including shared service organizations not related within the meaning of §413.17) involving plant facilities or equipment only if the following conditions are met:

(i) The rental charges are reasonable based on the following—

(A) Consideration of rental charges of comparable facilities and market conditions in the area;

(B) The type, expected life, condition, and value of the facilities or equipment rented; and

(C) Other provisions of the rental agreements.

(ii) Adequate alternative facilities or equipment that would serve the purpose are not or were not available at lower cost.

(iii) The leasing was based on economic and technical considerations.

(3) If the conditions of paragraph (b)(2) of this section are not met, the amount a provider may include in its capital-related costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest on mortgage, taxes, depreciation, and insurance costs.

(4) For sale and leaseback agreements for hospitals and SNFs entered into on or after October 23, 1992, the amount a provider may include in its capital-related costs as rental or lease expense may not exceed the amount that the provider would have included in its capital-related costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership). This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the annual costs of ownership, the provider may include in capital-related costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in capital-related costs may not exceed the aggregate costs of ownership that would have been included in capital-related costs over the useful life of the asset had the

provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in capital-related costs in the early years of the lease due to the costs of ownership limitation, and include these amounts in capital-related costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership.

(iii) In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iv) In the aggregate, the amount of rental or lease costs included in capital-related costs may not exceed the amount of the costs of ownership that the provider could have included in capital-related costs had the provider retained legal title to the asset.

(5) For lease purchase transactions entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(6)(i) If a lease is a virtual purchase under paragraph (b)(5) of this section, the rental charge is includable in capital-related costs only to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. A provider may not include in its capital-related costs accelerated depreciation in this situation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner, instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in the capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(7) Amounts included in lease or rental payments for repair or maintenance agreements are excluded from capital-related costs. If no amount is identified in the lease or rental agreement for maintenance, the entire lease payment is considered a capital-related cost subject to the provisions of paragraph (b)(1) of this section.

(8) For lease purchase transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is at least 75 percent of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (payments to be made during the lease term including bargain purchase option, guaranteed

residual value, and penalties for failure to renew) equals at least 90 percent of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. Present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is less than the lessee's incremental borrowing rate, in which case the interest rate implicit in the lease is used.

(9)(i) If a lease establishes a virtual purchase under paragraph (b)(8) of this section, the rental charge is includable in capital-related costs to the extent that it does not exceed the amount that the provider would have included in capital-related costs if it had legal title to the asset (the cost of ownership). The cost of ownership includes straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as capital-related costs is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be included in capital-related costs in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be included in capital-related costs to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the amount considered as depreciation, for the purpose of having computed the limitation on rental charges in paragraph (b)(9)(i) of this section, must be used in calculating the limitation on adjustments for the purpose of determining any gain or loss under §413.134(f) upon disposal of an asset.

(c) *Betterments and improvements.* (1) Betterments and improvements are changes which extend the estimated useful life of an asset at least two years beyond its original estimated useful life, or increase the productivity of an asset significantly over its original productivity.

(2) A provider must capitalize and prorate the costs of betterments and improvements over the remaining estimated useful life of the asset, as modified by the betterment or improvement.

(d) *Minor equipment.* A provider must include in its capital-related costs the costs of minor equipment that are capitalized rather than charged off to expense if—

(1) The net book value of minor equipment at the time the provider enters the program is prorated over three years (that is, one-third of the net book value is written off each year), and new purchases are also prorated over a 3-year period; or

(2) The cost of minor equipment is prorated over their actual useful lives.

(e) *Insurance.* (1) A provider must include in its capital-related costs the costs of insurance on depreciable assets used for patient care or insurance that provides for the payment of capital-related costs during business interruption.

(2) If an insurance policy also provides protection for other than the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance, only that portion of the premium related to the replacement of depreciable assets or to pay capital-related costs in the case of business interruption insurance is includable in capital-related costs.

(f) *Debt premiums and debt discounts.* Debt premiums or debt discount are applied as adjustments to capital-related costs if the associated debt is incurred for acquiring land or depreciable assets used for patient care or for refinancing

existing debt for which the original purpose was to acquire land or depreciable assets used for patient care.

(g) *Interest expense.* (1) A provider must include in its capital-related costs interest expense, as described in § 413.153, if such expense is incurred in—

(i) Acquiring land or depreciable assets (either through purchase or lease) used for patient care; or

(ii) Refinancing existing debt, if the original purpose of the refinanced debt was to acquire land or depreciable assets used for patient care.

(2) If investment income offset is required under § 413.153(b)(2)(iii), only that portion of investment income that bears the same relationship to total investment income, as the portion of capital-related interest expense bears to total interest expense, is offset against capital-related costs.

(h) *Costs of supplying organizations*—(1) *Supplying organizations related to the provider.* (i) If the supplying organization is related to the provider within the meaning of § 413.17, except as provided in paragraph (g)(1)(ii) of this section, a provider's capital-related costs include the capital-related costs of the supplying organization.

(ii) If the costs of the services, facilities or supplies being furnished exceed the open market price, or if the provisions of § 413.17(d) apply, no part of the cost to the provider of the services, facilities, or supplies are considered capital-related costs, unless the services, facilities, or supplies would otherwise be considered capital-related.

(2) *Supplying organizations not related to the provider.* If the supplying organization is not related to the provider within the meaning of § 413.17, no part of the charge to the provider may be considered a capital-related cost (unless the services, facilities, or supplies are capital-related in nature) unless—

(i) The capital-related equipment is leased or rented (as described in paragraph (b) of this section) by the provider;

(ii) The capital-related equipment is located on the provider's premises, or is located offsite and is on real estate owned, leased or rented by the provider; and

(iii) The capital-related portion of the charge is separately specified in the charge to the provider.

(i) *Costs excluded from capital-related costs.* The following costs are not capital-related costs. To the extent that they are allowable, they must be included in determining each provider's operating costs:

(1) Costs incurred for the repair or maintenance of equipment or facilities.

(2) Amounts included in rentals or lease payments for repair or maintenance agreements.

(3) Interest expense incurred to borrow working capital (for operating expenses).

(4) General liability insurance or any other form of insurance to provide protection other than for the replacement of depreciable assets or to pay capital-related costs in the case of business interruption.

(5) Taxes other than those assessed on the basis of some valuation of land or depreciable assets used for patient care. (Taxes not related to patient care, such as income taxes, are not allowable, and are therefore not included among either capital-related or operating costs.)

(6) The costs of minor equipment that are charged off to expense rather than capitalized as described in paragraph (d) of this section.

(7) The costs incurred for maintenance and repair insurance agreements (commonly referred to as maintenance agreements).

(j) *Reduction to capital-related costs.* (1) Except for sole community hospitals and critical access hospitals, the amount of capital-related costs of all hospital outpatient services is reduced by—

(i) 15 percent for portions of cost reporting periods occurring on or after October 1, 1989, through September 30, 1991; and

(ii) 10 percent for portions of cost reporting periods occurring on or after October 1, 1991 and until the first date that the prospective payment system under part 419 of this chapter is implemented.

(2) For purposes of determining the blended payment amounts for hospital outpatient services under §§ 413.118 and 413.122, the reduction is applicable only

to the hospital-specific portion of the blended amounts.

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§ 413.134 Depreciation: Allowance for depreciation based on asset costs.

(a) *Principle.* An appropriate allowance for depreciation on buildings and equipment used in the provision of patient care is an allowable cost. The depreciation must be—

(1) Identifiable and recorded in the provider's accounting records;

(2) Based on the historical cost of the asset, except as specified in paragraph (j) of this section regarding donated assets; and

(3) Prorated over the estimated useful life of the asset using—

(i) The straight-line method; or

(ii) Accelerated depreciation under a declining balance method (not to exceed double the straight-line rate) or the sum-of-the-years' digits method in the following situations:

(A) Depreciable assets for which accelerated depreciation was used for Medicare purposes before August 1, 1970, including those assets for which a timely request to change from straight-line depreciation to accelerated depreciation was received by an contractor before August 1, 1970;

(B) Depreciable assets acquired before August 1, 1970, if no election to use straight-line or accelerated depreciation was in effect on August 1, 1970, and the provider was participating in the program on August 1, 1970;

(C) Depreciable assets of a provider if construction of such depreciable asset began before February 5, 1970, and the provider was participating in the program on February 5, 1970; or

(D) Depreciable assets of a provider if a valid written contract was entered into by a provider participating in the program before February 5, 1970, for construction, acquisition, or for the permanent financing thereof, and such contract was binding on a provider on February 5, 1970, and at all times thereafter; or

(iii) A declining balance method, not to exceed 150 percent of the straight-line rate, for a depreciable asset acquired after July 31, 1970; however, this declining balance method may be used only if the cash flow from depreciation on the total assets of the institution during the reporting period, including straight-line depreciation on the assets in question, is insufficient (assuming funding of available capital not required currently for amortization and assuming reasonable interest income on such funds) to supply the funds required to meet the reasonable principal amortization schedules on the capital debts related to the provider's total depreciable assets. For each depreciable asset for which a provider requests authorization to use a declining balance method for Medicare reimbursement purposes, but not to exceed 150 percent of the straight-line rate, the provider must demonstrate to the contractor's satisfaction that the required cash flow need exists. For each depreciable asset in which a provider justifies the use of accelerated depreciation, the contractor must give written approval for the use of a depreciation method other than straight-line before basing any interim payment on this accelerated depreciation or making its reasonable cost determination which includes an allowance for such depreciation.

(b) *General rules*—(1) *Historical cost.* Historical cost is the cost incurred by the present owner in acquiring the asset.

(i) *All providers*—(A) *Depreciable assets acquired after July 31, 1970 and before December 1, 1997.* For depreciable assets acquired after July 31, 1970 and before December 1, 1997, and for a hospital or an SNF, acquired before July 18, 1984, the historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase or the fair market value of the asset at the time of its purchase.

(B) *Depreciable assets acquired on or after December 1, 1997.* For depreciable assets acquired on or after December 1, 1997, the historical cost of the asset that will be recognized under this program must not exceed the historical cost less depreciation allowed to the owner of record as of August 5, 1997 (or

if an asset did not exist as of August 5, 1997, the first owner of record after August 5, 1997). For this paragraph (b)(1)(i)(B), the following apply:

(*1*) An asset that was not in existence as of August 5, 1997 includes an asset that physically existed but was not owned by a provider participating in the Medicare program as of that date.

(*2*) The acquisition cost to the owner of record is subject to the limitation on historical costs described in paragraphs (g) (1), (2), and (3) of this section, and is reduced by any depreciation taken by the owner of record. The limitation on historical cost is also applied to the purchase of land, which is a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§ 413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining the allowable interest expense.)

(*3*) Acquisition cost to the owner of record includes the costs of betterment or improvements that extend the estimated useful life of an asset at least 2 years beyond its original estimated useful life or that increase the productivity of an asset significantly over its original productivity.

(*4*) For assets acquired prior to a provider's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost when acquired, rather than when the provider entered the program.

(*5*) For assets subject to the optional depreciation allowance as described in § 413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the provider changed to actual depreciation as described in § 413.139(e). If the provider did not change to actual depreciation, as described in § 413.139(e), for optional allowance assets, the acquisition cost to the owner of record is based on the provider's recorded historical cost of the asset when acquired. If the provider has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(*6*) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or consolidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the contractor under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(ii) *Hospitals and SNFs only.* (A) For assets acquired on or after July 18, 1984 and before December 1, 1997 and not subject to an enforceable agreement entered into before July 18, 1984, historical cost may not exceed the lowest of the following:

(*1*) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of July 18, 1984, the first owner of record of the asset after that date);

(*2*) The acquisition cost of the asset to the new owner; or

(*3*) The fair market value of the asset on the date of acquisition.

(B) For purposes of applying paragraph (b)(1)(ii)(A) of this section, an asset not in existence as of July 18, 1984 includes any asset that physically existed, but was not owned by a hospital or SNF participating in the Medicare program as of July 18, 1984.

(C) The acquisition cost to the owner of record is subject to any limitation on historical costs described in paragraphs (b)(1)(i) or (g)(1) and (2) of this section, and is not reduced by any depreciation taken by the owner of record. This limitation on historical cost is also applied to the purchase of land, a capital asset that is neither depreciable nor amortizable under any circumstances. (See §§ 413.153(d) and 413.157(b) for application of the limitation to the cost of land for purposes of determining allowable interest expense and return on equity capital or proprietary providers.)

(D) Acquisition cost to the owner of record includes the costs of betterments or improvements that extend the estimated useful life of an asset at least two years beyond its original estimated useful life or increase the productivity of an asset significantly over its original productivity.

(E) For assets acquired prior to a hospital's or SNF's entrance into the Medicare program, the acquisition cost to the owner of record is the historical cost of the asset when acquired, rather than when the hospital or SNF entered the program.

(F) For assets subject to the optional depreciation allowance as described in §413.139, the acquisition cost to the owner of record is the historical cost established for those assets when the hospital or SNF changed to actual depreciation as described in §413.139(e). If the hospital or SNF did not change to actual depreciation, as described in §413.139(e), for optional allowance assets, the acquisition cost to the owner of record is established by reference to the hospital's or SNF's recorded historical cost of the asset when acquired. If the hospital or SNF has no historical cost records for optional allowance assets, the acquisition cost to the owner of record is established by appraisal.

(G) The historical cost of an asset acquired on or after July 18, 1984 may not include costs attributable to the negotiation or settlement of the sale or purchase (by acquisition, merger, or consolidation) of any capital asset for which any payment was previously made under the Medicare program. The costs to be excluded include, but are not limited to, appraisal costs (except those incurred at the request of the contractor under paragraph (f)(2)(iv) of this section), legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies.

(iii) *Hospital-based providers other than SNFs and SNF-based providers.* For changes of ownership that involve assets of a hospital-based provider other than a SNF, or assets of a SNF-based provider, the provisions of paragraph (b)(1)(ii) of this section are not applicable. A reasonable allocation of the purchase price must be made, so that the hospital-based provider other than a SNF, or a SNF-based provider, is not affected by the limitations described in paragraph (b)(1)(ii) of this section. The historical cost of assets of providers other than hospitals and SNFs is governed by paragraph (b)(1)(i) of this section.

(2) *Fair market value.* Fair market value is the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

(3) *The straight-line method.* Under the straight-line method of depreciation, the cost or other basis (for example, fair market value in the case of donated assets) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

(4) *Declining balance method.* Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated cost of the asset each year by a uniform rate up to double the straight-line rate or 150 percent, as the case may be (see paragraph (a)(3) of this section for limitations on use of accelerated methods of depreciation).

(5) *Sum-of-the-years' digits method.* Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years' digits of useful life at the time of acquisition.

(6) *Current reproduction cost.* Current reproduction cost is the cost at current prices, in a particular locality or market area, of reproducing an item of property or a group of assets. Where depreciable assets are concerned, this means the reasonable cost to have built, reproduce in kind, or, in the case of equipment or similar assets, to purchase in the competitive market.

(7) *Useful life.* The estimated useful life of a depreciable asset is its normal operating or service life to the provider, subject to the provisions in paragraph (b)(7)(i) of this section. Factors to be considered in determining useful life include normal wear and tear; obsolescence due to normal economic and

technological changes; climatic and other local conditions; and the provider's policy for repairs and replacement.

(i) *Initial selection of useful life.* In selecting a proper useful life for computing depreciation under the Medicare program, providers must use the useful life guidelines published by CMS. If CMS has not published applicable useful life guidelines, providers must use—

(A) The edition of the American Hospital Association useful life guidelines, as specified in CMS Medicare program manuals; or

(B) A different useful life specifically requested by the provider and approved by the contractor. A different useful life may be approved by the contractor if the provider's request is properly supported by acceptable factors that affect the determination of useful life. However, such factors as an expected early sale, retirement, demolition or abandonment of an asset, or termination of the provider from the Medicare program may not be used.

(ii) *Application of guidelines.* The provisions concerning the selection of useful life guidelines described in paragraph (b)(7)(i) of this section apply to assets acquired on or after January 1, 1981. For assets acquired before January 1, 1981, providers must use the useful life guidelines published by the American Hospital Association in its 1973 edition of *Chart of Accounts for Hospitals*, or those published by the Internal Revenue Service, or those approved for use by contractors as provided in paragraph (b)(7)(i)(B) of this section.

(iii) *Changing useful life.* A change in the estimated useful life may be made if clear and convincing evidence justifies a redetermination of the useful life used by the provider. Such a change must be approved by the contractor in writing, and the factors cited in paragraphs (b)(7) and (b)(7)(i) of this section are applicable in making such redeterminations of useful life. If the request is approved, the change is effective with the reporting period immediately following the period in which the provider's request is submitted for approval.

(8) *Donated asset.* An asset is considered donated when the provider acquires the asset without making payment in the form of cash, new debt, assumed debt, property or services. Except as provided in paragraph (j)(3) of this section, if a provider makes payment in any form to acquire an asset, the payment is considered the purchase price for the purpose of determining allowable historical cost.

(9) *Net book value.* The net book value of an asset is the depreciable basis used for the Medicare program by the asset's last participating owner less depreciation recognized under the Medicare program.

(c) *Recording of depreciation.* Appropriate recording of depreciation includes the identification of the depreciable assets in use, the assets' historical costs, the assets' dates of acquisition, the method of depreciation, estimated useful lives, and the assets' accumulated depreciation.

(d) *Depreciation methods*—(1) *General.* Proration of the cost of an asset over its useful life is allowed on the straight-line method, or, when permitted under paragraph (a)(3) of this section, the declining balance or the sum-of-the-years' digits methods. One method may be used on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the undepreciated cost of the asset is treated as the cost of a new asset in computing depreciation.

(2) *Change in method.* Prior to August 1, 1970, a provider may change from the straight-line method to an accelerated method or vice versa, upon advance approval from the contractor on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider. Effective with August 1, 1970, a provider may only change from an accelerated method or optional method (see § 413.139) to the straight-line method. Such a change may be made without contractor approval and the basis for depreciation is the undepreciated cost reduced by the salvage value. Thereafter, once straight-line depreciation is selected for a particular asset,

an accelerated method may not be established for that asset.

(3) *Recovery of accelerated depreciation*—(i) *General.* If a provider who has used an accelerated method of depreciation for any of its assets terminates participation in the program, or if the Medicare proportion of its allowable costs decreases so that cumulatively substantially more depreciation was paid than would have been paid using the straight-line method of depreciation, the excess of reimbursable cost determined by using accelerated depreciation methods and paid under the program over the reimbursable cost that would have been determined and paid under the program by using the straight-line method of depreciation, will be recovered as an offset to current reimbursement due or, if the provider has terminated participation in the program, as an overpayment. In this determination of excess payment, recognition will be given to the effects the adjustment to straight-line depreciation would have on the return on equity capital and on the allowance in lieu of specific recognition of other costs in the respective years.

(ii) *Transaction between related organizations*—(A) *General.* If the termination of the provider agreement is due to a change in provider ownership, as defined in §489.18 of this chapter, resulting from a transaction between related organizations, as defined in §413.17, and the criteria in paragraph (b) of this section are met, the excess of reimbursable cost, as determined in paragraph (d)(3)(i) of this section may not be recovered if there is a continuation of participation by the facility in the Medicare program.

(B) *Criteria.* The following criteria must be met if the recovery of excess reimbursable cost is not to be made:

(*1*) The termination of the provider agreement is due to a change in ownership of the provider resulting from a transaction between related organizations.

(*2*) The successor provider continues to participate in the Medicare program.

(*3*) Control and the extent of the financial interest of the owners of the provider before and after the termination remain the same; that is, the successor owners acquire the same percentage of control or financial investment as the transferors had.

(*4*) All assets and liabilities of the terminated provider are transferred to the related successor participating provider.

(C) *Effect of transaction.* In transactions meeting the criteria specified in paragraph (d)(3)(ii)(B) of this section, the provision concerning recovery of excess reimbursable cost (§413.134(d)(3)(i)) is not applied, and the transaction is treated as follows:

(*1*) The successor provider must record the historical cost and accumulated depreciation and the method of depreciation recognized under the Medicare program, and these are considered as incurred by the successor provider for Medicare purposes.

(*2*) The Medicare program's utilization of the terminated provider is considered as having been incurred by the successor provider for Medicare purposes.

(*3*) The equity capital of the terminated provider as of the closing of its final cost reporting period must be wholly contained in the equity capital of the successor provider as of the beginning of its first cost reporting period.

(e) *Funding of depreciation.* Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets. Funded depreciation account funds must be placed in readily marketable investments of the type that assures the availability and conservation of the funds. Additions to the funded depreciation account must remain in the account for at least 6 months to be considered valid funding transactions.

(1) *Incentive.* As an incentive for funding, investment income on funded depreciation is not treated as a reduction of allowable interest expense provided such investment income is deposited in, and becomes part of, the funded depreciation account at the time of receipt by the provider. Investment income earned on deposits before the 6-month period elapses are not offset unless the deposits are withdrawn for an improper purpose during this period. If

a provider transfers assets of the funded depreciation account to a related organization (for example, pooling of several chain organization providers' funded depreciation accounts at the chain home office for investment purposes), these assets shall be treated as the provider's funds and are subject to all the requirements specified in paragraph (e) of this section.

(2) *Availability of funded depreciation.* (i) CMS considers funded depreciation available for use in the acquisition or replacement of depreciable assets related to patient care unless the funded depreciation funds have been committed by contract for the acquisition of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(ii) Borrowing for a purpose for which funded depreciation account funds should have been used makes the borrowing unnecessary to the extent that funded depreciation account funds were available at the time of the borrowing. Available funds in the funded depreciation account, to the extent of the unnecessary borrowing, are called ''tainted'' funds. Interest expense incurred on borrowing for a capital purpose is not an allowable cost to the extent that funded depreciation account funds were available at the time of the borrowing.

(iii) A provider can remove the ''unnecessary'' characterization of borrowing, and thereby cure tainted funded depreciation, by using the tainted funds for a proper purpose described in paragraph (e)(3)(i) of this section. However, any funded depreciation that existed at the time of the unnecessary borrowing and is not classified as tainted must be used before any of the tainted funds.

(iv) When only a portion of the borrowing is considered unnecessary under paragraph (e)(2)(ii) of this section, subsequent repayments of such borrowing from general funds are applied first to the allowable portion of the borrowing and then, when all of the allowable borrowing is repaid, to the unallowable portion of the borrowing. When funds from the funded depreciation account are used for the repayment of the unnecessary borrowing, an equivalent amount of tainted funds is cured without regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section. Similarly, where general funds are used to pay for the unallowable borrowing after the necessary borrowing has been repaid, an equivalent amount of tainted funded depreciation is cured without regard to the provisions of paragraphs (e)(2)(ii) and (e)(3)(i)(C) of this section.

(3) *Withdrawals of funded depreciation*—(i) *Proper withdrawals.* (A) Withdrawals from funded depreciation are considered proper if made either for the acquisition or replacement of depreciable assets related to the furnishing of patient care or for other capital purposes related to patient care.

(B) *First-in, first-out basis.* Proper withdrawals from funded depreciation are made on a first-in, first-out basis.

(C) *Exception.* If CMS determines that a borrowing is unnecessary because of the existence of available funded depreciation, and additional deposits have been made to funded depreciation after the occurrence of the unnecessary borrowing, withdrawals made after the date of the additional deposits are deemed to be made on a last-in, first-out basis.

(ii) *Improper withdrawals.* (A) Withdrawals from funded depreciation that do not meet the requirements for proper withdrawals under the provisions in paragraph (e)(3)(i)(A) of this section are considered improper withdrawals.

(B) Improper withdrawals from funded depreciation are made on a last-in, first-out basis. If improper withdrawals are made, interest expense is reduced in accordance with section § 413.153(c)(3).

(C) Improper withdrawals will result in the offset of otherwise allowable interest expense under the offset provisions in § 413.153(c)(3).

(4) *Loans from funded depreciation.* (i) When the general fund of the provider borrows from the funded depreciation to obtain working capital for normal operating expenses to furnish patient care, interest incurred by the general fund is an allowable operating cost only if the interest expense is supported by documents that evidence that the funds were borrowed and that payment of interest and repayment of the funds are required, is separately

identified in the provider's accounting records, and meets the necessary and proper tests described in §§413.153(b)(2) and (b)(3). However, if the general fund of the provider borrows from the funded depreciation account to acquire depreciable assets used in furnishing patient care, or for other capital purposes related to patient care, interest expense paid by the general fund to the funded depreciation account is not an allowable cost. Providers are expected to use the funded depreciation for these purposes.

(ii) Loans from funded depreciation to the general fund are considered investments of funded depreciation, but do not have to meet the readily marketable test described in paragraph (e) of this section. Loans made from funded depreciation are subject to the requirement that funded depreciation must be available for the acquisition of depreciable assets used to furnish patient care, or for other capital purposes related to patient care. Costs incurred to secure lines of credit from lending institutions to ensure such availability are not allowable costs.

(iii) Funding of depreciation from general funds will not be recognized to the extent of any outstanding loans from the funded depreciation account to the general fund. Deposits from the general fund into the funded depreciation account must be first applied to reduce any loans outstanding from the funded depreciation to the general fund. When the loans are repaid in full, general funds deposited in the funded depreciation account are considered as repayments of the general fund. Therefore, any subsequent interest expense of the general fund paid to the funded depreciation fund is not an allowable cost.

(iv) A provider may loan its funded depreciation to a related organization for any purpose subject to the following conditions:

(A) Authorization for such a loan by the provider's appropriate managing body of the provider, such as Board of Trustees or Board of Directors, must be on file.

(B) The funded depreciation loaned must remain available, as specified in paragraph (e)(2) of this section, to the provider making the loan. Costs incurred for lines of credit to assure such availability are not allowable costs. During the period of time that the loan is outstanding, if the provider making the loan resorts to outside borrowing for a purpose for which its funded depreciation should have been used, interest expense on an amount of the outside borrowing up to the amount of the funded depreciation that should have been available would be disallowed as unnecessary.

(C) Such loans shall be considered investments of the provider's funded depreciation, but the requirement that funded depreciation be invested in readily marketable investments as required in paragraph (e) of this section is waived for such loans.

(D) The funded depreciation account must earn interest on such loans at a rate that does not exceed the rate that would be charged for a comparable loan from an independent lending institution. This investment income will not be used to reduce the provider's interest expense if all the other conditions in paragraph (e) of this section are met. If the entity borrowing the funds is another provider participating in the Medicare program, the interest expense incurred on such loans would be allowable if the loan meets all of the interest expense requirements specified in §413.153. (For purposes of §413.153(b)(3)(ii), such loans are not considered to be with a related lender.)

(f) *Gains and losses on disposal of assets*—(1) *General.* Depreciable assets may be disposed of through sale, scrapping, trade-in, exchange, demolition, abandonment, condemnation, fire, theft, or other casualty.

(i) *Disposal of an asset before December 1, 1997.* If disposal of a depreciable asset, including the sale or scrapping of an asset before December 1, 1997, results in a gain or loss, an adjustment is necessary in the provider's allowable cost.

(A) The amount of a gain included in the determination of allowable cost is limited to the amount of depreciation previously included in Medicare allowable costs.

(B) The amount of a loss to be included is limited to the undepreciated basis of the asset permitted under the program.

(C) The treatment of the gain or loss depends upon the manner of disposition of the asset, as specified in paragraphs (f)(2) through (6) of this section.

(D) The gain or loss on the disposition of depreciable assets has no retroactive effect on a proprietary provider's equity capital for years prior to the year of disposition.

(ii) *Disposal of an asset on or after December 1, 1997.* No gain or loss is recognized on either the sale or scrapping of an asset that occurs on or after December 1, 1997, regardless of whether the asset is sold incident to a provider's change of ownership, or otherwise sold or scrapped as an asset of a Medicare participating provider. Gains or losses on dispositions other than sales or scrapping are recognized to the same extent as prior to December 1, 1997.

(2) *Bona fide sale or scrapping before December 1, 1997.* For the bona fide sale or scrapping of depreciable assets before December 1, 1997, the following apply:

(i) Except as specified in paragraph (f)(3) of this section, gains and losses realized from the bona fide sale or scrapping of depreciable assets are included in the determination of allowable cost only if the sale or scrapping occurs while the provider is participating in Medicare. The extent to which such gains and losses are included is calculated by prorating the basis for depreciation of the asset in accordance with the proportion of the asset's useful life for which the provider participated in Medicare. For purposes of this paragraph (f)(2)(i), scrapping refers to the physical removal from the provider's premises of tangible personal properties that are no longer useful for their intended purpose and are only salable for their scrap or junk value.

(ii) If the total amount of gains or losses realized from bona fide sales or scrapping does not exceed $5,000 within the cost reporting period or if the provider's cumulative utilization under the Medicare program is less than 5 percent, the net amount of gains or losses realized from sale or scrapping will be allowed as a depreciation adjustment in the period of disposal. For purposes of this paragraph (f)(2)(ii), the provider's cumulative Medicare utilization precentage is determined by comparing the cumulative total of the Medicare inpatient days for all reporting periods in which depreciation on the asset disposed of was claimed under the Medicare program to the cumulative total of inpatient days of the participating provider for the same reporting periods.

(iii) If the conditions specified in paragraph (f)(2)(ii) of this section are not met, the adjustment to reimbursable cost in the reporting period of asset disposition is calculated as follows:

(A) The total amount of gains or losses shall be allocated to all reporting periods under the Medicare program, based on the ratio of the depreciation allowed on the assets in each reporting period to the total depreciation allowed under the Medicare program.

(B) The results of this allocation are multiplied by the ratio of Medicare reimbursable cost to total allowable cost for each reporting period.

(C) The results of this multiplication are then added.

(D) Effective for cost reporting periods beginning on or after October 1, 1991, no adjustment will be made for the portion of gains or losses allocated to inpatient hospital services for which the hospital was paid under the fully prospective payment methodology as described in § 412.340 of this chapter or under the hold-harmless methodology based on the Federal rate as described in § 412.344(a)(1) of this chapter for new capital costs or in § 412.344(a)(2) of this chapter.

(iv) If a provider sells more than one asset for a lump sum sales price, the gain or loss on the sale of each depreciable asset must be determined by allocating the lump sum sales price among all the assets sold, in accordance with the fair market value of each asset as it was used by the provider at the time of sale. If the buyer and seller cannot agree on an allocation of the sales price, or if they do agree but there is insufficient documentation of the current fair market value of each asset, the contractor for the selling provider will require an appraisal by an independent appraisal expert to establish the fair market value of each asset

and will make an allocation of the sales price in accordance with the appraisal.

(3) *Sale within 1 year after termination.* Gains and losses realized from a bona fide sale of depreciable assets within 1 year immediately following the date on which the provider terminates participation in the Medicare program are also included in the determination of allowable cost, in accordance with the procedure specified in paragraph (f)(2) of this section. However, if several assets are sold for a lump sum sales price, the determination of fair market value must be based on the appraised value of the assets as they were last used by the provider while participating in the Medicare program.

(4) *Exchange, trade-in or donation.* Gains or losses realized from the exchange, trade-in, or donation of depreciable assets are not included in the determination of allowable cost. When the disposition of an asset is by means of exchange or trade-in, the historical cost of the new asset is the sum of the undepreciated cost of the asset disposed of and the additional cash or other assets transferred (or to be transferred) to acquire the new asset. However, if the asset disposed of was acquired by the provider before its participation in the Medicare program and the sum of the undepreciated cost and the cash or other assets transferred (or to be transferred) exceed the list price or fair market value of the new asset, the historical cost of the new asset is limited to the lower of its list price or fair market value.

(5) *Demolition or abandonment.* (i) For purposes of this section, the term ''abandonment'' means the permanent retirement of an asset for any future purpose, not merely the provider's ceasing to use the asset for patient care purposes. To claim an abandonment under the Medicare program, the provider must have relinquished all rights, title, claim, and possession of the asset with the intention of never reclaiming it or resuming its ownership, possession, or enjoyment.

(ii) If losses resulting from the demolition or abandonment of depreciable assets do not exceed $5,000 within the cost-reporting period, the losses are to be allowed in the period of disposal.

(iii) If losses exceed $5,000 and, at the date of disposition, the demolished or abandoned assets are at least 80 percent depreciated as computed under the straight-line method, such losses are includable in the determination of allowable cost under the Medicare program in the period of disposal and the procedure provided in paragraph (f)(2)(iii) of this section must be used in determining the adjustment to reimbursable cost.

(iv) Losses in excess of $5,000 resulting from the demolition or abandonment of assets, which at the date of disposition are not 80 percent depreciated as computed under the straight-line method, must be capitalized as a deferred charge and amortized as follows:

(A) If the State Health Planning and Development Agency (SHPDA) designated under section 1521 of the Public Health Service Act approves the demolition or abandonment of a depreciable asset as being consistent with the health systems plan of the health service area in which the provider is located, the net loss realized shall be capitalized as a deferred charge and amortized over the remaining life of the demolished or abandoned asset, or at the rate of $5,000 per year, whichever is greater. If no SHPDA exists or if such agency is unable or unwilling to perform this function, the provider must submit a request for approval to the contractor. The contractor, after reviewing this request and before issuing the approval, will submit the request along with its recommendation to the appropriate Regional Office for its approval.

(B) If a provider fails to obtain approval as specified in paragraph (f)(5)(iv)(A) of this section, a loss is not allowable unless the demolished or abandoned asset is replaced. If the asset is replaced, the loss resulting from the unapproved demolition or abandonment must be capitalized as a deferred charge and amortized over the estimated useful life of the replacement asset or at the rate of $5,000 per year, whichever is greater.

(v) If a loss resulting from the demolition or abandonment is deferred and amortized and the provider terminates

its participation in the Medicare program or ceases to use a replacement asset in the provision of patient care services, the unamortized deferred charge remaining at that time must not be included in determining allowable cost under the Medicare program.

(vi) Losses on demolition must include the demolition cost incurred by the provider for razing and removal of the asset, less any salvage value recovered by the provider. However, if a provider demolishes a depreciable asset for the purpose of preparing land for future sale, the net demolition cost incurred by the provider (razing and removal costs less salvage recovered) is considered a capital expenditure and added to the historical basis of the land.

(vii) If a provider purchases land on which there is a building, no depreciation will be allowed under the Medicare program unless the building is used in providing patient care. If the building is demolished, the entire purchase price and demolition cost shall be considered the historical cost of the land. If the building is used for patient care, but demolished within 5 years of purchase, the entire purchase price, less allowed depreciation, plus demolition cost will be considered the historical cost of the land.

(6) *Involuntary conversion.* (i) Losses resulting from the involuntary conversion of depreciable assets, such as condemnation, fire, theft, or other casualty, are generally included in the determination of allowable cost on a deferred basis if the asset is restored or replaced. However, losses resulting from a provider's imprudent management of its depreciable assets, such as the failure to obtain proper insurance coverage, are not included in the determination of allowable cost.

(ii) The net allowable loss from involuntary conversion must consist of the undepreciated cost of unrecovered book value of the asset, less amounts received from insurance proceeds gifts, and grants received from local, State, or Federal government, or any other source as a result of the involuntary conversion.

(iii) If the asset is replaced and the net allowable loss in any cost-reporting period does not exceed $5,000, the entire amount must be included in allowable cost in the period in which the loss is incurred. If the asset is replaced and the net allowable loss in any cost-reporting period exceeds $5,000, the loss must be capitalized as a deferred charge and amortized over the useful life of the replacement or restored asset. If a replaced or restored asset ceases to be used in the provision of patient care services or the provider terminates its participation in the Medicare program, the unamortized deferred charge remaining at that time will not be included in determining allowable cost under the Medicare program.

(iv) If the provider fails to replace or restore an involuntarily converted asset, the loss is not included in determining allowable cost. However, if the provider intends to replace or restore the asset but is unable to do so because the designated SHPDA finds such replacement or restoration to be inconsistent with the health systems plan of the provider's health service area, the loss is allowable so long as the provider continues to participate in Medicare. In this case, the loss must be capitalized as a deferred charge and amortized over the remaining life of the involuntarily converted asset, or at the rate of $5,000 per year, whichever is greater.

(v) If a gain is realized from an involuntary conversion of depreciable assets, the net amount realized reduces the basis of the restored or replacement asset. If the asset is not restored or replaced, the gain is to be treated in accordance with paragraph (f)(2) of this section.

(7) *Effect on equity capital.* The unrecovered loss entered on the books of the provider as a deferred charge, in accordance with paragraphs (f) (5) and (6) of this section, is not includable in the computation of equity capital under § 413.157.

(8) *Sale of replacement or restored assets.* If a provider sells a replacement or restored asset while participating in the Medicare program or within 1 year immediately following the date on which it terminates its participation in the Medicare program, the unrecovered loss entered on the books of the provider as a deferred charge in accordance with paragraphs (f) (5) and (6) of

this section will not be included in determining the gain or loss realized from the sale of the replacement or restored asset. However, if the sale of such asset is made to a related organization, as defined in §413.17, and the purchasing organization continues as a provider in the Medicare program, the remaining deferred charge representing the unrecovered depreciable basis of the demolished, abandoned or destroyed asset must continue to be amortized over the remaining expected useful life of the replacement or restored asset. If the sale is made to an unrelated organization, further amortization of the deferred charge is not allowed.

(g) *Establishment of cost basis on purchase of facility as an ongoing operation*—(1) *Assets acquired after July 1, 1966 and before August 1, 1970.* The cost basis for the assets of a facility purchased as an ongoing operation after July 1, 1966, and before August 1, 1970, is the lowest of the—

(i) Total price paid for the facility by the purchaser, as allocated to the individual assets of the facility;

(ii) Total fair market value of the facility at the time of the sale, as allocated to the individual assets; or

(iii) Combined fair market value of the individually identified assets at the time of the sale.

(2) *Assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984.* For depreciable assets acquired after July 31, 1970 and, for hospitals and SNFs, before July 18, 1984, in addition to the limitations specified in paragraph (g)(1) of this section, the cost basis of the depreciable assets may not exceed the current reproduction cost depreciated on a straight-line basis over the life of the asset to the time of the sale.

(3) *Assets acquired by hospitals and SNFs on or after July 18, 1984 and not subject to an enforceable agreement entered into before that date.* Subject to paragraphs (b)(1)(ii) (B) through (G) and (b)(1)(iii) of this section, historical cost may not exceed the lowest of the following:

(i) The allowable acquisition cost of the asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of July 18, 1984, the first owner of record of the asset);

(ii) The acquisition cost to the new owner; or

(iii) The fair market value of the asset on the date of acquisition.

(4) *Assets acquired by all providers on or after December 1, 1997.* Subject to the provisions of paragraph (b)(1)(i)(A) of this section, the historical cost may not exceed the historical cost of the asset, as recognized under the Medicare program, less depreciation allowed, to the owner of record as of August 5, 1997 (or for an asset not in existence as of August 5, 1997, the first owner of record after August 5, 1997).

(5) *Transactions other than bona fide.* If the purchaser cannot demonstrate that the sale was bona fide, in addition to the limitations specified in paragraph (g)(1), (2), and (3) of this section, the purchaser's cost basis may not exceed the seller's cost basis, less accumulated depreciation.

(h) *Sale and leaseback agreements and other lease transactions.* (1) For sale and leaseback agreements for all providers, and for sale and leaseback agreements for hospitals and SNFs entered into before October 23, 1992, a provider may include in its allowable costs incurred rental charges, as specified in a sale and leaseback agreement with a nonrelated purchaser involving plant facilities or equipment, only if—

(i) The rental charges are reasonable based on consideration of rental charges of comparable facilities and market conditions in the area; the type, expected life, condition, and value of the facilities or equipment rented; and other provisions of the rental agreement;

(ii) Adequate alternate facilities or equipment that would serve the purpose are not or were not available at lower cost; and

(iii) The leasing was based on economic and technical considerations.

(2) If the conditions of paragraph (h)(1) of this section are not met, the amount a provider may include in its allowable costs as rental or lease expense under a sale and leaseback agreement may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or

equipment such as interest expense on mortgages, taxes, depreciation, and insurance costs.

(3) For hospitals and SNFs entering into sale and leaseback agreements on or after October 23, 1992, the amount a provider may include in its allowable costs as rental or lease expense may not exceed the amount that the provider would have included in its allowable costs had the provider retained legal title to the facilities or equipment, such as interest expense on mortgages, taxes, depreciation, and insurance costs (the costs of ownership). This limitation applies both on an annual basis and over the useful life of the asset.

(i) If in the early years of the lease, the annual rental or lease costs are less than the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are more than the annual costs of ownership, in the years that the annual rental or lease costs are more than the costs of ownership the provider may include in allowable costs annually the actual amount of rental or lease costs. The aggregate rental or lease costs included in allowable costs may not exceed the aggregate costs of ownership that would have been included in allowable costs over the useful life of the asset had the provider retained legal title to the asset.

(ii) If in the early years of the lease, the annual rental or lease costs exceed the annual costs of ownership, but in the later years of the lease the annual rental or lease costs are less than the annual costs of ownership, the provider may carry forward amounts of rental or lease costs that were not included in allowable costs in the early years of the lease due to the costs of ownership limitation, and include these amounts in allowable costs in the years of the lease when the annual rental or lease costs are less than the annual costs of ownership. In any given year the amount of actual annual rental or lease costs plus the amount carried forward to that year may not exceed the amount of the costs of ownership for that year.

(iii) In the aggregate, the amount of rental or lease costs included in allowable costs may not exceed the amount of the costs of ownership that the provider could have included in allowable costs had the provider retained legal title to the asset.

(4) For lease transactions of all providers entered into before October 23, 1992, a lease that meets the following conditions establishes a virtual purchase:

(i) The rental charge exceeds rental charges of comparable facilities or equipment in the area.

(ii) The term of the lease is less than the useful life of the facilities or equipment.

(iii) The provider has the option to renew the lease at a significantly reduced rental, or the provider has the right to purchase the facilities or equipment at a price that appears to be significantly less than what the fair market value of the facilities or equipment would be at the time acquisition by the provider is permitted.

(5)(i) If a lease is a virtual purchase under paragraph (h)(4) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the cost of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost in this paragraph, a provider may not include accelerated depreciation.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and must be capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time

at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(6) For lease transactions entered into on or after October 23, 1992, a lease that meets any one of the following conditions establishes a virtual purchase:

(i) The lease transfers title of the facilities or equipment to the lessee during the lease term.

(ii) The lease contains a bargain purchase option.

(iii) The lease term is 75 percent or more of the useful life of the facilities or equipment. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment.

(iv) The present value of the minimum lease payments (that is, payments to be made during the lease term, including bargain purchase option, guaranteed residual value, or penalties for failure to renew) equals 90 percent or more of the fair market value of the leased property. This provision is not applicable if the lease begins in the last 25 percent of the useful life of the facilities or equipment. The present value is computed using the lessee's incremental borrowing rate, unless the interest rate implicit in the lease is known and is less than the lessee's incremental borrowing rate, in which case, the interest rate implicit in the lease is used.

(7)(i) If a lease is a virtual purchase under paragraph (h)(6) of this section, the rental charge is includable in allowable costs only to the extent that it does not exceed the amount that the provider would have included in allowable costs if it had legal title to the asset (the costs of ownership), such as straight-line depreciation, insurance, and interest. For purposes of computing the limitation on allowable rental cost as described in this paragraph, a provider may not include accelerated depreciation in its allowable costs.

(ii) The difference between the amount of rent paid and the amount of rent allowed as rental expense is considered a deferred charge and is capitalized as part of the historical cost of the asset when the asset is purchased.

(iii) If an asset is returned to the owner instead of being purchased, the deferred charge may be expensed in the year the asset is returned.

(iv) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase still exists, the deferred charge may be expensed to the extent of increasing the reduced rental to an amount not in excess of the cost of ownership.

(v) If the term of the lease is extended for an additional period of time at a reduced lease cost and the option to purchase no longer exists, the deferred charge may be expensed to the extent of increasing the reduced rental to a fair rental value.

(vi) If the lessee becomes the owner of the leased asset (either by operation of the lease or by other means), the amount considered as depreciation, for the purpose of having computed the limitation expressed in paragraph (h)(7)(i) of this section, must be used in calculating the limitation on adjustments to depreciation for the purpose of determining any gain or loss upon disposal of an asset under paragraph (f) of this section.

(i) *Intergovernmental transfer of facilities.* The basis for depreciation of assets transferred under appropriate legal authority from one governmental entity to another is as follows:

(1) The historical cost incurred by the present owner in acquiring the asset under a bona fide sale. The historical cost may not exceed the lower of current reproduction cost adjusted for straight-line depreciation over the life of the asset to the time of the purchase of fair market value at the time of the purchase.

(2) The fair market value at the time of donation under a bona fide donation of the asset (subject to the limitations set forth under paragraph (i) of this section). An asset is considered donated when a governmental entity acquires the asset without assuming the functions for which the transferor used the asset or making any payment for it in the form of cash, property, or services.

(3) If neither paragraph (h) (1) nor (2) of this section applies, for example, the transfer was solely to facilitate administration or to reallocate jurisdictional responsibility, or the transfer constituted a taking over in whole or in part of the function of one governmental entity by another governmental entity, the basis for depreciation is—

(i) With respect to an asset on which the transferor has claimed depreciation under the Medicare program, the transferor's basis under the Medicare program prior to the transfer. The method of depreciation used by the transferee may be the same as that used by the transferor, or the transferee may change the method, as permitted under paragraph (d)(2) of this section; or

(ii) With respect to an asset on which the transferor has not claimed depreciation under the Medicare program, the cost incurred by the transferor in acquiring the asset (not to exceed the basis that would have been recognized had the transferor participated in the Medicare program) less depreciation calculated on the straight-line basis over the life of the asset to the time of transfer.

(j) *Basis of assets donated to a provider*—(1) Assets not used or depreciated under the Medicare program. If an asset has never been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the fair market value of the asset at the time of donation.

(2) *Assets used or depreciated under the Medicare program.* If an asset has been used or depreciated under the Medicare program and is donated to a provider, the basis for the purpose of calculating depreciation and equity capital (if applicable) is the lesser of—

(i) The fair market value at the time of donation; or

(ii) The net book value in the hands of the owner last participating in the Medicare program.

(3) *Transfers of State hospitals to nonprofit corporations without monetary consideration.* If a State transfers a hospital to a nonprofit corporation without monetary consideration on or after July 18, 1984, the depreciable basis of the assets to the new owner is the net book value of the assets as recorded on the State's books at the time of the transfer. For purposes of this section, monetary consideration includes cash, new debt, and assumed debt.

(k) *Transactions involving a provider's capital stock*—(1) *Acquisition of capital stock of a provider.* If the capital stock of a provider is acquired, the provider's assets may not be revalued. For example, if Corporation A purchases the capital stock of Corporation B, the provider, Corporation B continues to be the provider after the purchase and Corporation A is merely the stockholder. Corporation B's assets may not be revalued.

(2) *Statutory merger.* A statutory merger is a combination of two or more corporations under the corporation laws of the State, with one of the corporations surviving. The surviving corporation acquires the assets and liabilities of the merged corporation(s) by operation of State law. The effect of a statutory merger upon Medicare reimbursement is as follows:

(i) *Statutory merger between unrelated parties.* If the statutory merger is between two or more corporations that are unrelated (as specified in § 413.17), the assets of the merged corporation(s) acquired by the surviving corporation may be revalued in accordance with paragraph (g) of this section. If the merged corporation was a provider before the merger, then it is subject to the provisions of paragraphs (d)(3) and (f) of this section concerning recovery of accelerated depreciation and the realization of gains and losses. The basis of the assets owned by the surviving corporation are unaffected by the transaction. An example of this type of transaction is one in which Corporation A, a nonprovider, and Corporation B, the provider, are combined by a statutory merger, with Corporation A being the surviving corporation. In such a case the assets of Corporation B acquired by Corporation A may be revalued in accordance with paragraph (g) of this section.

(ii) *Statutory merger between related parties.* If the statutory merger is between two or more related corporations (as specified in § 413.17), no revaluation of assets is permitted for those assets

acquired by the surviving corporation. An example of this type of transaction is one in which Corporation A purchase the capital stock of Corporation B, the provider. Immediately after the acquisition of the capital stock of Corporation B, there is a statutory merger of Corporation B and Corporation A, with Corporation A being the surviving corporation. Under these circumstances, at the time of the merger the transaction is one between related parties and is not a basis for revaluation of the provider's assets.

(3) *Consolidation.* A consolidation is the combination of two or more corporations resulting in the creation of a new corporate entity. If at least one of the original corporations is a provider, the effect of a consolidation upon Medicare reimbursement for the provider is as follows:

(i) *Consolidation between unrelated parties.* If the consolidation is between two or more corporations that are unrelated (as specified in §413.17), the assets of the provider corporation(s) may be revalued in accordance with paragraph (g) of this section.

(ii) *Consolidation between related parties.* If the consolidation is between two or more related corporations (as specified in §413.17), no revaluation of provider assets is permitted.

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43456, Aug. 30, 1991; 57 FR 3017, Jan. 27, 1992; 57 FR 39830, Sept. 1, 1992; 57 FR 43919, Sept. 23, 1992; 58 FR 17528, Apr. 5, 1993; 59 FR 45401, Sept. 1, 1994; 63 FR 1382, Jan. 9, 1998; 65 FR 8662, Feb. 22, 2000; 82 FR 38515, Aug. 14, 2017]

§413.139 Depreciation: Optional allowance for depreciation based on a percentage of operating costs.

(a) *Principle.* With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the provider's 1965 operating costs or the provider's current year's allowable costs, whichever are the lower. The percentage to be applied is 5 percent starting with the year 1966–67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965; however, if the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the straight-line depreciation on assets acquired after 1965 (including the estimated depreciation on assets held on a rental basis during the current year) may not exceed 6 percent of the provider's allowable cost for the current year.

(b) *Definitions*—(1) *Operating costs.* Operating costs are the total costs incurred by the provider in operating the institution or facility.

(2) *Allowable costs.* Allowable costs are the costs of a provider that are includable under the principles for cost reimbursement. Through application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost that is attributable to covered services for beneficiaries is determined.

(c) *Application.* If a provider has inadequate historical cost records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has records of the cost of pre-1966 depreciable assets currently in use.

(d) *Allowance based on a percentage of operating costs.* (1) The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles or the current year's allowable operating costs, whichever is lower. The percentage to be applied is five for the reporting period that starts before or during 1966–67, four and one-half for the reporting period that begins during 1967–68, and continues to decline annually by equal amounts to become zero in 1976–77.

(2) If used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs,

or return on equity capital. Such exclusions are to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs of services furnished to Medicare beneficiaries during the reporting period.

(e) *Change to actual depreciation.* (1) A provider that elects this allowance may at any time before 1976 change to actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

(2) If the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost may be made through appropriate means involving expert consultation with the determination being subject to review and approval by the contractor.

(f) *Determination of optional allowance based on percentage of operating costs illustrated.* The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Example No. 1. The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets. The current year's allowable cost also does not include any allowance in lieu of specific recognition of other costs or return on equity capital.

YEAR 1966

Current year's allowable cost	$1,100,000
Operating cost for 1965 [1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

YEAR 1967

Current year's allowable cost	$1,200,000
Operating cost for 1965 [1]	$1,000,000
Percent for determining the allowance [2]	5
Allowance	$50,000

[1] 1965 Operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

[2] Since the reporting period began during the year 1966–1967 (July 1, 1966–June 30, 1967) 5 percent is the percentage to be used.

YEAR 1968

Operating cost for 1965	$1,000,000
Current year's allowable cost [1]	$900,000
Percent for determining the allowance [2]	4½
Allowance	$40,500

[1] The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

[2] Since the reporting period began during the year 1967–1968 (July 1, 1967–June 30, 1968) 4½ percent is the percentage to be used.

Example No. 2. When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation, allowance in lieu of specific recognition of other costs, or return on equity capital. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

YEAR 1966

Adjusted current year's allowable cost	$1,100,000
Adjusted operating cost for 1965 [1]	$1,000,000
Percent for determining the allowance	5
Allowance	$50,000
Less estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966	$3,000
Adjusted allowance	$47,000

[1] 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

(g) *Limitation on depreciation if optional allowance is used.* This optional allowance only is subject to a limitation based on the provider's total allowable operating cost for the current year. To determine this limitation, compute the sum of the actual depreciation claimed, the allowance based on a percentage of operating costs, and the estimated straight-line depreciation on depreciable-type assets rented after 1965. If this sum exceeds six percent of the provider's current year's allowable cost (exclusive of any actual

depreciation claimed, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital), the allowance for depreciation based on a percentage of operating costs is reduced by the amount of excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis, it must be converted to a straight-line basis only for use in calculating this limitation. It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation of six percent, as it affects the availability of the allowance, is designed as a safeguard if the presumption is not borne out. If the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the six percent limitation.

Example No. 1. The following illustration demonstrates how this limitation would be determined.

YEAR 1966

[The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation, the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.]

Adjusted operating cost for 1965	$1,000,000
Percent for determining the allowance	5
In 1966 assets were acquired which produce a straight-line depreciation of	$18,000
Estimated depreciation on assets rented in 1966	$2,000
Adjusted allowable operating cost for 1966	$1,100,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS

Gross allowance	
5 percent times adjusted 1965 operating costs ($1,000,000)	$50,000
Estimated depreciation on assets rented in 1966	2,000
Straight-line depreciation on post-1965 assets	18,000
Total	70,000
6 percent of adjusted 1966 allowable operating cost	66,000
Reduction in allowance	4,000
Allowance	50,000
Reduction	4,000
Adjusted allowance	46,000
Total depreciation allowance for 1966 ($18,000 actual depreciation plus $46,000 allowance based on operating cost)	64,000

Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was $3,500. In that case, it would include in its 1966 allowable cost not only the $46,000 allowance based on operating costs but also $36,000 (in this instance 2 × straight-line rate is used) in actual depreciation and the rental expense of $3,500—or a total of $85,500 covering all its depreciable assets.

§ 413.144 Depreciation: Allowance for depreciation on fully depreciated or partially depreciated assets.

(a) *Principle.* Depreciation on assets being used by a provider at the time it enters into the Medicare program is allowed. This principle applies even though such assets may be fully or partially depreciated on the provider's books.

(b) *Application.* Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the contractor. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method (§ 413.139), in which case the correction should be made at the time of discontinuing the use of that method. If an asset has become fully depreciated under Medicare, further depreciation is not appropriate or allowable, even though the asset may continue in use.

(c) *Example of an allowance for a fully-depreciated asset.* For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use

that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost.

(d) *Corrections to depreciation.* If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life. Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the contractor.

§ 413.149 Depreciation: Allowance for depreciation on assets financed with Federal or public funds.

(a) *Principle.* Depreciation is allowed on assets financed with Hill-Burton or other Federal or public funds.

(b) *Application.* Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in furnishing services. It is the function of payment of depreciation to provide funds that make it possible to maintain the assets and preserve the capital employed in the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the program, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation is not treated as a reduction of allowable interest expense under § 413.153(a).

§ 413.153 Interest expense.

(a)(1) *Principle.* Necessary and proper interest on both current and capital indebtedness is an allowable cost. However, interest costs are not allowable if incurred as a result of—

(i) Judicial review by a Federal court (as described in § 413.64(j));

(ii) An interest assessment on a determined overpayment (as described in § 405.377 of this chapter); or

(iii) Interest on funds borrowed to repay an overpayment (as described in § 413.64(j) or § 405.378 of this chapter), up to the amount of the overpayment, unless the provider had made a prior commitment to borrow funds for other purposes (for example, capital improvements).

(2) *Exception.* In those cases of administrative or judicial reversal, interest paid on funds borrowed to repay an overpayment is an allowable cost, in accordance with this section.

(b) *Definitions*—(1) *Interest.* Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

(2) *Necessary.* Necessary interest is interest that meets the following requirements:

(i) It is incurred on a loan made to satisfy a financial need of the provider. Loans that result in excess funds or investments are not considered necessary.

(ii) It is incurred on a loan made for a purpose reasonably related to patient care.

(iii) It is reduced by investment income except income from—

(A) Gifts, grants, and endowments, whether held separately or pooled with other funds;

(B) Funded depreciation that meets the program's qualifying criteria;

(C) The provider's qualified pension funds;

(D) The provider's deferred compensation funds that meet the program's qualifying criteria; and

(E) The provider's self-insurance trust funds that meet the program's qualifying criteria.

(iv) It is not reduced by interest received as a result of judicial review by

a Federal court (as described in §413.64(j)).

(3) *Proper.* Proper requires that interest be—

(i) Incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made; and

(ii) Paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds, the funded depreciation account, or the provider's qualified pension fund.

(4) *Zero coupon bonds.* Zero coupon bonds are issued by government agencies, corporations, and banks at a price substantially below the face value. The difference between the purchase price and the face value reflects the actual amount of interest and is neither a discount nor an adjustment to the interest rate as with other bonds. Interest is paid at maturity when the bond is redeemed at face value.

(c) *Borrower-lender relationship.* (1) Except as described in paragraph (c)(2) of this section, to be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the ''bargaining'' process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary loans. Loans should be made under terms and conditions that a prudent borrower would make in armslength transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable. Thus, interest paid by the provider to partners, stockholders, or related organizations of the provider would not be allowable. If the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds. Therefore, if interest on loans by partners, stockholders, or related organizations is disallowed as a cost solely because of the relationship factor, the principal of such loans is treated as invested funds in the computation of the provider's equity capital under §413.157.

(2) Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Interest on loans to providers by partners, stockholders, or related organizations made prior to July 1, 1966, is allowable as cost, provided that the terms and conditions of payment of such loans have been maintained in effect without modification subsequent to July 1, 1966. If the general fund of a provider ''borrows'' from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment is accorded interest paid by the general fund on money ''borrowed'' from the funded depreciation account of the provider or from the provider's qualified pension fund. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

(3) If funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment is accorded deposits in the provider's qualified pension fund if such deposits are used for other than the purpose for which the fund was established.

(d) *Loans not reasonably related to patient care.* (1) The following types of loans are not considered to be for a purpose reasonably related to patient care:

(i) For loans made to finance acquisition of a facility, that portion of the cost that exceeds—

(A) Historical cost as determined under §413.134(b); or

(B) The cost basis determined under §413.134(g); and

(ii) Loans made to finance capital stock acquisitions, mergers, or consolidations for which revaluation of assets is not allowed under §413.134(k).

(2) In determining whether a loan was made for the purpose of acquiring

a facility, we apply any owner's investment or funds first to the tangible assets, then to the intangible assets other than goodwill, and lastly to the goodwill. If the owner's investment or funds are not sufficient to cover the cost allowed for tangible assets, we apply funds borrowed to finance the acquisition to the portion of the allowed cost of the tangible assets not covered by the owner's investment, then to the intangible assets other than goodwill, and lastly to the goodwill. Repayments of the funds borrowed are applied first to the borrowing related to the tangible assets, then to the borrowing related to the intangible assets other than goodwill, and lastly to the borrowing related to the goodwill.

(3) When a provider borrows funds, but only some of the funds are necessary, repayments of the loan (principal and interest portions) are applied first to pay for the necessary portion of the loan. Only after all of the necessary portion of the loan (principal and interest) has been repaid are any repayments applied to the unnecessary portion of the loan. Repayments toward non-allowable borrowing pertaining to assets or activities not related to patient care are considered investments, and the provisions of paragraph (b)(2)(iii) of this section are applied.

(e) *Zero coupon bonds*—(1) *Interest on bonds issued on or after August 15, 1996.* For zero coupon bonds issued on or after August 15, 1996, interest expense incurred to provide funds for patient care-related costs is an allowable expense, and interest income earned for investment purposes is an allowable offset, in the cost reporting period in which the interest accrues.

(2) *Interest income offset.* Interest income from zero coupon bonds must be offset against allowable interest expense as prescribed in paragraph (b)(2) of this section and in §413.130(g)(2). If zero coupon bonds are purchased with the proceeds of an advanced refunding of debt, offset of the investment income is required under §413.153(b)(2)(iii), but the investment income is not prorated under §413.130(g)(2).

(3) *Use of effective interest method.* (i) Interest expense and interest income from zero coupon bonds that are reported as they accrue must be amortized using the effective interest method. This method recognizes the actual accrual of interest expense or income for each interest computation period (as specified by the bond instrument) throughout the life of the bond.

(ii) A constant effective yield rate is determined and applied to the book value (outstanding loan balance including prior accrued interest) of the bond at the beginning of each period to determine the total interest for the period.

(iii) If the interest computation period involves portions of more than one cost reporting period, the amount of interest for that computation period shall be apportioned to each cost reporting period.

(iv) An example of the computation of interest using the effective interest method follows:

Facts

Life of zero coupon bond: 15 years.

Value at maturity: $50,000.

Bondholder pays $6,996 for the bond.

Annual interest rate is 13.5506% compounded semi-annually.

From the table below, interest for the first year would be $980.11 ($474.00 plus $506.11).

Col 1 Six-month periods	Col 2 Book value beginning of period	Col. 3 Effective interest*	Col. 4 Book value end of period (columns 2 + 3)
1	$6,996.00	$474.00	$7,470.00
2	7,470.00	506.11	7,976.11
3	7,976.11	540.40	8,516.51
4	8,516.51	577.02	9,093.53
29	43,855.94	2,971.37	46,827.31
30	46,827.31	3,172.69	50,000.00

*Computed by multiplying the book value at the beginning of each period (Column 2) by 6.7753% (the annual interest rate of 13.5506% 2 = 6.7753%).

[51 FR 34793, Sept. 30, 1986, as amended at 56 FR 43457, Aug. 30, 1991; 59 FR 45402, Sept. 1, 1994; 61 FR 37014, July 16, 1996; 61 FR 63748, 63479, Dec. 2, 1996; 65 FR 8662, Feb. 22, 2000]

§ 413.157 Return on equity capital of proprietary providers.

(a) *Definitions.* For purposes of this section—

Proprietary provider means a provider that is organized and operated with the expectation of earning a profit for its

owners (as distinguished from a provider that is organized and operated on a nonprofit basis). Proprietary providers may be sole proprietorships, partnerships, or corporations. Effective for cost reporting periods beginning on or after July 6, 1987, the term applies only to proprietary hospitals and SNFs.

(b) *General rule.* A reasonable return on equity capital invested and used in the provision of patient care is paid as an allowance in addition to the reasonable cost of covered services furnished to beneficiaries by proprietary providers.

(1) *Rate of return applicable to proprietary providers for cost reporting periods beginning before July 6, 1987.* Except as provided in paragraphs (b)(2), (b)(3), and (b)(4) of this section, the amount allowable on an annual basis, for cost reporting periods beginning before July 6, 1987, is determined by multiplying the provider's equity capital by a percentage equal to one and one-half times the average of the rates of interest on special issues of public debt obligations issued for purchase by the Medicare Part A Trust Fund for each of the months during the provider's reporting period or portion thereof covered under the program.

(2) *Rate of return for inpatient hospital services furnished by proprietary hospitals.* The rate used in determining the return for inpatient hospital services is a percentage of the average of the rates of interest described in paragraph (b)(1) of this section. The percentages applicable to inpatient hospital services are as follows:

(i) 150 percent for cost reporting periods beginning before April 20, 1983.

(ii) 100 percent for cost reporting periods beginning on or after April 20, 1983 and before October 1, 1986.

(iii) 75 percent for cost reporting periods beginning on or after October 1, 1986 and before October 1, 1987.

(iv) 50 percent for cost reporting periods beginning on or after October 1, 1987 and before October 1, 1988.

(v) 25 percent for cost reporting periods beginning on or after October 1, 1988 and before October 1, 1989.

(vi) Zero percent for cost reporting periods beginning on or after October 1, 1989.

(3) *Rate of return related to proprietary SNFs.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for SNF services furnished before October 1, 1993, is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for SNF services furnished on or after October 1, 1993.

(4) *Rate of return related to outpatient hospital services.* (i) For cost reporting periods beginning on or after October 1, 1985, the rate used in determining the return for outpatient hospital services furnished before January 1, 1988 is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) There is no allowance for return for outpatient hospital services furnished on or after January 1, 1988.

(5) *Rate of return for proprietary services of all nonhospital and non-SNF providers.* (i) For cost reporting periods beginning on or after October 1, 1985, but before July 6, 1987, the rate used in determining the return for services of all nonhospital and non-SNF providers is a percentage equal to the average of the rates of interest described in paragraph (b)(1) of this section.

(ii) For cost reporting periods beginning on or after July 6, 1987, there is no allowance for return on equity capital for nonhospital and non-SNF providers.

(c) *Application*—(1) *Computation of equity capital.* For purposes of computing the allowable return, the provider's equity capital means—

(i) The provider's investment in plant, property, and equipment related to patient care (net of depreciation) and funds deposited by a provider who leases plant, property, or equipment related to patient care and is required by the terms of the lease to deposit such funds (net of noncurrent debt related to such investment or deposited funds); and

(ii) Net working capital maintained for necessary and proper operation of patient care activities. However, debt representing loans from partners, stockholders, or related organizations on which interest payments would be

allowable as costs but for the provisions of § 413.153(b)(3)(ii), is not subtracted in computing the amount of equity capital in order that the proceeds from such loans be treated as part of the provider's equity capital. In computing the amount of equity capital upon which a return is allowable, investment in facilities is recognized on the basis of the historical cost, or other basis, used for depreciation and other purposes under Part A of Medicare.

(2) *Acquisitions after July 1970.* With respect to a facility or any tangible assets of a facility acquired on or after August 1, 1970, the excess of the price paid for such facility or such tangible assets over the historical cost, as defined in § 413.134(b), or the cost basis, as determined under § 413.134(g) (whichever is appropriate), is not includable in equity capital, and loans made to finance such excess portion of the cost of such acquisitions (see § 413.153(d)) are excluded in computing equity capital.

(3) *Acquisitions prior to August 1970.* With respect to a facility or any tangible assets of a facility acquired before August 1970, the excess of the price paid for such facility or assets over the fair market value of tangible assets at the time of purchase is includable in equity capital to the extent that it is reasonable except that the cumulative allowable return for such excess may not exceed 100 percent of such excess. For purposes of this section, the cumulative allowable return means the sum of the allowable rate of return on equity capital for all months starting from August 1, 1970. For example, if the allowable rates of return on equity capital for a provider are 9 percent for the first year (and such year started August 1, 1970), 8.5 percent for the second year, and 10.5 percent for the third year, the cumulative allowable return at the end of the third year would be 28 percent. After the cumulative allowable return equals 100 percent, the inclusion in equity capital of the excess is no longer allowable.

(4) *Computation of return on equity capital.* For purposes of computing the allowable return, the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to time based upon interest rates in accordance with this principle, is determined by CMS and communicated through contractors. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs.

Example of calculation of cumulative allowable return. X purchased a provider on July 1, 1969, paying $100,000 in excess f the fair market value of the assets acquired. Provider X files its cost report on a calendar-year basis. The allowable rate of return on equity capital for August 1, 1970-December 31, 1970 (4.538 percent), is obtained by multiplying the allowable rate of return for the period ending December 31, 1970 (10.891) by 5/12 (a fraction of which the numerator is the number of months from August 1, 1970, to the end of the cost-reporting period and the denominator is the number of months in the cost-reporting period). The cumulative allowable return for Provider X for the period August 1, 1970-December 31, 1973, (32.367 percent) is computed as follows:

Cost reporting year ending	Rate of return on equity capital (percent)
Dec. 31, 1970	4.538
Dec. 31, 1971	8.969
Dec. 31, 1972	8.891
Dec. 31, 1973	9.969
Total	32.367

(The $100,000 paid in excess of the fair market value of the assets acquired is included in equity capital until the sum of the allowable rate of return on equity capital equals 100 percent. Of course, no portion of the $100,000 may be amortized as an allowable cost or is otherwise allowable for any program reimbursement purposes other than for determining the provider's equity capital.

[51 FR 34793, Sept. 30, 1986, as amended at 52 FR 21225, June 4, 1987; 52 FR 23398, June 19, 1987; 52 FR 32921, Sept. 1, 1987; 53 FR 12017, Apr. 12, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 26960, May 25, 1994]

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

SOURCE: 62 FR 43668, Aug. 15, 1997, as amended at 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

§413.170 Scope.

This subpart implements sections 1881(b)(2), (b)(4), (b)(7), and (b)(12) through (b)(14) of the Act by—

(a) Setting forth the principles and authorities under which CMS is authorized to establish a prospective payment system for outpatient maintenance dialysis services in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in §413.171(c).

(b) Providing procedures and criteria under which a pediatric ESRD facility (an ESRD facility with at least a 50 percent pediatric patient mix as specified in §413.184 of this subpart) may receive an exception to its prospective payment rate prior to January 1, 2011; and

(c) Establishing procedures that a facility must follow to appeal its payment amount under the prospective payment system.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§413.171 Definitions.

For purposes of this subpart, the following definitions apply:

Base rate. The average payment amount per-treatment, standardized to remove the effects of case-mix and area wage levels and further reduced for budget neutrality and the outlier percentage. The base rate is the amount to which the patient-specific case-mix adjustments and any ESRD facility adjustments, if applicable, are applied.

Composite Rate Services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.

ESRD facility. An ESRD facility is an independent facility or a hospital-based provider of services (as described in §413.174(b) and (c) of this chapter), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in §494.10 of this chapter and meets the supervision requirements described in part 494 of this chapter, and that furnishes institutional dialysis services and supplies under §410.50 and §410.52 of this chapter.

New ESRD facility. A new ESRD facility is an ESRD facility (as defined above) that is certified for Medicare participation on or after January 1, 2011.

Pediatric ESRD Patient. A pediatric ESRD patient is defined as an individual less than 18 years of age who is receiving renal dialysis services.

Renal dialysis services. Effective January 1, 2011, the following items and services are considered ''renal dialysis services,'' and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:

(1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;

(2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;

(3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.

(5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

Separately billable items and services. Items and services used in the provision of outpatient maintenance dialysis for the treatment of individuals with ESRD that were or would have been, prior to January 1, 2011, separately payable under Title XVIII of the Act and not included in the payment systems established under section 1881(b)(7) and section 1881(b)(12) of the Act.

[75 FR 49198, Aug. 12, 2010]

§ 413.172 Principles of prospective payment.

(a) Payment for renal dialysis services as defined in § 413.171 and home dialysis services as defined in § 413.217 of this chapter are based on payment rates set prospectively by CMS.

(b) All approved ESRD facilities must accept the prospective payment rates established by CMS as payment in full for covered renal dialysis services as defined in § 413.171 or home dialysis services. Approved ESRD facility means—

(1) Any independent ESRD facility or hospital-based provider of services (as defined in § 413.174(b) and § 413.174(c) of this part) that has been approved by CMS to participate in Medicare as an ESRD supplier; or

(2) Any approved independent facility with a written agreement with the Secretary. Under the agreement, the independent ESRD facility agrees—

(i) To maintain compliance with the conditions for coverage set forth in part 494 of this chapter and to report promptly to CMS any failure to do so; and

(ii) Not to charge the beneficiary or any other person for items and services for which the beneficiary is entitled to have payment made under the provisions of this part.

(c) CMS publishes the methodology used to establish payment rates and the changes specified in § 413.196(b) in the FEDERAL REGISTER.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 75 FR 49198, Aug. 12, 2010]

§ 413.174 Prospective rates for hospital-based and independent ESRD facilities.

(a) *Establishment of rates.* CMS establishes prospective payment rates for ESRD facilities using a methodology that—

(1) Differentiates between hospital-based providers of services and independent ESRD facilities for items and services furnished prior to January 1, 2009;

(2) Does not differentiate between hospital-based providers of services and independent ESRD facilities for items and services furnished on or after January 1, 2009; and

(3) Requires the labor share be based on the labor share otherwise applied to independent ESRD facilities when applying the geographic index to hospital-based ESRD providers of services, on or after January 1, 2009.

(b) *Determination of independent facility.* For purposes of rate-setting and payment under this section, CMS considers any facility that does not meet all of the criteria of a hospital-based facility to be an independent facility. A determination under this paragraph (b) is an initial determination under § 498.3 of this chapter.

(c) *Determination of hospital-based facility.* A determination under this paragraph (c) is an initial determination under § 498.3 of this chapter. CMS determines that a facility is hospital-based if the—

(1) Facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;

(2) Facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through him or her to the governing board;

(3) Facility personnel policies and practices conform to those of the hospital;

(4) Administrative functions of the facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

(5) Facility and hospital are financially integrated, as evidenced by the cost report, which reflects allocation of overhead to the facility through the required step-down methodology.

(d) *Nondetermination of hospital-based facility.* In determining whether a facility is hospital-based, CMS does not consider—

(1) An agreement between a facility and a hospital concerning patient referral;

(2) A shared service arrangement between a facility and a hospital; or

(3) The physical location of a facility on the premises of a hospital.

(e) *Add-on amounts.* If all the physicians furnishing services to patients in an ESRD facility elect the initial method of payment (as described in §414.313(c) of this chapter), the prospective rate (as described in paragraph (a) of this section) paid to that facility is increased by an add-on amount as described in §414.313.

(f) *Additional payment for separately billable drugs and biologicals.* Prior to January 1, 2011, CMS makes additional payment directly to an ESRD facility for certain ESRD-related drugs and biologicals furnished to ESRD patients.

(1) Only on an assignment basis, directly to the facility which must accept, as payment in full, the amount that CMS determines;

(2) Subject to the Part B deductible and coinsurance;

(3) For drugs furnished prior to January 1, 2006, payment is made to hospital-based ESRD providers of services on a reasonable cost basis. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs furnished by a hospital-based ESRD provider of service is based on the methodology specified in §414.904 of this chapter.

(4) For drugs furnished prior to January 1, 2006, payment is made to independent ESRD facilities based on the methodology specified in §405.517 of this chapter. Effective January 1, 2006, and prior to January 1, 2011, payment for drugs and biological furnished by independent ESRD facilities is based on the methodology specified in §414.904 of this chapter.

(5) Effective January 1, 2011, except as provided below, payment to an ESRD facility for renal dialysis service drugs and biologicals as defined in §413.171, furnished to ESRD patients on or after January 1, 2011 is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

(6) Effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in §413.230 and separate payment will no longer be provided.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70330, Nov. 21, 2005; 73 FR 69935, Nov. 19, 2008; 75 FR 49198, Aug. 12, 2010; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015]

§413.176 Amount of payments.

For items and services, for which payment is made under section 1881(b)(7), section 1881(b)(12), and section 1881(b)(14) of the Act:

(a) If the beneficiary has incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, Medicare pays the ESRD facility 80 percent of its prospective rate.

(b) If the beneficiary has not incurred the full deductible applicable under Part B of Medicare before the dialysis treatment, CMS subtracts the amount applicable to the deductible from the ESRD facility's prospective rate and pays the facility 80 percent of the remainder, if any.

[75 FR 49199, Aug. 12, 2010]

§413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under §413.171, except for those renal dialysis services furnished during payment year 2022, in the case of an ESRD facility that does not earn enough points under the program described at §413.178 to meet or exceed the minimum total performance score (as defined at §413.178(a)(8)) established by CMS for a payment year (as defined at §413.178(a)(10)), payments otherwise made to the facility under §413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

(1) For every 10 points that the total performance score (as defined at §413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

(2) [Reserved]

(b) Any payment reduction will apply only to the payment year involved and will not be taken into account in computing the single payment amount

under this subpart for services provided in a subsequent payment year.

[76 FR 646, Jan. 5, 2011, as amended at 83 FR 57068, Nov. 14, 2018; 86 FR 62020, Nov. 8, 2021]

§ 413.178 ESRD quality incentive program.

(a) *Definitions.* As used in this section:

(1) *Achievement threshold* means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.

(2) *Baseline period* means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.

(3) *Benchmark* means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment year.

(4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (e)(1)(i) through (v) of this section.

(5) *End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)* means the program authorized under section 1881(h) of the Social Security Act.

(6) *ESRD facility* means an ESRD facility as defined in § 413.171.

(7) *Improvement threshold* means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year except payment year 2023, the total performance score that an ESRD facility would receive if it performed at the 50th percentile of national ESRD facility performance on all clinical measures during the baseline period, and it performed at the median of national ESRD facility performance on all reporting measures using data from the most recently available year before the performance period.

(9) *Payment reduction* means the reduction, as specified by CMS, to each payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.

(10) *Payment year* means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.

(11) *Performance period* means the time period during which data are collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment year.

(12) *Performance standards* are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) *Reporting measure* means a measure that is scored for a payment year using the methodology described in paragraph (e)(1)(vi) of this section.

(14) *Total performance score (TPS)* means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment year.

(b) *Applicability of the ESRD QIP.* The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number (CCN) effective date.

(c) *ESRD QIP measure selection, retention, and removal*—(1) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include:

(i) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management;

(ii) Measures on dialysis adequacy;

(iii) To the extent feasible, a measure (or measures) of patient satisfaction;

(iv) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula);

(v) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based; and

(vi) Other measures that CMS specifies.

(2) *Use of endorsed measures*—(i) *General rule.* Measures specified by CMS under paragraph (c)(1) of this section will be endorsed by the entity with a contract under section 1890(a) of the Social Security Act, unless the exception in paragraph (c)(2)(ii) of this section applies.

(ii) *Exception.* CMS may specify a measure under paragraph (c)(1) of this section that does not meet the requirement in paragraph (c)(2)(i) of this section if:

(A) CMS has determined that a specified area or medical topic is appropriate for inclusion in the ESRD QIP;

(B) CMS has not identified a feasible and practical measure with respect to that specified area or medical topic that has been endorsed by the entity with a contract under section 1890(a) of the Social Security Act; and

(C) CMS has given due consideration to measures that have been endorsed or adopted by a consensus organization.

(3) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the ESRD QIP. CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

(4) *Measure retention.* All measures specified for the ESRD QIP measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(5) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made.

(B) *Factor 2.* Performance or improvement on a measure does not result in better or the intended patient outcomes.

(C) *Factor 3.* A measure no longer aligns with current clinical guidelines or practice.

(D) *Factor 4.* A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.

(E) *Factor 5.* A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative or unintended consequences.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a measure that meets one or more of the measure removal factors described in paragraph (c)(5)(i) of this section for reasons including, but not limited to, that the measure addresses a gap in quality that is so significant that removing the measure would lower the quality of care furnished by facilities, or that the measure is statutorily required.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for facilities to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the ESRD QIP measure set. CMS will, upon removal of the measure—

(A) Provide notice to facilities and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if facilities continued to submit data on the measure; and

(B) Provide notice of the removal in the FEDERAL REGISTER.

(d) *Data submission requirement.* (1) Except as provided in paragraph (d)(3)

and (4) of this section, and for a payment year, facilities must submit to CMS data on each measure specified by CMS under paragraph (c) of this section. Facilities must submit these data in the form, manner, and at a time specified by CMS.

(2) For purposes of paragraph (d)(1) of this section, the baseline period that applies to each of payment year 2023 and payment year 2024 is calendar year 2019 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2019 for purposes of calculating the improvement threshold. The baseline period that applies to payment year 2025 is calendar year 2021 for purposes of calculating the achievement threshold, benchmark and minimum total performance score, and calendar year 2022 for purposes of calculating the improvement threshold, and the performance period that applies to payment year 2025 is calendar year 2023. Beginning with payment year 2026, the performance period and corresponding baseline periods are each advanced 1 year for each successive payment year.

(3) A facility may request and CMS may grant exceptions to the reporting requirements under paragraph (d)(1) of this section for one or more calendar days, when there are certain extraordinary circumstances beyond the control of the facility.

(4) A facility may request an exception within 90 days of the date that the extraordinary circumstances occurred by submitting the Extraordinary Circumstances Exception request form, which is available on the QualityNet website (*https://www.qualitynet.org/*), to CMS via email to the ESRD QIP mailbox at *ESRDQIP@cms.hhs.gov*. Facilities must provide the following information on the form:

(i) Facility CCN.

(ii) Facility name.

(iii) CEO name and contact information.

(iv) Additional contact name and contact information.

(v) Reason for requesting an exception.

(vi) Dates affected.

(vii) Date the facility will start submitting data again, with justification for this date.

(viii) Evidence of the impact of the extraordinary circumstances, including but not limited to photographs, newspaper, and other media articles.

(5) CMS will not consider an exception request unless the facility requesting such exception has complied with the requirements in paragraph (d)(4) of this section.

(6) CMS may grant exceptions to facilities without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) An unresolved issue with a CMS data system affected the ability of a facility to submit data in accordance with paragraph (d)(1) of this section and CMS was unable to provide the facility with an alternative method of data submission.

(7) With the exception of first and second quarter 2020 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility that has been granted an exception to the data submission requirements under paragraph (d)(6) of this section may notify CMS that it will continue to submit data under paragraph (d)(1) of this section by sending an email signed by the CEO or another designated contact to the ESRD QIP mailbox at *ESRDQIP@cms.hhs.gov*. Upon receipt of an email under this clause, CMS will notify the facility in writing that CMS is withdrawing the exception it previously granted to the facility. With respect to fourth quarter 2019 ESRD QIP data for which CMS granted an exception under paragraph (d)(6) of this section, a facility is deemed to have met the requirements of this paragraph if the facility actually submitted the data by the March 31, 2020 submission deadline but did not notify CMS that it would do so.

(e) *Performance scoring under the ESRD QIP.* (1) CMS will award points to an ESRD facility based on its performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree

to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment year.

(i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark specified for that measure.

(ii) CMS will award 0 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period falls below the achievement threshold specified for that measure.

(iii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iv) CMS will award 0 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period is below the improvement threshold specified for that measure.

(v) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

(vi) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.

(2) CMS calculates the TPS for an ESRD facility for a payment year as follows:

(i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (e)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.

(ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the payment year.

(f) *Public availability of ESRD QIP performance information.* (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (f)(1) of this section available to the public, CMS will provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(g) *Limitation on review.* There is no administrative or judicial review of the following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

(3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.

(4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.

(h) *Special rule for payment year 2022.* (1) CMS will calculate a measure rate for all measures specified by CMS under paragraph (c) of this section for the PY 2022 ESRD QIP but will not score facility performance on any of

those measures or calculate a TPS for any facility under paragraph (e) of this section.

(2) CMS will not establish a mTPS for PY 2022.

(i) *Special rules for payment year 2023.* (1) CMS will calculate a measure rate for, but will not score facility performance on or include in the TPS for any facility under paragraph (e) of this section, the following measures: Standardized Hospitalization Ratio (SHR) clinical measure, Standardized Readmission Ratio (SRR) clinical measure, Long-Term Catheter Rate clinical measure, Standardized Fistula Rate clinical measure, ICH CAHPS clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy clinical measure.

(2) The mTPS for payment year 2023 is the total performance score that an ESRD facility would receive if, during the calendar year 2019 baseline period, it performed at the 50th percentile of national ESRD facility performance on Hypercalcemia clinical measure, NHSN Blood Stream Infection (BSI) clinical measure, and the median of national ESRD facility performance on Clinical Depression Screening and Follow-Up reporting measure, Standardized Transfusion Ratio (STrR) reporting measure, Ultrafiltration Rate reporting measure, NHSN Dialysis Event reporting measure, and Medication Reconciliation (MedRec) reporting measure.

[83 FR 57068, Nov. 14, 2018, as amended at 84 FR 60803, Nov. 8, 2019; 85 FR 54872, Sept. 2, 2020; 86 FR 62020, Nov. 8, 2021; 87 FR 67302, Nov. 7, 2022; 88 FR 76504, Nov. 6, 2023]

§ 413.180 Procedures for requesting exceptions to payment rates.

(a) *Outpatient maintenance dialysis payments.* All payments for outpatient maintenance dialysis furnished at or by facilities are made on the basis of prospective payment rates.

(b) *Criteria for requesting an exception.* If a pediatric ESRD facility projects on the basis of prior year costs and utilization trends that it has an allowable cost per treatment higher than its prospective rate set under § 413.174, and if these excess costs are attributable to one or more of the factors in § 413.182, the facility may request, in accordance with paragraph (e) of this section, that CMS approve an exception to that rate and set a higher prospective payment rate.

(c) *Application of deductible and coinsurance.* The higher payment rate is subject to the application of deductible and coinsurance in accordance with § 413.176.

(d) *Payment rate exception request.* Effective October 1, 2002, CMS may approve exceptions to a pediatric ESRD facility's updated prospective payment rate, if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002. A pediatric ESRD facility may request an exception to its payment rate at any time after it is in operation for at least 12 consecutive months.

(e) *Documentation for a payment rate exception request.* If the facility is requesting an exception to its payment rate, it must submit to CMS its most recently completed cost report as required under § 413.198 and whatever statistics, data, and budgetary projections as determined by CMS to be needed to adjudicate each type of exception. CMS may audit any cost report or other information submitted. The materials submitted to CMS must—

(1) Separately identify elements of cost contributing to costs per treatment in excess of the facility's payment rate;

(2) Show that the facility's costs, including those costs that are not directly attributable to the exception criteria, are allowable and reasonable under the reasonable cost principles set forth in this part;

(3) Show that the elements of excessive cost are specifically attributable to one or more conditions specified in § 413.182;

(4) Specify the amount of additional payment per treatment the facility believes is required for it to recover its justifiable excess costs; and

(5) Specify that the facility has compared its most recently completed cost report with cost reports from (at least 2) prior years. The facility must explain any material statistical data or cost changes, or both, and include an explanation with the documentation supporting the exception request.

(f) *Completion of requirements and criteria.* The facility must demonstrate to CMS's satisfaction that the requirements of this section and the criteria in §413.182 are fully met. The burden of proof is on the facility to show that one or more of the criteria are met and that the excessive costs are justifiable under the reasonable cost principles set forth in this part.

(g) *Approval of an exception request.* An exception request is deemed approved unless it is disapproved within 60 working days after it is filed with its contractor.

(h) *Determination of an exception request.* In determining the facility's payment rate under the exception process, CMS excludes all costs that are not reasonable or allowable under the reasonable cost principles set forth in this part.

(i) *Period of approval: Payment exception request.* A prospective exception payment rate approved by CMS applies for the period from the date the complete exception request was filed with its contractor until 30 days after the contractor's receipt of the facility's letter notifying the contractor of the facility's request to give up its exception rate and be subject to the basic case-mix adjusted composite payment rate methodology. ESRD facilities electing to retain their nonpediatric or pediatric exception rates (including self-dialysis training) do not need to notify their contractors. Once a facility notifies its contractor in writing that it cannot retain its current exception rate, that decision cannot be subsequently reversed.

(j) *Denial of an exception request.* CMS denies exception requests submitted without the documentation specified in §413.182 and the applicable regulations cited there.

(k) *Criteria for refiling a denied exception request.* A pediatric ESRD facility that was denied an exception request may immediately file another exception request. Any subsequent exception request must address and document the issues cited in CMS' denial letter.

(l) *Periods of exceptions.* (1) Prior to December 31, 2000, an ESRD facility may receive an exception to its composite payment rate for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities.

(2) Effective December 31, 2000, an ESRD facility not subject to paragraph (l)(3), is no longer granted any new exception to the composite payment rate as defined in §413.180(1).

(3) Effective April 1, 2004 through September 27, 2004, and on an annual basis, an ESRD facility with at least 50 percent pediatric patient mix as specified in §413.184 of this part, that did not have an exception rate in effect as of October 1, 2002, may apply for an exception to its composite payment rate.

(4) For ESRD facilities that are paid a blended rate for renal dialysis services provided during the transition described in §413.239 of this part, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are used as the payment amount in place of the composite rate, and will be terminated for ESRD services furnished on or after January 1, 2014.

(5) For ESRD facilities that, in accordance with §413.239(b) of this part, elect to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under §413.220, any existing exceptions for isolated essential facilities, self dialysis training costs, atypical service intensity (patient mix) and pediatric facilities are terminated for ESRD services furnished on or after January 1, 2011.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005; 75 FR 49199, Aug. 12, 2010]

§413.182 Criteria for approval of exception requests.

(a) CMS may approve exceptions to a pediatric ESRD facility's prospective payment rate if the pediatric ESRD facility did not have an approved exception rate as of October 1, 2002.

(b) The pediatric ESRD facility must demonstrate, by convincing objective evidence, that its total per treatment costs are reasonable and allowable under the relevant cost reimbursement principles of part 413 and that its per treatment costs in excess of its payment rate are directly attributable to any of the following criteria:

(1) Pediatric patient mix, as specified in § 413.184.

(2) Self-dialysis training costs in pediatric facilities, as specified in § 413.186.

[70 FR 70331, Nov. 21, 2005]

§ 413.184 Payment exception: Pediatric patient mix.

(a) *Qualifications.* To qualify for an exception to its prospective payment rate based on its pediatric patient mix a facility must demonstrate that—

(1) At least 50 percent of its patients are individuals under 18 years of age;

(2) Its nursing personnel costs are allocated properly between each mode of care;

(3) The additional nursing hours per treatment are not the result of an excess number of employees;

(4) Its pediatric patients require a significantly higher staff-to-patient ratio than typical adult patients; and

(5) These services, procedures, or supplies and their per treatment costs are clearly prudent and reasonable when compared to those of pediatric facilities with a similar patient mix.

(b) *Documentation.* (1) A pediatric ESRD facility must submit a listing of all outpatient dialysis patients (including all home patients) treated during the most recently completed and filed cost report (in accordance with cost reporting requirements under § 413.198) showing—

(i) Age of patients and percentage of patients under the age of 18;

(ii) Individual patient diagnosis;

(iii) Home patients and ages;

(iv) In-facility patients, staff-assisted, or self-dialysis;

(v) Diabetic patients; and

(vi) Patients isolated because of contagious disease.

(2) The facility also must—

(i) Submit documentation on costs of nursing personnel (registered nurses, licensed practical nurses, technicians, and aides) incurred during the most recently completed fiscal year cost report showing—

(A) Amount each employee was paid;

(B) Number of personnel;

(C) Amount of time spent in the dialysis unit; and

(D) Staff-to-patient ratio based on total hours, with an analysis of productive and nonproductive hours.

(ii) Submit documentation on supply costs incurred during the most recently completed fiscal or calendar year cost report showing—

(A) By modality, a complete list of supplies used routinely in a dialysis treatment;

(B) The make and model number of each dialyzer and its component cost; and

(C) That supplies are prudently purchased (for example, that bulk discounts are used when available).

(iii) Submit documentation on overhead costs incurred during the most recently completed fiscal or calendar year cost reporting year showing—

(A) The basis of the higher overhead costs;

(B) The impact on the specific cost components; and

(C) The effect on per treatment costs.

[62 FR 43668, Aug. 15, 1997, as amended at 70 FR 70331, Nov. 21, 2005]

§ 413.186 Payment exception: Self-dialysis training costs in pediatric facilities.

(a) *Qualification.* To qualify for an exception to the prospective payment rate based on self-dialysis training costs, the pediatric ESRD facility must establish that it incurs per treatment costs for furnishing self-dialysis and home dialysis training that exceed the facility's payment rate for the training sessions.

(b) *Justification.* To justify its exception request, a facility must—

(1) Separately identify those elements contributing to its costs in excess of the composite training rate; and

(2) Demonstrate that its per treatment costs are reasonable and allowable.

(c) *Criteria for determining proper cost reporting.* CMS considers the pediatric ESRD facility's total costs, cost finding and apportionment, including its allocation of costs, to determine if costs are properly reported by treatment modality.

(d) *Limitation of exception requests.* Exception requests for a higher training

rate are limited to those cost components relating to training such as technical staff, medical supplies, and the special costs of education (manuals and education materials). These requests may include overhead and other indirect costs to the extent that these costs are directly attributable to the additional training costs.

(e) *Documentation.* The pediatric ESRD facility must provide the following information to support its exception request:

(1) A copy of the facility's training program.

(2) Computation of the facility's cost per treatment for maintenance sessions and training sessions including an explanation of the cost difference between the two modalities.

(3) Class size and patients' training schedules.

(4) Number of training sessions required, by treatment modality, to train patients.

(5) Number of patients trained for the current year and the prior 2 years on a monthly basis.

(6) Projection for the next 12 months of future training candidates.

(7) The number and qualifications of staff at training sessions.

(f) *Accelerated training exception.* (1) A pediatric ESRD facility may bill Medicare for a dialysis training session only when a patient receives a dialysis treatment (normally 3 times a week for hemodialysis). Continuous cycling peritoneal dialysis (CCPD) and continuous ambulatory peritoneal dialysis (CAPD) are daily treatment modalities; ESRD facilities are paid the equivalent of three hemodialysis treatments for each week that CCPD and CAPD treatments are provided.

(2) If a pediatric ESRD facility elects to train all its patients using a particular treatment modality more often than during each dialysis treatment and, as a result, the number of billable training dialysis sessions is less than the number of actual training sessions, the facility may request a composite rate exception, limited to the lesser of the—

(i) Facility's projected training cost per treatment; or

(ii) Cost per treatment the facility receives in training a patient if it had trained patients only during a dialysis treatment, that is, three times per week.

(3) An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD training.

(4) In computing the payment amount under an accelerated training exception, CMS uses a minimum number of training sessions per patient (15 for hemodialysis and 5 for CAPD and CCPD) when the facility actually provides fewer than the minimum number of training sessions.

(5) To justify an accelerated training exception request, an ESRD facility must document that a significant number of training sessions for a particular modality are provided during a shorter but more condensed period.

(6) The facility must submit with the exception request a list of patients, by modality, trained during the most recent cost report period. The list must include each beneficiary's—

(i) Name;

(ii) Age; and

(iii) Training status (completed, not completed, being retrained, or in the process of being trained).

(7) The total treatments from the patient list must be the same as the total treatments reported on the cost report filed with the request.

[70 FR 70331, Nov. 21, 2005]

§413.194 Appeals.

(a) *Appeals under section 1878 of the Act.* (1) A facility that disputes the amount of its allowable Medicare bad debts reimbursed by CMS under §413.89(h)(3) may request review by the contractor or the Provider Reimbursement Review Board (PRRB) in accordance with subpart R to part 405 of this chapter.

(2) A facility must request and obtain a final agency decision prior to seeking judicial review of a dispute regarding the amount of allowable Medicare bad debts.

(b) *Other appeals.* (1) A facility that has requested higher payment per treatment in accordance with §413.180 may request review from the contractor or the PRRB if CMS has denied the request in whole or in part. In such a case, the procedure in subpart R of

part 405 of this chapter is followed to the extent that it is applicable.

(2) The PRRB has the authority to review the action taken by CMS on the facility's requests. However, the PRRB's decision is subject to review by the Administrator under § 405.1875 of this chapter.

(3) A facility must request and obtain a final agency decision, in accordance with paragraph (b)(1) of this section, prior to seeking judicial review of the denial, in whole or in part, of the exception request.

(c) *Procedure.* (1) The facility must request review within 180 days of the date of the decision on which review is sought.

(2) The facility may not submit to the reviewing entity, whether it is the contractor or the PRRB, any additional information or cost data that had not been submitted to CMS at the time CMS evaluated the exception request.

(d) *Determining amount in controversy.* For purposes of determining PRRB jurisdiction under subpart R of part 405 of this chapter for the appeals described in paragraph (b) of this section—

(1) The amount in controversy per treatment is determined by subtracting the amount of program payment from the amount the facility requested under § 413.180; and

(2) The total amount in controversy is calculated by multiplying the amount in controversy per treatment by the projected number of treatments for the exception request period.

[62 FR 43668, Aug. 15, 1997, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.195 Limitation on Review.

Administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following is prohibited: The determination of payment amounts under section 1881(b)(14)(A) of the Act, the establishment of an appropriate unit of payment under section 1881(b)(14)(C) of the Act, the identification of renal dialysis services included in the bundled payment, the adjustments under section 1881(b)(14)(D) of the Act, the application of the phase-in under section 1881(b)(14)(E) of the Act, and the establishment of the market basket percentage increase factors under section 1881(b)(14)(F) of the Act.

[75 FR 49199, Aug. 12, 2010]

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

(a) CMS or the facility's contractor notifies each facility of changes in its payment rate. This notice includes changes in individual facility payment rates resulting from corrections or revisions of particular geographic labor cost adjustment factors.

(b) Changes in payment rates resulting from incorporation of updated cost data or general revisions of geographic labor cost adjustment factors are announced by notice published in the FEDERAL REGISTER without opportunity for prior comment. Revisions of the rate-setting methodology are published in the FEDERAL REGISTER in accordance with the Department's established rulemaking procedures.

(c) Effective for items and services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor.

(d) Effective for items and services furnished on or after January 1, 2012, CMS updates on an annual basis the following:

(1) The per-treatment base rate and the composite rate portion of the basic case-mix adjusted composite payment system described in § 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

(2) The wage index using the most current hospital wage data.

(3) The fixed dollar loss amount as defined in § 413.237 of this part to ensure that outlier payments continue to be 1.0 percent of total payments to ESRD facilities.

[62 FR 43668, Aug. 15, 1997, as amended at 75 FR 49199, Aug. 12, 2010]

§ 413.198 Recordkeeping and cost reporting requirements for outpatient maintenance dialysis.

(a) *Purpose and scope.* This section implements sections 1881(b)(2)(B)(i) and 1881(b)(14) of the Act by specifying recordkeeping and cost reporting requirements for ESRD facilities under part 494 of this chapter. The records and reports will enable CMS to determine the costs incurred in furnishing outpatient maintenance dialysis as defined in § 413.170(a).

(b) *Recordkeeping and reporting requirements.* (1) Each facility must keep adequate records and submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively.

(2) The cost reimbursement principles set forth in this part (beginning with § 413.134, Depreciation, and excluding the principles listed in paragraph (b)(4) of this section), apply in the determination and reporting of the allowable cost incurred in furnishing outpatient maintenance dialysis treatments to patients dialyzing in the facility, or incurred by the facility in furnishing home dialysis service, supplies, and equipment.

(3) Allowable cost is the reasonable cost related to dialysis treatments. Reasonable cost includes all necessary and proper expenses incurred by the facility in furnishing the dialysis treatments, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. Reasonable cost does not include costs that—

(i) Are not related to patient care for outpatient maintenance dialysis;

(ii) Are for services or items specifically not reimbursable under the program;

(iii) Flow from the provision of luxury items or services (items or services substantially in excess of or more expensive than those generally considered necessary for the provision of needed health services); or

(iv) Are found to be substantially out of line with other institutions in the same area that are similar in size, scope of services, utilization, and other relevant factors.

(4) The following principles of this part do not apply in determining adjustments to allowable costs as reported by ESRD facilities:

(i) Section 413.157, Return on equity capital of proprietary providers;

(ii) Section 413.420, Payment to independent organ procurement organizations and to histocompatibility laboratories for kidney acquisition costs;

(iii) Section 413.9, Cost related to patient care (except for the principles stated in paragraph (b)(3) of this section); and

(iv) Sections 413.64, Payments to providers, and §§ 413.13, 413.30, 413.35, 413.40, 413.74, and §§ 415.55 through 415.70, § 415.162, and § 415.164 of this chapter, Principles of reimbursement for services by hospital-based physicians.

(5) Each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. Beginning January 1, 2025, the data and information must include, but is not limited to the following:

(i) Information reported on ESRD prospective payment system (PPS) claims for renal dialysis services regarding the number of minutes between the start and end of hemodialysis treatment, without accounting for any interruptions, received by a beneficiary in center in an ESRD facility;

(ii) Information reported on ESRD PPS claims about the total number of billing units (or the expected number of billing units, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), of any discarded amount of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS, using the JW modifier (or any successor modifier that includes the same data); and

(iii) Information reported on ESRD PPS claims about any renal dialysis

drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS for which there is no discarded amount (or no discarded amount expected, for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217 of this chapter or oral forms of renal dialysis drugs and biological products), using the JZ modifier (or any successor modifier that includes the same data).

(6) Beginning January 1, 2025, each ESRD facility must document in the beneficiary's medical record any discarded amounts of a renal dialysis drug or biological product from a single-dose container or single-use package that is paid for under the ESRD PPS.

[62 FR 43668, Aug. 15, 1997, as amended at 73 FR 20474, Apr. 15, 2008; 87 FR 72287, Nov. 23, 2022; 88 FR 76504, Nov. 6, 2023]

§ 413.200 [Reserved]

§ 413.202 Organ procurement organization (OPO) cost for kidneys sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

An OPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. OPOs, as defined in § 486.302 of this chapter, must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal contractors. Medicare costs are based on the ratio of the number of usable kidneys transplanted into Medicare beneficiaries to the total number of usable kidneys applied to reasonable costs. Certain long-standing arrangements that existed before March 3, 1988 (for example, an OPO that procures kidneys at a military transplant hospital for transplant at that hospital), will be deemed to be Medicare kidneys for cost reporting statistical purposes. The OPO must submit a request to the contractor for review and approval of these arrangements.

[62 FR 43668, Aug. 15, 1997, as amended at 71 FR 31046, May 31, 2006]

§ 413.203 Transplant center costs for organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries.

(a) A transplant center's total costs for all organs is reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. Organs are defined in § 486.302 (only covered organs will be paid for on a reasonable cost basis).

(b) Transplant center hospitals must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare fiscal contractors.

(c) Medicare costs are based on the ratio of the number of usable organs transplanted into Medicare beneficiaries to the total number of usable organs applied to reasonable costs.

§ 413.210 Conditions for payment under the end-stage renal disease (ESRD) prospective payment system.

Except as noted in § 413.174(f), items and services furnished on or after January 1, 2011, under section 1881(b)(14)(A) of the Act and as identified in § 413.217 of this part, are paid under the ESRD prospective payment system described in § 413.215 through § 413.235 of this part.

(a) *Qualifications for payment.* To qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter.

(b) *Payment for items and services.* CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.

[75 FR 49199, Aug. 12, 2010]

§ 413.215 Basis of payment.

(a) Except as otherwise provided under § 413.235 or § 413.174(f) of this part, effective January 1, 2011, ESRD facilities receive a predetermined per treatment payment amount described in § 413.230 of this part, for renal dialysis services, specified under section 1881(b)(14) of the Act and as defined in § 413.217 of this part, furnished to Medicare Part B fee-for-service beneficiaries.

(b) In addition to the per-treatment payment amount, as described in paragraph (a) of this section, the ESRD facility may receive payment for bad debts of Medicare beneficiaries as specified in § 413.89(h)(3).

[75 FR 49200, Aug. 12, 2010, as amended at 81 FR 77965, Nov. 4, 2016]

§ 413.217 Items and services included in the ESRD prospective payment system.

The following items and services are included in the ESRD prospective payment system effective January 1, 2011:

(a) Renal dialysis services as defined in § 413.171; and

(b) Home dialysis services, support, and equipment as identified in § 410.52 of this chapter.

[75 FR 49200, Aug. 12, 2010]

§ 413.220 Methodology for calculating the per-treatment base rate under the ESRD prospective payment system effective January 1, 2011.

(a) *Data sources.* The methodology for determining the per treatment base rate under the ESRD prospective payment system utilized:

(1) Medicare data available to estimate the average cost and payments for renal dialysis services.

(2) ESRD facility cost report data capturing the average cost per treatment.

(3) The lowest per patient utilization calendar year as identified from Medicare claims is calendar year 2007.

(4) Wage index values used to adjust for geographic wage levels described in § 413.231 of this part.

(5) An adjustment factor to account for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by ESRD facilities.

(b) *Determining the per treatment base rate for calendar year 2011.* Except as noted in § 413.174(f), the ESRD prospective payment system combines payments for the composite rate items and services as defined in § 413.171 of this part and the items and services that, prior to January 1, 2011, were separately billable items and services, as defined in § 413.171 of this part, into a single per treatment base rate developed from 2007 claims data. The steps to calculating the per-treatment base rate for 2011 are as follows:

(1) *Per patient utilization in CY 2007, 2008, or 2009.* CMS removes the effects of enrollment and price growth from total expenditures for 2007, 2008 or 2009 to determine the year with the lowest per patient utilization.

(2) *Update of per treatment base rate to 2011.* CMS updates the per-treatment base rate under the ESRD prospective payment system in order to reflect estimated per treatment costs in 2011.

(3) *Standardization.* CMS applies a reduction factor to the per treatment base rate to reflect estimated increases resulting from the facility-level and patient-level adjustments applicable to the case as described in § 413.231 through § 413.235 of this part.

(4) *Outlier percentage.* CMS reduces the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD prospective payment system that are outlier payments as described in § 413.237 of this part.

(5) *Budget neutrality.* CMS adjusts the per treatment base rate so that the aggregate payments in 2011 are estimated to be 98 percent of the amount that would have been made under title XVIII of the Social Security Act if the ESRD prospective payment system described in section 1881(b)(14) of the Act were not implemented.

(6) *First 4 Years of the ESRD prospective payment system.* During the first 4 years of ESRD prospective payment system (January 1, 2011 to December 31, 2013), CMS adjusts the per-treatment base rate in accordance with § 413.239(d).

[75 FR 49200, Aug. 12, 2010]

§ 413.230 Determining the per treatment payment amount.

The per-treatment payment amount is the sum of:

(a) The per treatment base rate established in § 413.220, adjusted for wages as described in § 413.231, and adjusted for facility-level and patient-level characteristics described in §§ 413.232 and 413.235 of this part;

(b) Any outlier payment under § 413.237;

(c) Any training adjustment add-on under § 413.235(c);

(d) Any transitional drug add-on payment adjustment under § 413.234(c);

(e) Any transitional add-on payment adjustment for new and innovative equipment and supplies under § 413.236(d); and

(f) Any add-on payment adjustment for new renal dialysis drugs or biological products in existing ESRD PPS functional categories after the payment period for the transitional drug add-on payment adjustment has ended, as described in § 413.234(c)(3) and (g).

[75 FR 49200, Aug. 12, 2010, as amended at 84 FR 60803, Nov. 8, 2019; 88 FR 76505, Nov. 6, 2023]

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located.

(b) The application of the wage index is made on the basis of the location of the ESRD facility in an urban or rural area as defined in this paragraph (b).

(1) *Urban area* means a Metropolitan Statistical Area or a Metropolitan division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by OMB.

(2) *Rural area* means any area outside an urban area.

(c) Beginning January 1, 2023, CMS applies a cap on decreases to the wage index, such that the wage index applied to an ESRD facility is not less than 95 percent of the wage index applied to that ESRD facility in the prior calendar year.

(d) Beginning January 1, 2023, CMS applies a floor of 0.6000 to the wage index, such that the wage index applied to an ESRD facility is not less than 0.6000.

[75 FR 49200, Aug. 12, 2010, as amended at 87 FR 67302, Nov. 7, 2022]

§ 413.232 Low-volume adjustment.

(a) CMS adjusts the base rate for low-volume ESRD facilities, as defined in paragraph (b) of this section.

(b) A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5) of this section) preceding the payment year; and

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year, except as specified in paragraph (g)(6) of this section.

(c) For the purpose of determining the number of treatments under paragraph (b)(1) of this section, the number of treatments considered furnished by the ESRD facility shall equal the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both:

(1) Under common ownership with, and

(2) Five (5) road miles or less from the ESRD facility in question.

(d) Common ownership means the same individual, individuals, entity, or entities, directly, or indirectly, own 5 percent or more of each ESRD facility.

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an

attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor (MAC) that the facility meets all the criteria established in this section, except that:

(1) For payment year 2012, the attestation must be provided by January 3, 2012;

(2) For payment year 2015, the attestation must be provided by December 31, 2014;

(3) For payment year 2016, the attestation must be provided by December 31, 2015; and

(4) For payment year 2021, the attestation must be provided by December 31, 2020.

(f) The low-volume adjustment applies only for dialysis treatments provided to adults (18 years or older).

(g) To receive the low-volume adjustment, an ESRD facility must include in its attestation provided pursuant to paragraph (e) of this section a statement that the ESRD facility meets the definition of a low-volume facility in paragraph (b) of this section. To determine eligibility for the low-volume adjustment, the MAC on behalf of CMS relies upon as filed or final settled 12-consecutive month cost reports, except as specified in paragraphs (g)(4) and (5) of this section, for the 3 cost reporting years preceding the payment year to verify the number of treatments, except that:

(1) In the case of a hospital-based ESRD facility as defined in §413.174(c), the MAC relies upon the attestation submitted pursuant to paragraph (e) of this section and may consider other supporting data in addition to the total treatments reported in each of the 12-consecutive month cost reports for the 3 cost reporting years preceding the payment year to verify the number of treatments that were furnished by the individual hospital-based ESRD facility seeking the adjustment; and

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 consecutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(3) In the case of an ESRD facility that has changed its cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3-cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(4) For payment years 2021, 2022, and 2023, the attestation specified in paragraph (e)(4) of this section must indicate that the ESRD facility meets all the criteria specified in this section, except that, for a facility that would not otherwise meet the number of treatments criterion specified in paragraph (b)(1) of this section because of the COVID–19 PHE, the facility may attest that it furnished less than 2,000 treatments in any six months during the cost-reporting period ending in 2020. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the payment year due to temporary patient shifting as a result of the COVID–19 PHE; and

(ii) The MAC relies on the attestation and multiplies the total number of treatments for the 6-month period by 2.

(5) For payment year 2024 and subsequent payment years, an ESRD facility may attest in the attestation specified in paragraph (e) of this section that it would have met the requirements of paragraph (b)(1) of this section, except that for one or more of the most recent

3 cost reporting years the facility furnished 4,000 or more treatments because of temporary patient-shifting as a result of the closure or operational disruption of another ESRD facility due to a disaster or other emergency. For the purposes of the exception in this paragraph (g)(5), temporary patient-shifting is defined as providing renal dialysis services to one or more displaced patient(s) at any time through the end of the CY following the 12-month period beginning when an ESRD facility first begins providing renal dialysis services to one or more displaced patients. For any facility that so attests—

(i) The facility must also attest that it furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(ii) The facility must request an exception under this paragraph (g)(5) from CMS, in the form and manner specified by CMS, no later than the attestation deadline specified in paragraph (e) of this section or 30 days after the end of the cost reporting year, whichever is later, for each cost reporting year that the facility furnishes treatments equal to or in excess of 4,000 due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency;

(iii) Within 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility furnished treatments equal to or in excess of 4,000 in the cost reporting year due to temporary patient-shifting as a result of the closure or operational disruption of an ESRD facility resulting from a disaster or other emergency, or deny the request, and will notify the facility and the MAC of its decision;

(iv) If CMS approves the request, the ESRD facility is paid the low-volume adjustment on claims for Medicare beneficiaries, on the basis of the exception in this paragraph (g)(5), during the payment year in which the temporary patient-shifting occurred, so long as all other requirements for the low-volume adjustment are met. For any future payment year, the ESRD facility would not be prevented from receiving the low-volume adjustment if the ESRD facility meets or exceeds the 4,000 treatment threshold in a cost reporting year due to temporary patient-shifting as a result of the disaster or other emergency that resulted in another ESRD facility's closure or operational disruption, so long as all other requirements for the low-volume adjustment are met; and

(v) The facility must maintain documentation of the number of displaced patients treated and information about the ESRD facility or facilities that closed or experienced operational disruptions due to a disaster or other emergency and previously treated those patients, and must provide such supporting documentation to CMS and the MAC upon request.

(6) In the case of an ESRD facility that closes due to a disaster or other emergency and later reopens, the ESRD facility may attest in the attestation specified in paragraph (e) of this section that CMS has granted an exception to the requirements specified in paragraph (b)(2) of this section because it closed due to a disaster or other emergency. For any facility that so attests—

(i) The ESRD facility would need to request such an exception from CMS, in the form and manner specified by CMS, within 60 days of the facility's closure, and the ESRD facility must inform the MAC of this request in writing;

(ii) With 30 days of CMS's receipt of the facility's request, CMS will review the request and either approve the request based on a determination that the ESRD facility closed due to a disaster or other emergency, or deny the request, and will inform both the facility and the MAC of its decision; and

(iii) If CMS approves the request, the exception under this paragraph (g)(6) will be applicable for a period consisting of the remainder of the cost reporting year (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent, except as specified in paragraph (g)(4) of this section) in which the closure occurred and the following full 2 cost reporting

years. After this period the ESRD facility would follow the general attestation process for the low-volume adjustment specified in paragraph (e) of this section and this paragraph (g).

(iv) The ESRD facility that attests under this paragraph (g)(6) to have closed due to a disaster or other emergency would need to notify CMS and the MAC, in the form and manner specified by CMS, within 30 days reopening and providing renal dialysis services. Within 30 days of CMS's receipt of the facility's notification, CMS will confirm receipt to the facility and the MAC of the facility's notification and the ESRD facility will be able to receive the low-volume adjustment as of the date of reopening, so long as all other requirements for the low-volume adjustment are met.

(v) The ESRD facility must maintain documentation regarding its closure, and must provide such supporting documentation to CMS and/or the MAC upon request.

(h) When an ESRD facility provides an attestation in accordance with paragraph (e) of this section, for the third eligibility year, the MAC verifies the as-filed cost report and takes one of the following actions:

(1) If the MAC determines an ESRD facility meets the definition of a low-volume facility as described in paragraph (b) of this section, CMS adjusts the low-volume facility's base rate for the entire payment year; or

(2) If the MAC determines an ESRD facility does not meet the definition of a low-volume facility as described in paragraph (b) of this section, the MAC reprocesses claims and recoups low-volume adjustments paid during the payment year.

[75 FR 49200, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 79 FR 66262, Nov. 6, 2014; 80 FR 69076, Nov. 6, 2015; 83 FR 57069, Nov. 23, 2018; 85 FR 71485, Nov. 9, 2020; 88 FR 76505, Nov. 6, 2023]

§ 413.233 Rural facility adjustment.

CMS adjusts the base rate for facilities in rural areas, as defined in § 413.231(b)(2).

[80 FR 69077, Nov. 6, 2015]

§ 413.234 Drug designation process.

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

ESRD PPS functional category. A distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

Oral-only drug. A drug or biological product with no injectable equivalent or other form of administration other than an oral form.

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) Except as provided in paragraph (e) of this section, the new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(iii) The new renal dialysis drug or biological product is paid for using the add-on payment adjustment described

in paragraphs (c)(3) and (g) of this section, referred to as the post- transitional drug add-on payment adjustment (TDAPA) add-on payment adjustment.

(2) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new renal dialysis drug or biological product is used to treat or manage;

(ii) The new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

(1) A new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment for 2 years.

(i) Following payment of the transitional drug add-on payment adjustment, the new renal dialysis drug or biological product is paid the post-TDAPA add-on payment adjustment as set forth in paragraphs (c)(3) and (g) of this section.

(ii) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

(2) A new renal dialysis drug or biological product that is not considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

(3) For any new renal dialysis drug or biological product that is eligible for payment using the transitional drug add-on payment adjustment described in paragraphs (b)(1)(iii) and (c)(1) of this section, CMS applies a post-TDAPA add-on payment adjustment to all ESRD PPS claims that is calculated using the methodology set forth in paragraph (g) of this section. CMS will apply the post-TDAPA add-on payment adjustment beginning 8 calendar quarters after the first calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product, and ending 12 calendar quarters after the end of the last

calendar quarter in which the transitional drug add-on payment adjustment is paid for the applicable product. If CMS stops receiving the latest full calendar quarter of ASP data for the applicable renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) of this section or during the 3-year period following such applicable time period, CMS will not pay any post-TDAPA add-on payment adjustment for such product in any future year.

(d) *Oral-only drug determination.* An oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.

(e) *Exclusion criteria for the transitional drug add-on payment adjustment.* A new renal dialysis drug used to treat or manage a condition for which there is an ESRD PPS functional category is not eligible for payment using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section if the drug is approved by FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or the new drug application (NDA) for the drug is classified by FDA as Type 3, 5, 7, or 8, Type 3 in combination with Type 2 or Type 4, or Type 5 in combination with Type 2, or Type 9 when the parent NDA is a Type 3, 5, 7 or 8 as described in paragraphs (e)(1) through (7) of this section, respectively:

(1) Type 3 NDA—New Dosage Form.

(i) A *Type 3 NDA* is for a new dosage form of an active ingredient that has been approved or marketed in the United States (U.S.) by the same or another applicant but in a different dosage form. The indication for the drug product does not need to be the same as that of the already marketed drug product. Once a new dosage form has been approved for an active ingredient, subsequent applications for the same dosage form and active ingredient should be classified as a *Type 5 NDA*, as described in paragraph (e)(2) of this section.

(ii) [Reserved]

(2) Type 5 NDA—New Formulation or Other Differences.

(i) A *Type 5 NDA* is for a product, other than a new dosage form, that differs from a product already approved or marketed in the U.S. because of one of the following:

(A) The product involves changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval and is submitted as an original NDA rather than as a supplement by the applicant of the approved product;

(B) The product is a duplicate of a drug product by another applicant (same active ingredient, same dosage form, same or different indication, or same combination), and

(*1*) Requires bioequivalence testing (including bioequivalence studies with clinical endpoints), but is not eligible for submission as a section 505(j) of the FD&C Act application; or

(*2*) Requires safety or effectiveness testing because of novel inactive ingredients; or

(*3*) Requires full safety or effectiveness testing because it is:

(*i*) Subject to exclusivity held by another applicant, or

(*ii*) A product of biotechnology and its safety and/or effectiveness are not assessable through bioequivalence testing, or

(*iii*) A crude natural product, or

(*iv*) Ineligible for submission under section 505(j) of the FD&C Act because it differs in bioavailability (for example, products with different release patterns); or

(*4*) The applicant has a right of reference to the application.

(C) The product contains an active ingredient or active moiety that has been previously approved or marketed in the U.S. only as part of a combination. This applies to active ingredients previously approved or marketed as part of a physical or chemical combination, or as part of a mixture derived from recombinant deoxyribonucleic acid technology or natural sources.

(D) The product is a combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution of a new ester or salt or other noncovalent derivative of an active ingredient for one or more of the

active ingredients. In the latter case, the NDA would be classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 5 NDA* as described in paragraph (e)(2) of this section.

(E) The product contains a different strength of one or more active ingredients in a previously approved or marketed combination. A *Type 5 NDA*, as described in paragraph (e)(2) of this section, would generally be submitted by an applicant other than the holder of the approved application for the approved product. A similar change in an approved product by the applicant of the approved product would usually be submitted as a supplemental application.

(F) The product differs in bioavailability (for example, superbioavailable or different controlled-release pattern) and, therefore, is ineligible for submission as an abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act.

(G) The product involves a new plastic container that requires safety studies beyond limited confirmatory testing (see 21 CFR 310.509, *Parenteral drug products in plastic containers*).

(ii) [Reserved]

(3) Type 7 NDA—Previously Marketed But Without an Approved NDA.

(i) A *Type 7 NDA* is for a drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the U.S. This classification applies only to the first NDA approved for a drug product containing this (these) active moiety(ies). *Type 7 NDAs* include, but are not limited to:

(A) The first post-1962 application for an active moiety marketed prior to 1938.

(B) The first application for an active moiety first marketed between 1938 and 1962 that is identical, related or similar (IRS) to a drug covered by a Drug Efficacy Study Implementation notice. Regulation at 21 CFR 310.6(b)(1) states that an identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as any of drug moiety related in chemical structure or known pharmacological properties.

(C) The first application for an IRS drug product first marketed after 1962.

(D) The first application for an active moiety that was first marketed without an NDA after 1962.

(ii) [Reserved]

(4) Type 8 NDA—Prescription to Over-the-Counter (OTC).

(i) A *Type 8 NDA* is for a drug product intended for OTC marketing that contains an active ingredient that has been approved previously or marketed in the U.S. only for dispensing by prescription (OTC switch). A *Type 8 NDA* may provide for a different dosing regimen, different strength, different dosage form, or different indication from the product approved previously for prescription sale.

(ii) If the proposed OTC switch will apply to all indications, uses, and strengths of an approved prescription dosage form (leaving no prescription-only products of that particular dosage form on the market), the application holder should submit the change as a supplement to the approved application. If the applicant intends to switch only some indications, uses, or strengths of the dosage form to OTC status (while continuing to market other indications, uses, or strengths of the dosage form for prescription-only sale), the applicant should submit a new NDA for the OTC products, which would be classified as a *Type 8 NDA*.

(5) *Combination of Type 3 NDA*. Type 3 NDA, as described in paragraph (e)(1) of this section, in combination with a Type 2 NDA, as described in paragraph (e)(5)(i) of this section, or in combination with a Type 4 NDA, as described in paragraph (e)(5)(ii) of this section;

(i) Type 2 NDA—New Active Ingredient.

(A) A *Type 2 NDA* is for a drug product that contains a new active ingredient, but not a new molecular entity (NME). A new active ingredient includes those products whose active moiety has been previously approved or marketed in the U.S., but whose particular ester, salt, or noncovalent derivative of the unmodified parent molecule has not been approved by FDA or marketed in the U.S., either alone, or as part of a combination product. Similarly, if any ester, salt, or noncovalent derivative has been marketed first, the

unmodified parent molecule would also be considered a new active ingredient, but not an NME. The indication for the drug product does not need to be the same as that of the already marketed product containing the same active moiety.

(B) If the active ingredient is a single enantiomer and a racemic mixture containing that enantiomer has been previously approved by FDA or marketed in the U.S., or if the active ingredient is a racemic mixture containing an enantiomer that has been previously approved by FDA or marketed in the U.S., the NDA will be classified as a *Type 2 NDA*.

(ii) Type 4 NDA—New Combination.

(A) A *Type 4 NDA* is for a new drug-drug combination of two or more active ingredients. An application for a new drug-drug combination product may have more than one classification code if at least one component of the combination is an NME or a new active ingredient. The new product may be a physical or chemical (for example, covalent ester or noncovalent derivative) combination of two or more active moieties.

(B) A new *physical combination* may be two or more active ingredients combined into a single dosage form, or two or more drugs packaged together with combined labeling. When at least one of the active moieties is classified as an NME, the NDA is classified as a combination of a *Type 1 NDA*, as described in paragraph (e)(5)(ii)(B)(*1*) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section. When none of the active moieties is an NME, but at least one is a new active ingredient, the NDA is classified as a combination of a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA*, as described in paragraph (e)(5)(ii) of this section.

(*1*) Type 1 NDA—New Molecular Entity.

(*i*) A *Type 1 NDA* is for a drug product that contains an NME. An NME is an active ingredient that contains no active moiety that has been previously approved by FDA in an application submitted under section 505 of the FD&C Act or has been previously marketed as a drug in the U.S. A pure enantiomer or a racemic mixture is an NME only when neither has been previously approved or marketed.

(*ii*) An NDA for a drug product containing an active moiety that has been marketed as a drug in the U.S., but never approved in an application submitted under section 505 of the FD&C Act, would be considered a *Type 7 NDA* as described in paragraph (e)(3) of this section, not a *Type 1 NDA*.

(*iii*) An NDA for a drug-drug combination product containing an active moiety that is an NME in combination with another active moiety that had already been approved by FDA would be classified as a new combination containing an NME (that is, *Type 1,4 NDA*, as described in paragraph (e)(5)(ii) of this section). For example, a drug-drug combination can include a fixed-combination drug product or a co-packaged drug product with two or more active moieties.

(*iv*) An active moiety in a radiopharmaceutical (or radioactive drug product) which has not been approved by the FDA or marketed in the U.S. is classified as an NME.

(*v*) In addition, if a change in isotopic form results in an active moiety that has never been approved by the FDA or marketed in the U.S., the active ingredient is classified as an NME.

(C) An NDA for an active ingredient that is a *chemical combination* of two or more previously approved or marketed active moieties that are linked by an ester bond is classified as a combination of a *Type 2 NDA* as described in paragraph (e)(5)(i) of this section, with a *Type 4 NDA* as described in paragraph (e)(5)(ii) of this section, if the active moieties have not been previously marketed or approved as a physical combination. If the physical combination has been previously marketed or approved, however, such a product would no longer be considered a *new* combination and the NDA would thus be classified as a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(6) *Combination of Type 5 NDA*. Type 5 NDA, as described in paragraph (e)(2) of this section, in combination with a *Type 2 NDA*, as described in paragraph (e)(5)(i) of this section.

(7) *Type 9 NDA when the parent NDA is a Type 3, Type 5, Type 7, or a Type 8*. A

Type 9 NDA, as described in paragraph (e)(7)(i) of this section when the parent NDA is a *Type 3* NDA as described in paragraph (e)(1) of this section or a *Type 5* NDA as described in paragraph (e)(2) of this section or *Type 7* NDA as described in paragraph (e)(3) of this section or a *Type 8* NDA as described in paragraph (e)(4) of this section.

(i) Type 9 NDA—New Indication or Claim, Drug Not to be Marketed under Type 9 NDA after Approval.

(A) A *Type 9* NDA is for a new indication or claim for a drug product that is currently being reviewed under a different NDA (the ''parent NDA''), and the applicant does not intend to market this drug product under the *Type 9* NDA after approval. Generally, a *Type 9* NDA is submitted as a separate NDA so as to be in compliance with the guidance for industry on *Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees*.

(B) When the *Type 9* NDA is submitted, it will be given the same NDA classification as the pending NDA. When one application is approved, the other will be reclassified as *Type 9* regardless of whether it was the first or second NDA actually submitted. After the approval of a *Type 9* NDA, FDA will ''administratively close'' the *Type 9* NDA and thereafter only accept submissions to the ''parent'' NDA.

(ii) [Reserved]

(f) *Methodology for modifying the ESRD PPS base rate to account for the costs of calcimimetics in the ESRD PPS bundled payment.* Beginning January 1, 2021, payment for calcimimetics is included in the ESRD PPS base rate using the following data sources and methodology:

(1) The methodology specified in paragraph (f)(2) of this section for determining the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate uses the following data sources:

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for the third and fourth quarters of calendar year 2018 and for the full calendar year 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in the third and fourth quarter of calendar year 2018 and the full calendar year 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

(g) *Post-TDAPA add-on payment adjustment methodology.* CMS uses the following methodology to calculate the post-TDAPA add-on payment adjustment described in paragraph (c)(3) of this section:

(1) CMS bases the calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. If the most recent full calendar quarter of ASP data reflects zero or

negative sales, then the calculation is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(2) CMS calculates the post-TDAPA add-on payment adjustment annually as the expenditure for the new renal dialysis drug or biological product divided by the total number of ESRD PPS treatments during the same period.

(3) CMS applies a reduction factor to the post-TDAPA add-on payment adjustment for case mix standardization to reflect estimated increases resulting from the application of the patient-level adjustments as described in paragraph (g)(5) of this section. This reduction factor is calculated based on the patient-level adjustments (as described in §413.235) applicable to the most recent 12-month period of utilization of ESRD PPS claims.

(4) The amount of the post-TDAPA add-on payment adjustment is equal to 65 percent of the amount calculated in paragraph (g)(2) of this section, multiplied by the reduction factor specified in paragraph (g)(3) of this section, and multiplied by the latest available forecast of annual growth in the ESRD bundled market basket composite price proxy for pharmaceuticals.

(5) The post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjsuted by any applicable patient-level case-mix adjustments under §413.235.

[80 FR 69077, Nov. 6, 2015, as amended at 83 FR 57070, Nov. 14, 2018; 84 FR 60803, Nov. 8, 2019; 85 FR 71485, Nov. 9, 2020; 88 FR 76506, Nov. 6, 2023]

EFFECTIVE DATE NOTE: At 87 FR 67302, Nov. 7, 2022, §413.234 paragraph (a) was amended by adding the word ''functional'' before the word ''equivalent'' in the definition of ''Oral-only drug'', effective Jan. 1, 2025.

§413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for Pediatric ESRD Patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act as follows:

(1) To account for patient age and treatment modality; and

(2) Beginning January 1, 2024, to provide a per-treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount under §413.230 for renal dialysis services furnished to Pediatric ESRD Patients during calendar years 2024, 2025, and 2026.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010, as amended at 88 FR 76506, Nov. 6, 2023]

§413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset new) that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under § 413.171;

(2) Is new, meaning a complete application has been submitted to CMS under paragraph (c) of this section within 3 years of the date of the Food and Drug Administration (FDA) marketing authorization;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in § 412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in § 413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in § 413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a per treatment amount for use in calculating the pre-adjusted per treatment amount by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(iii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by subtracting the average per treatment offset amount (as determined using the data sources and methodology specified in paragraphs (f)(2) and (3) of this section, respectively, of this section) from the per treatment amount (as determined in paragraph (f)(1)(ii) of this section) to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own.

(2) The methodology specified in paragraph (f)(3) of this section for determining the average per treatment offset amount uses the following data sources:

(i) Dialysis machine and equipment cost, total cost across all dialysis modalities, the number of hemodialysis-equivalent home dialysis treatment counts, and the number of hemodialysis-equivalent total treatment counts are obtained from renal facility cost reports (CMS form 265–11) and hospital cost reports (CMS form 2552–10) using calendar years 2017–2019 cost reports.

(A) Dialysis machine and equipment costs are obtained by summing lines 8.01 through 17.02 from Worksheet B, Column 4 for renal facility cost reports, and by summing lines 2 through 11 from Worksheet I–2 for hospital cost reports.

(B) Total cost across all dialysis modalities are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 2 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 2 for the hospital cost reports.

(C) Hemodialysis-equivalent total treatment counts are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 1 for the hospital cost reports.

(D) Hemodialysis-equivalent home dialysis treatment counts are obtained by summing lines 14.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 7 through 10 from Worksheet I–4, Column 1 for the hospital cost reports. In both renal facility and hospital cost reports, home Continuous Ambulatory Peritoneal Dialysis and home Continuous Cyclic Peritoneal Dialysis are reported as patient weeks, so a conversion factor of 3 is applied to obtain hemodialysis-equivalent treatment counts.

(ii) [Reserved]

(3) CMS uses the following methodology to calculate the average per treatment offset amount for home dialysis machines that is subtracted from the per treatment amount as determined in paragraph (f)(1)(ii) of this section to determine the pre-adjusted per treatment amount specified in paragraph (f)(1)(iii) of this section:

(i) Calculates annualized values for calendar year 2018 at the ESRD facility

level for the metrics specified in paragraph (f)(2)(i) of this section by dividing the numbers of days the cost report spanned to compute a per-day metric, then multiplying the resulting value by the number of days in 2018 the cost report covered to compute the metrics attributable to the period covered by the cost report in 2018. Next, for ESRD facilities with multiple cost reports covering 2018 the resulting metrics are aggregated. Finally, each ESRD facility's aggregated metrics are annualized to cover the full calendar year 2018. The annualization factor for an ESRD facility is the total number of days in 2018 divided by the total days in 2018 covered by the ESRD facility's cost report(s).

(ii) Calculates an estimated home dialysis machine and equipment cost for each ESRD facility by multiplying the annualized dialysis machine and equipment cost determined in paragraph (f)(3)(i) of this section by the ESRD facility's hemodialysis-equivalent home dialysis treatment percentage. The hemodialysis-equivalent home dialysis treatment percentage for each facility is calculated by dividing annualized hemodialysis-equivalent home treatment count determined in paragraph (f)(3)(i) of this section by annualized hemodialysis-equivalent treatment count across all modalities determined in paragraph (f)(3)(i) of this section.

(iii) Calculates an average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 by dividing the sum of the estimated home dialysis machine and equipment cost in paragraph (f)(3)(ii) of this section across all ESRD facilities by the sum of annualized hemodialysis-equivalent home treatment counts determined in paragraph (f)(3)(i) of this section across all facilities.

(iv) Calculates the amount subtracted from the pre-adjusted treatment amount determined in paragraph (f)(1)(iii) of this section by inflating the average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 determined in paragraph (f)(3)(iii) to calendar year 2021. The average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 is inflated to calendar year 2021 by multiplying this value by the payment rate update factor required under section 1881(b)(14)(F)(i) of the Social Security Act for calendar years 2019, 2020, and 2021. This value is then divided by a scaling factor to be converted to the ESRD PPS payment scale. The scaling factor is calculated by dividing the calendar year 2018 total cost per treatment inflated to calendar year 2021 by the average ESRD PPS payment per treatment projected for calendar year 2021.

(v) Effective January 1, 2022, CMS annually updates the amount determined in paragraph (f)(3)(iv) of this section by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

[84 FR 60805, Nov. 8, 2019, as amended at 85 FR 71486, Nov. 9, 2020; 88 FR 76506, Nov. 6, 2023]

§ 413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle:

(i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236, after the payment period has ended.

(vi) As of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel

are excluded from the definition of outlier services.

(2) *Adult predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to an adult beneficiary by an ESRD facility.

(3) *Pediatric predicted ESRD outlier services Medicare allowable payment (MAP) amount* means the predicted per-treatment case-mix adjusted amount for ESRD outlier services furnished to a pediatric beneficiary by an ESRD facility.

(4) *Adult fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to an adult beneficiary must exceed the adult predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(5) *Pediatric fixed dollar loss amount* is the amount by which an ESRD facility's imputed per-treatment MAP amount for furnishing ESRD outlier services to a pediatric beneficiary must exceed the pediatric predicted ESRD outlier services MAP amount to be eligible for an outlier payment.

(6) *Outlier Percentage:* This term has the meaning set forth in §413.220(b)(4).

(b) *Eligibility for outlier payments*—(1) *Adult beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to an adult beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the adult predicted ESRD outlier services MAP amount plus the adult fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for an adult beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the adult beneficiary by the number of dialysis treatments furnished to the adult beneficiary in the relevant month. A beneficiary is considered an adult beneficiary if the beneficiary is 18 years old or older.

(2) *Pediatric beneficiaries.* An ESRD facility will receive an outlier payment for a treatment furnished to a pediatric beneficiary if the ESRD facility's per-treatment imputed MAP amount for ESRD outlier services exceeds the pediatric predicted ESRD outlier services MAP amount plus the pediatric fixed dollar loss amount. To calculate the ESRD facility's per-treatment imputed MAP amount for a pediatric beneficiary, CMS divides the ESRD facility's monthly imputed MAP amount of providing ESRD outlier services to the pediatric beneficiary by the number of dialysis treatments furnished to the pediatric beneficiary in the relevant month. A beneficiary is considered a pediatric beneficiary if the beneficiary is under 18 years old.

(c) *Outlier payment amount:* CMS pays 80 percent of the difference between:

(1) The ESRD facility's per-treatment imputed MAP amount for the ESRD outlier services, and

(2) The adult or pediatric predicted ESRD outlier services MAP amount plus the adult or pediatric fixed dollar loss amount, as applicable.

[75 FR 49201, Aug. 12, 2010, as amended at 76 FR 70314, Nov. 10, 2011; 78 FR 72252, Dec. 2, 2013; 79 FR 66262, Nov. 6, 2014; 80 FR 69077, Nov. 6, 2015; 84 FR 60806, Nov. 8, 2019; 85 FR 71487, Nov. 9, 2020]

§413.239 Transition period.

(a) *Duration of transition period and composition of the blended transition payment.* ESRD facilities not electing under paragraph (b) of this section to be paid based on the payment amount determined under §413.230 of this part, will be paid a per-treatment payment amount for renal dialysis services (as defined in §413.171 of this part) and home dialysis, provided during the transition as follows—

(1) For services provided on and after January 1, 2011 through December 31, 2011, a blended rate equal to the sum of:

(i) 75 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 25 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(2) For services provided on and after January 1, 2012 through December 31,

2012, a blended rate equal to the sum of:

(i) 50 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b)(12) of the Act and items and services separately paid under Part B; and

(ii) 50 percent of the payment rate determined in accordance with section 1881(b)(14) of the Act;

(3) For services provided on and after January 1, 2013 through December 31, 2013, a blended rate equal to the sum of:

(i) 25 percent of the payment amount determined under the ESRD payment methodology in effect prior to January 1, 2011 in accordance with section 1881(b) (12) of the Act and items and services separately paid under Part B; and

(ii) 75 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act;

(4) For services provided on and after January 1, 2014, 100 percent of the payment amount determined in accordance with section 1881(b)(14) of the Act.

(b) *One-time election.* Except as provided in paragraph (b)(2) of this section, ESRD facilities may make a one-time election to be paid for renal dialysis services provided during the transition based on 100 percent of the payment amount determined under § 413.215 of this part, rather than based on the payment amount determined under paragraph (a) of this section.

(1) Except as provided in paragraph (b)(3) of this section, the election must be received by each ESRD facility's Medicare administrative contractor (MAC) by November 1, 2010. Requests received by the MAC after November 1, 2010, will not be accepted regardless of postmarks, or delivered dates. MACs will establish the manner in which an ESRD facility will indicate their intention to be excluded from the transition and paid entirely based on payment under the ESRD PPS. Once the election is made, it may not be rescinded.

(2) If the ESRD facility fails to submit an election, or the ESRD facility's election is not received by their MAC by November 1, 2010, payments to the ESRD facility for items and services provided during the transition will be based on the payment amounts determined under paragraph (a) of this section.

(3) ESRD facilities that become certified for Medicare participation and begin to provide renal dialysis services, as defined in § 413.171 of this part, between November 1, 2010 and December 31, 2010, must notify their designated MAC of their election choice at the time of enrollment.

(c) *Treatment of new ESRD facilities.* For renal dialysis services as defined in § 413.171, furnished during the transition period, new ESRD facilities as defined in § 413.171, are paid based on the per-treatment payment amount determined under § 413.215 of this part.

(d) *Transition budget-neutrality adjustment.* During the transition, CMS adjusts all payments, including payments under this section, under the ESRD prospective payment system so that the estimated total amount of payment equals the estimated total amount of payments that would otherwise occur without such a transition.

[75 FR 49201, Aug. 12, 2010]

§ 413.241 Pharmacy arrangements.

Effective January 1, 2011, an ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs and biologicals must ensure that the pharmacy has the capability to provide all classes of renal dialysis service drugs and biologicals to patients in a timely manner.

[75 FR 49202, Aug. 12, 2010]

Subpart I—Prospectively Determined Payment Rates for Low-Volume Skilled Nursing Facilities, for Cost Reporting Periods Beginning Prior to July 1, 1998

SOURCE: 60 FR 37594, July 21, 1995, unless otherwise noted.

§ 413.300 Basis and scope.

(a) *Basis.* This subpart implements section 1888(d) of the Act, which provides for optional prospectively determined payment rates for qualified SNFs.

(b) *Scope.* This subpart sets forth the eligibility criteria an SNF must meet to qualify, the process governing election of prospectively determined payment rates, and the basis and methodology for determining prospectively determined payment rates.

§ 413.302 Definitions.

For purposes of this subpart—

Area wage level means the average wage per hour for all classifications of employees as reported by health care facilities within a specified area.

Census region means one of the 9 census divisions, comprising the 50 States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes.

Routine capital-related costs means the capital-related costs, allowable for Medicare purposes (as described in subpart G of this part), that are allocated to the SNF participating inpatient routine service cost center as reported on the Medicare cost report.

Routine operating costs means the cost of regular room, dietary, and nursing services, and minor medical and surgical supplies for which a separate charge is not customarily made. It does not include the costs of ancillary services, capital-related costs, or, where appropriate, return on equity.

Rural area means any area outside an urban area in a census region.

Urban area means—

(1) Prior to October 1, 2004, a Metropolitan Statistical Area (MSA), or New England County Metropolitan Area (NECMA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as listed in § 412.62(f)(1)(ii)(B) of this chapter.

(2) Effective October 1, 2004, a Metropolitan Statistical Area (MSA), as defined by the Office of Management and Budget, or a New England county deemed to be an urban area as specified under § 412.64.

[60 FR 37594, July 21, 1995, as amended at 69 FR 49265, Aug. 11, 2004]

§ 413.304 Eligibility for prospectively determined payment rates.

(a) *General rule.* An SNF is eligible to receive a prospectively determined payment rate for a cost reporting period if it had fewer than 1,500 Medicare covered inpatient days as reported on a Medicare cost report in its immediately preceding cost reporting period. This criterion applies even if the SNF received a prospectively determined payment rate during the preceding cost reporting period.

(b) *Less than a full cost reporting period.* If the cost reporting period that precedes an SNF's request for prospectively determined payment is not a full cost reporting period, the SNF is eligible to receive prospectively determined payment rates only if the average daily Medicare census for the period (Medicare inpatient days divided by the total number of days in the cost reporting period) is not greater than 4.1.

(c) *Newly-participating SNFs.* An SNF is eligible to receive prospectively determined payment rates for its first cost reporting period for which it is approved to participate in Medicare.

§ 413.308 Rules governing election of prospectively determined payment rates.

(a) *Requirements.* An SNF must notify its contractor at least 30 calendar days before the beginning of the cost reporting period for which it requests to receive such payment that it elects prospectively determined payment rates. A separate request must be made for each cost reporting period for which an SNF seeks prospectively determined payment. A newly participating SNF with no preceding cost reporting period must make its election within 30 days of its notification of approval to participate in Medicare.

(b) *Contractor notice.* After evaluating an SNF's request for prospectively determined payment rates, the contractor notifies the SNF in writing as to whether the SNF meets any of the eligibility criteria described in § 413.304 and the timely election requirements

under §413.308(a). The contractor must notify the SNF of its initial and final determinations within 10 working days after it receives all the data necessary to make each determination. The contractor's determination is limited to one cost reporting period.

(c) *Prohibition against revocation.* An SNF may not revoke its request after it has received the initial determination of eligibility from the contractor and the cost reporting period has begun.

(d) *Revocation by contractor.* If an SNF is given tentative approval to receive a prospectively determined payment rate, and, after the start of the applicable cost reporting period, the contractor determines that the SNF does not meet the eligibility criteria, the contractor must revoke the prospectively determined payment option.

§413.310 Basis of payment.

(a) *Method of payment.* Under the prospectively determined payment rate system, a qualified SNF receives a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. Each SNF's routine per diem payment rate is determined according to the methodology described in §413.312 and is based on various components of SNF costs.

(b) *Payment in full.* The payment rate represents payment in full for routine services as described in §413.314 (subject to applicable coinsurance as described in subpart G of part 409 of this title), and for routine capital costs. Payment is made in lieu of payment on a reasonable cost basis for routine services and for routine capital costs.

§413.312 Methodology for calculating rates.

(a) *Data used.* (1) To calculate the prospectively determined payment rates, CMS uses:

(i) The SNF cost data that were used to develop the applicable routine service cost limits;

(ii) A wage index to adjust for area wage differences; and

(iii) The most recent projections of increases in the costs from the SNF market basket index.

(2) In the annual schedule of rates published in the FEDERAL REGISTER under the authority of §413.320, CMS announces the wage index and the annual percentage increases in the market basket used in the calculation of the rates.

(b) *Calculation of per diem rate*—(1) *Routine operating component of rate*—(i) *Adjusting cost report data.* The SNF market basket index is used to adjust the routine operating cost from the SNF cost report to reflect cost increases occurring between cost reporting periods represented in the data collected and the midpoint of the initial cost reporting period to which the payment rates apply.

(ii) *Calculating a per diem cost.* For each SNF, an adjusted routine operating per diem cost is computed by dividing the adjusted routine operating cost (see paragraph (b)(1)(i) of this section) by the SNF's total patient days.

(iii) *Adjusting for wage levels.* (A) The SNF's adjusted per diem routine operating cost calculated under paragraph (b)(1)(ii) of this section is then divided into labor-related and nonlabor-related portions.

(B) The labor-related portion is obtained by multiplying the SNF's adjusted per diem routine operating cost by a percentage that represents the labor-related portion of cost from the market basket. This percentage is published when the revised rates are published as described in §413.320.

(C) The labor-related portion of each SNF's per diem cost is divided by the wage index applicable to the SNF's geographic location to arrive at the adjusted labor-related portion of routine cost.

(iv) *Group means.* SNFs are grouped by urban or rural location by census region. Separate means of adjusted labor-related and nonlabor routine operating costs for each SNF group are established in accordance with the SNF's region and urban or rural location. For each group, the mean labor-related and mean nonlabor-related per diem routine operating costs are multiplied by 105 percent.

(2) *Computation of routine capital-related cost.* (i) The SNF routine capital-related cost for both direct and indirect capital costs allocated to routine services, as reported on the Medicare

cost report, is obtained for each SNF in the data base.

(ii) For each SNF, the per diem capital-related cost is calculated by dividing the SNF's routine capital costs by its inpatient days.

(iii) SNFs are grouped by urban and rural location by census region, and mean per diem routine capital-related cost is determined for each group.

(iv) Each group mean per diem capital-related cost is multiplied by 105 percent.

(3) *Computation of return on owner's equity for services furnished before October 1, 1993.* (i) Each proprietary SNF's Medicare return on equity is obtained from its cost report and the portion attributable to the routine service cost is determined as described in § 413.157.

(ii) For each proprietary SNF, per diem return on equity is calculated by dividing the routine cost related return on equity determined under paragraph (b)(3)(i) of this section by the SNF's total Medicare inpatient days.

(iii) Separate group means are computed for per diem return on equity of proprietary SNFs, based on regional and urban or rural classification.

(iv) Each group mean is multiplied by 105 percent.

§ 413.314 Determining payment amounts: Routine per diem rate.

(a) *General rule.* An SNF that elects to be paid under the prospectively determined payment rate system, and qualifies for such payment, is paid a per diem rate for inpatient routine services. This rate is adjusted to reflect area wage differences and the cost reporting period beginning date (if necessary) and is subject to the limitation specified in paragraph (d) of this section.

(b) *Per diem rate.* The prospectively determined payment rate for each urban and rural area in each census region is comprised of the following:

(1) A routine operating component, which is divided into:

(i) A labor-related portion adjusted by the appropriate wage index; and

(ii) A nonlabor-related portion.

(2) A routine capital-related cost portion.

(3) For proprietary SNFs only, a portion that is based on the return on owner's equity related to routine cost, applicable only for services furnished before October 1, 1993.

(c) *Adjustment for cost reporting period.* (1) If a facility has a cost reporting period beginning after the beginning of the Federal fiscal year, the contractor increases the labor-related and nonlabor-related portions of the prospective payment rate that would otherwise apply to the SNF by an adjustment factor. Each factor represents the projected increase in the market basket index for a specific 12-month period. The factors are used to account for inflation in costs for cost reporting periods beginning after October 1. Adjustment factors are published in the annual notice of prospectively determined payment rates described in § 413.320.

(2) If a facility uses a cost reporting period that is not 12 months in duration, the contractor must obtain a special adjustment factor from CMS for the specific period.

(d) *Limitation of prospectively determined payment rate.* The per diem prospectively determined payment rate for an SNF, excluding capital-related costs and excluding return on equity for services furnished prior to October 1, 1993, may not exceed the individual SNF's routine service cost limit. Under § 413.30, the routine service cost limit is the limit determined without regard to exemptions, exceptions, or retroactive adjustments, and is the actual limit in effect when the provider elects to be paid a prospectively determined payment rate.

§ 413.316 Determining payment amounts: Ancillary services.

Ancillary services are paid on the basis of reasonable cost in accordance with section 1861(v)(1) of the Act and § 413.53.

§ 413.320 Publication of prospectively determined payment rates or amounts.

At least 90 days before the beginning of a Federal fiscal year to which revised prospectively determined payment rates are to be applied, CMS publishes a notice in the FEDERAL REGISTER:

(a) Establishing the prospectively determined payment rates for routine services; and

(b) Explaining the basis on which the prospectively determined payment rates are calculated.

§ 413.321 Simplified cost report for SNFs.

SNFs electing to be paid under the prospectively determined payment rate system may file a simplified cost report. The cost report contains a simplified method of cost finding to be used in lieu of cost methods described in § 413.24(d). This method is specified in the instructions for Form CMS–2540S, contained in sections 3000–3027.3 of Part 2 of the Provider Reimbursement Manual. This form may not be used by hospital-based SNFs or SNFs that are part of a health care complex. Those SNFs must file a cost report that reflects the shared services and administrative costs of the hospital and any other related facilities in the health care complex.

Subpart J—Prospective Payment for Skilled Nursing Facilities

SOURCE: 63 FR 26309, May 12, 1998, unless otherwise noted.

§ 413.330 Basis and scope.

(a) *Basis.* This subpart implements section 1888(e) of the Act, which provides for the implementation of a prospective payment system for SNFs for cost reporting periods beginning on or after July 1, 1998.

(b) *Scope.* This subpart sets forth the framework for the prospective payment system for SNFs, including the methodology used for the development of payment rates and associated adjustments, the application of a transition phase, and related rules.

§ 413.333 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the resident classification system.

Market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing services.

Resident classification system means a system for classifying SNF residents into mutually exclusive groups based on clinical, functional, and resource-based criteria. For purposes of this subpart, this term refers to the current version of the resident classification system, as set forth in the annual publication of Federal prospective payment rates described in § 413.345.

Rural area means, for services provided on or after July 1, 1998, but before October 1, 2005, an area as defined in § 412.62(f)(1)(iii) of this chapter. For services provided on or after October 1, 2005, *rural area* means an area as defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means, for services provided on or after July 1, 1998, but before October 1, 2005, an area as defined in § 412.62(f)(1)(ii) of this chapter. For services provided on or after October 1, 2005, *urban area* means an area as defined in §§ 412.64(b)(1)(ii)(A) and 412.64(b)(1)(ii)(B) of this chapter.

[63 FR 26309, May 12, 1998; 63 FR 53307, Oct. 5, 1998, as amended at 73 FR 46440, Aug. 8, 2008; 82 FR 36633, Aug. 4, 2017]

§ 413.335 Basis of payment.

(a) *Method of payment.* Under the prospective payment system, SNFs receive a per diem payment of a predetermined rate for inpatient services furnished to Medicare beneficiaries. The per diem payments are made on the basis of the Federal payment rate described in § 413.337 and, during a transition period, on the basis of a blend of the Federal rate and the facility-specific rate described in § 413.340. These per diem payment rates are determined according to the methodology described in §§ 413.337 and 413.340.

(b) *Payment in full.* (1) The payment rates represent payment in full (subject to applicable coinsurance as described in subpart G of part 409 of this chapter) for all costs (routine, ancillary, and capital-related) associated with furnishing inpatient SNF services to Medicare beneficiaries other than costs associated with approved educational activities as described in § 413.85.

(2) In addition to the Federal per diem payment amounts, SNFs receive payment for bad debts of Medicare beneficiaries, as specified in § 413.89 of this part.

[63 FR 26309, May 12, 1998, as amended at 73 FR 46440, Aug. 8, 2008]

§ 413.337 Methodology for calculating the prospective payment rates.

(a) *Data used.* (1) To calculate the prospective payment rates, CMS uses—

(i) Medicare data on allowable costs from freestanding and hospital-based SNFs for cost reporting periods beginning in fiscal year 1995. SNFs that received ''new provider'' exemptions under § 413.30(e)(2) are excluded from the data base used to compute the Federal payment rates. In addition, allowable costs related to exceptions payments under § 413.30(f) are excluded from the data base used to compute the Federal payment rates;

(ii) An appropriate wage index to adjust for area wage differences;

(iii) The most recent projections of increases in the costs from the SNF market basket index;

(iv) Resident assessment and other data that account for the relative resource utilization of different resident types; and

(v) Medicare Part B SNF claims data reflecting amounts payable under Part B for covered SNF services (other than those services described in § 411.15(p)(2) of this chapter) furnished during SNF cost reporting periods beginning in fiscal year 1995 to individuals who were residents of SNFs and receiving Part A covered services.

(b) *Methodology for calculating the per diem Federal payment rates*—(1) *Determining SNF costs.* In calculating the initial unadjusted Federal rates applicable for services provided during the period beginning July 1, 1998 through September 30, 1999, CMS determines each SNF's costs by summing its allowable costs for the cost reporting period beginning in fiscal year 1995 and its estimate of Part B payments (described in paragraphs (a)(1)(i) and (a)(1)(v) of this section).

(2) *Use of market basket index.* The SNF market basket index is used to adjust the SNF cost data to reflect cost increases occurring between cost reporting periods represented in the data and the initial period (beginning July 1, 1998 and ending September 30, 1999) to which the payment rates apply. For each year, the cost data are updated by a factor equivalent to the annual market basket index percentage minus 1 percentage point.

(3) *Calculation of the per diem cost.* For each SNF, the per diem cost is computed by dividing the cost data for each SNF by the corresponding number of Medicare days.

(4) *Standardization of data for variation in area wage levels and case-mix.* The cost data described in paragraph (b)(2) of this section are standardized to remove the effects of geographic variation in wage levels and facility variation in case-mix.

(i) The cost data are standardized for geographic variation in wage levels using the wage index. The application of the wage index is made on the basis of the location of the facility in an urban or rural area as defined in § 413.333.

(ii) Starting on October 1, 2022, CMS applies a cap on decreases to the wage index such that the wage index applied to a SNF is not less than 95 percent of the wage index applied to that SNF in the prior FY.

(iii) The cost data are standardized for facility variation in case-mix using the case-mix indices and other data that indicate facility case-mix.

(5) *Calculation of unadjusted Federal payment rates.* CMS calculates the national per diem unadjusted payment rates by urban and rural classification in the following manner:

(i) By computing the average per diem standardized cost of freestanding SNFs weighted by Medicare days.

(ii) By computing the average per diem standardized cost of freestanding and hospital-based SNFs combined weighted by Medicare days.

(iii) By computing the average of the amounts determined under paragraphs (b)(5)(i) and (b)(5)(ii) of this section.

(c) *Calculation of adjusted Federal payment rates for case-mix and area wage levels.* The Federal rate is adjusted to account for facility case-mix using a resident classification system and associated case-mix indices that account for the relative resource utilization of

different patient types. This classification system utilizes the resident assessment instrument completed by SNFs as described at §483.20 of this chapter, according to the assessment schedule described in §413.343(b). The Federal rate is also adjusted to account for geographic differences in area wage levels using an appropriate wage index.

(d) *Annual updates of Federal unadjusted payment rates.* CMS updates the unadjusted Federal payment rates on a fiscal year basis.

(1) *Update formula.* The unadjusted Federal payment rate shall be updated as follows:

(i) For the initial period beginning on July 1, 1998, and ending on September 30, 1999, the unadjusted Federal payment rate is equal to the rate computed under paragraph (b)(5)(iii) of this section increased by a factor equal to the SNF market basket index percentage change for such period minus 1.0 percentage point.

(ii) For fiscal year 2000, the unadjusted Federal payment rate is equal to the rate computed for the initial period described in paragraph (d)(1)(i) of this section increased by a factor equal to the SNF market basket index percentage change for that period minus 1.0 percentage point.

(iii) For fiscal year 2001, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year.

(iv) For fiscal years 2002 and 2003, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved minus 0.5 percentage points.

(v) For each subsequent fiscal year, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved, except as provided in paragraphs (d)(1)(vi) and (vii) of this section.

(vi) For fiscal year 2018, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF market basket index percentage change of 1 percent (after application of paragraphs (d)(2) and (3) of this section).

(vii) For fiscal year 2019, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF market basket index percentage change of 2.4 percent (after application of paragraphs (d)(2) and (3) of this section).

(2) *Forecast error adjustment.* Beginning with fiscal year 2004, an adjustment to the annual update of the previous fiscal year's rate will be computed to account for forecast error. The initial adjustment (in fiscal year 2004) to the update of the previous fiscal year's rate will take into account the cumulative forecast error between fiscal years 2000 and 2002. Subsequent adjustments in succeeding fiscal years will take into account the forecast error from the most recently available fiscal year for which there is final data. The forecast error adjustment applies whenever the difference between the forecasted and actual percentage change in the SNF market basket index exceeds the following threshold:

(i) 0.25 percentage points for fiscal years 2004 through 2007; and

(ii) 0.5 percentage points for fiscal year 2008 and subsequent fiscal years.

(3) *Multifactor productivity (MFP) adjustment.* For fiscal year 2012 and each subsequent fiscal year, the SNF market basket index percentage change for the fiscal year (as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section) shall be reduced by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The reduction of the market basket index percentage change by the MFP adjustment may result in the market basket index percentage change being less than zero for a fiscal year, and may result in the unadjusted Federal payment rates for a fiscal year being less than such payment rates for the preceding fiscal year.

(4) *Penalty for failure to report quality data.* For fiscal year 2018 and subsequent fiscal years—

(i) In the case of a SNF that does not meet the requirements in §413.360, for a

fiscal year, the SNF market basket index percentage change for the fiscal year (as specified in paragraph (d)(1)(v) of this section, as modified by any applicable forecast error adjustment under paragraph (d)(2) of this section, reduced by the MFP adjustment specified in paragraph (d)(3) of this section, and as specified for FY 2018 in section 1888(e)(5)(B)(iii) of the Act), is further reduced by 2.0 percentage points.

(ii) The application of the 2.0 percentage point reduction specified in paragraph (d)(4)(i) of this section to the SNF market basket index percentage change may result in such percentage being less than zero for a fiscal year, and may result in payment rates for that fiscal year being less than such payment rates for the preceding fiscal year.

(iii) Any 2.0 percentage point reduction applied pursuant to paragraph (d)(4)(i) of this section will apply only to the fiscal year involved and will not be taken into account in computing the payment amount for a subsequent fiscal year.

(e) Pursuant to section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) as revised by section 314 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), using the best available data, the Secretary will issue a new regulation with a newly refined case-mix classification system to better account for medically complex patients. Upon issuance of the new regulation, the temporary increases in payment for certain high cost patients will no longer be applicable.

(f) *Adjustments to payment rates under the SNF Value-Based Purchasing Program.* Beginning with payment for services furnished on October 1, 2018, the adjusted Federal per diem rate (as defined in § 413.338(a)) otherwise applicable to a SNF for the fiscal year is reduced by the applicable percent (as defined in § 413.338(a)). The resulting amount is then adjusted by the value-based incentive payment amount (as defined in § 413.338(a)) based on the SNF performance score calculated for the SNF for that fiscal year under § 413.338.

[63 FR 26309, May 12, 1998, as amended at 66 FR 39600, July 31, 2001; 68 FR 46070, Aug. 4, 2003; 76 FR 48539, Aug. 8, 2011; 82 FR 36633, Aug. 4, 2017; 83 FR 39289, Aug. 8, 2018; 87 FR 47616, Aug. 3, 2022; 89 FR 64160, Aug. 6, 2024]

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) *Definitions.* As used in this section:

Achievement threshold (or achievement performance standard) means the 25th percentile of SNF performance on a measure during the baseline period for a fiscal year.

Adjusted Federal per diem rate means the payment made to SNFs under the skilled nursing facility prospective payment system (as described under section 1888(e)(4)(G) of the Act).

Applicable percent means for FY 2019 and subsequent fiscal years, 2.0 percent.

Baseline period means the time period used to calculate the achievement threshold, benchmark, and improvement threshold that apply to a measure for a fiscal year.

Benchmark means, for a fiscal year, the arithmetic mean of the top decile of SNF performance on a measure during the baseline period for that fiscal year.

Eligible stay means, for purposes of the SNF readmission measure, an index SNF admission that would be included in the denominator of that measure.

Health equity adjustment (HEA) bonus points means the points that a SNF can earn for a fiscal year based on its performance and proportion of SNF residents who are members of the underserved population.

Improvement threshold (or improvement performance standard) means an individual SNF's performance on a measure during the applicable baseline period for that fiscal year.

Logistic exchange function means the function used to translate a SNF's performance score into a value-based incentive payment percentage.

Low-volume SNF means a SNF with fewer than 25 eligible stays included in the SNF readmission measure denominator during the performance period

for each of fiscal years 2019 through 2022.

Measure performance scaler means, for a fiscal year, the sum of the points assigned to a SNF for each measure on which the SNF is a top tier performing SNF.

Performance period means the time period during which SNF performance on a measure is calculated for a fiscal year.

Performance standards are the levels of performance that SNFs must meet or exceed to earn points on a measure under the SNF VBP Program for a fiscal year.

Ranking means the ordering of SNFs based on each SNF's performance score under the SNF VBP Program for a fiscal year.

SNF performance score means the numeric score ranging from 0 to 100 awarded to each SNF based on its performance under the SNF VBP Program for a fiscal year.

SNF readmission measure means, prior to October 1, 2027, the SNF 30-Day All-Cause Readmission Measure (SNFRM) specified under section 1888(g)(1) of the Social Security Act. Beginning October 1, 2027, the term SNF readmission measure means the SNF Within-Stay Potentially Preventable Readmission (SNF WS PPR) Measure specified under section 1888(g)(2) of the Social Security Act.

SNF Value-Based Purchasing (VBP) Program means the program required under section 1888(h) of the Act.

Top tier performing SNF means a SNF whose performance on a measure during the applicable fiscal year meets or exceeds the 66.67th percentile of SNF performance on the measure during the same fiscal year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of SNF residents who are members of the underserved population out of the SNF's total Medicare population, as identified from the SNF's Part A claims, during the performance period that applies to the 1-year measures for the applicable fiscal year.

Underserved population means Medicare beneficiaries who are SNF residents in a Medicare Part A stay who are also dually eligible, both partial and full, for Medicaid.

Value-based incentive payment adjustment factor is the number that will be multiplied by the adjusted Federal per diem rate for services furnished by a SNF during a fiscal year, based on its performance score for that fiscal year, and after such rate is reduced by the applicable percent.

Value-based incentive payment amount is the portion of a SNF's adjusted Federal per diem rate that is attributable to the SNF VBP Program.

(b) *Applicability of the SNF VBP Program.* The SNF VBP Program applies to SNFs, including facilities described in section 1888(e)(7)(B) of the Act. Beginning with fiscal year 2023, the SNF VBP Program does not include a SNF, with respect to a fiscal year, if:

(1) The SNF does not have the minimum number of cases that applies to each measure for the fiscal year, as specified by CMS; or

(2) The SNF does not have the minimum number of measures for the fiscal year, as specified by CMS.

(c) *Process for reducing the adjusted Federal per diem rate and applying the value-based incentive payment adjustment factor under the SNF VBP Program*—(1) *General.* CMS will make value-based incentive payments to each SNF based on its performance score for a fiscal year under the SNF VBP Program under the requirements and conditions specified in this paragraph.

(2) *Value-based incentive payment amount*—(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs under paragraph (d)(3) of this section. Beginning with the FY 2023 SNF VBP, the total amount available for value-based incentive payments for a fiscal year is 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS. Beginning with the FY 2027 SNF VBP, the total amount available

for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the application of the Health equity adjustment bonus points as calculated under paragraph (k) of this section.

(ii) *Calculation of the value-based incentive payment amount.* The value-based incentive payment amount is calculated by multiplying the adjusted Federal per diem rate by the value-based incentive payment adjustment factor, after the adjusted Federal per diem rate has been reduced by the applicable percent.

(iii) *Calculation of the value-based incentive payment adjustment factor.* The value-based incentive payment adjustment factor is calculated by estimating Medicare spending under the skilled nursing facility prospective payment system to estimate the total amount available for value-based incentive payments, ordering SNFs by their SNF performance scores, then assigning an adjustment factor value for each performance score subject to the limitations set by the exchange function.

(iv) *Reporting of adjustment to SNF payments.* CMS will inform each SNF of the value-based incentive payment adjustment factor that will be applied to its adjusted Federal per diem rate for services furnished during a fiscal year at least 60 days prior to the start of that fiscal year.

(d) *Performance scoring under the SNF VBP Program (applicable, as described in this paragraph, to fiscal year 2019 through and including fiscal year 2025).* (1) CMS will award points to SNFs based on their performance on the SNF readmission measure applicable to a fiscal year during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 99 points for achievement to each SNF whose performance meets or exceeds the achievement threshold but is less than the benchmark.

(ii) CMS will award from 0 to 90 points for improvement to each SNF whose performance exceeds the improvement threshold but is less than the benchmark.

(iii) CMS will award 100 points to a SNF whose performance meets or exceeds the benchmark.

(iv) CMS will not award points for improvement to a SNF that has fewer than 25 eligible stays during the baseline period.

(2) The highest of the SNF's achievement, improvement and benchmark score will be the SNF's performance score for the fiscal year.

(3) If, with respect to a fiscal year beginning with fiscal year 2019 through and including fiscal year 2022, CMS determines that a SNF is a low-volume SNF, CMS will assign a performance score to the SNF for the fiscal year that, when used to calculate the value-based incentive payment amount (as defined in paragraph (a)(17) of this section), results in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate (as defined in paragraph (a)(2) of this section) that would apply to the SNF for the fiscal year without application of §413.337(f).

(e) *Performance scoring under the SNF VBP Program beginning with fiscal year 2026.* (1) *Points awarded based on SNF performance.* CMS will award points to SNFs based on their performance on each measure for which the SNF reports the applicable minimum number of cases during the performance period applicable to that fiscal year as follows:

(i) CMS will award from 1 to 9 points for achievement to each SNF whose performance on a measure during the applicable performance period meets or exceeds the achievement threshold for that measure but is less than the benchmark for that measure.

(ii) CMS will award 10 points for achievement to a SNF whose performance on a measure during the applicable performance period meets or exceeds the benchmark for that measure.

(iii) CMS will award from 0 to 9 points for improvement to each SNF whose performance on a measure during the applicable performance period exceeds the improvement threshold but is less than the benchmark for that measure.

(iv) CMS will not award points for improvement to a SNF that does not meet the case minimum for a measure for the applicable baseline period.

(v) The highest of the SNF's achievement and improvement score for a given measure will be the SNF's score on that measure for the applicable fiscal year.

(2) *Calculation of the SNF performance score for fiscal year 2026.* The SNF performance score for FY 2026 is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year to calculate the SNF's point total.

(ii) CMS will normalize the point total such that the resulting SNF performance score is expressed as a number of points earned out of a total of 100.

(3) *Calculation of the SNF performance score beginning with fiscal year 2027.* The SNF performance score for a fiscal year is calculated as follows:

(i) CMS will sum all points awarded to a SNF as described in paragraph (e)(1) of this section for each measure applicable to a fiscal year.

(ii) CMS will normalize the SNF's point total such that the resulting point total is expressed as a number of points earned out of a total of 100.

(iii) CMS will add to the SNF's point total under paragraph (e)(3)(ii) of this section any applicable health equity adjustment bonus points calculated under paragraph (k) of this section such that the resulting point total is the SNF Performance Score for the fiscal year, except that no SNF Performance Score may exceed 100 points.

(f) *Confidential feedback reports and public reporting.*

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on each measure specified for the fiscal year. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, CMS calculates the measure rates included in those reports using data that are current as of a specified date as follows:

(i) For the SNFRM, the specified date is 3 months after the last index SNF admission in the applicable baseline period or performance period.

(ii) For the Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization (''SNF HAI''), Discharge to Community—Post-Acute Care Measure for Skilled Nursing Facilities (''DTC PAC SNF''), and Skilled Nursing Facility Within-Stay Potentially Preventable Readmissions (''SNF WS PPR'') measure, the specified date is 3 months after the last SNF discharge in the applicable baseline period or performance period.

(iii) For the Number of Hospitalizations per 1,000 Long Stay Residents (''Long Stay Hospitalization'') measure, the specified date is 3 months after the last day of the final quarter of the applicable baseline period or performance period.

(iv) For the Total Nursing Hours per Resident Day Staffing (''Total Nurse Staffing'') measure and the Total Nursing Staff Turnover (''Nursing Staff Turnover'') measure, the specified date is 45 days after the last day of each quarter of the applicable baseline period or performance period.

(v) For the Discharge Function Score for SNFs (''DC Function measure'') and Percent of Residents Experiencing One of More Falls with Major Injury (Long Stay) (''Falls with Major Injury (Long Stay)'') measure, the specified date is the February 15th that is approximately 4.5 months after the last day of the applicable baseline period or performance period.

(2) Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides in each of these reports to review and submit corrections to the measure rate calculations contained in that report. The underlying data used to calculate the measure rates are not subject to review and correction under this paragraph (f)(2). Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's name;

(iii) The correction requested; and

(iv) The reason for requesting the correction, including any available evidence to support the request.

(3) Beginning not later than 60 days prior to each fiscal year, CMS will provide reports to SNFs on their performance under the SNF VBP Program for a fiscal year. SNFs will have the opportunity to review and submit corrections to their SNF performance scores and ranking contained in these reports for 30 days following the date that CMS provides the reports. Any such correction requests must include:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's name;

(iii) The correction requested; and

(iv) The reason for requesting the correction, including any available evidence to support the request.

(4) CMS will publicly report the information described in paragraphs (f)(2) and (3) of this section on the Nursing Home Compare website or a successor website. Beginning with information publicly reported on or after October 1, 2019, and ending with information publicly reported on September 30, 2022 the following exceptions apply:

(i) If CMS determines that a SNF has fewer than 25 eligible stays during the baseline period for a fiscal year but has 25 or more eligible stays during the performance period for that fiscal year, CMS will not publicly report the SNF's baseline period SNF readmission measure rate and improvement score for that fiscal year;

(ii) If CMS determines that a SNF is a low-volume SNF with respect to a fiscal year and assigns a performance score to the SNF under paragraph (d)(3) of this section, CMS will not publicly report the SNF's performance period SNF readmission measure rate, achievement score or improvement score for the fiscal year; and

(iii) If CMS determines that a SNF has zero eligible cases during the performance period with respect to a fiscal year, CMS will not publicly report any information for that SNF for that fiscal year.

(5) Beginning with the information publicly reported on or after October 1, 2022, the following exceptions apply:

(i) If a SNF does not have the minimum number of cases during the baseline period that applies to a measure for a fiscal year, CMS will not publicly report the SNF's baseline period measure rate for that particular measure, although CMS will publicly report the SNF's performance period measure rate and achievement score if the SNF had the minimum number of cases for the measure during the performance period of the same program year;

(ii) If a SNF does not have the minimum number of cases during the performance period that applies to a measure for a fiscal year, CMS will not publicly report any information with respect to the SNF's performance on that measure for the fiscal year;

(iii) If a SNF does not have the minimum number of measures during the performance period for a fiscal year, CMS will not publicly report any data for that SNF for the fiscal year.

(g) *Limitations on review.* There is no administrative or judicial review of the following:

(1) The methodology used to determine the value-based incentive payment percentage and the amount of the value-based incentive payment under section 1888(h)(5) of the Act.

(2) The determination of the amount of funding available for value-based incentive payments under section 1888(h)(5)(C)(ii)(III) of the Act and the payment reduction under section 1888(h)(6) of the Act.

(3) The establishment of the performance standards under section 1888(h)(3) of the Act and the performance period.

(4) The methodology developed under section 1888(h)(4) of the Act that is used to calculate SNF performance scores and the calculation of such scores.

(5) The ranking determinations under section 1888(h)(4)(B) of the Act.

(h) *Special rules for the FY 2022 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2022, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF,

with the exception of those SNFs qualifying for the low-volume scoring adjustment described in paragraph (d)(3) of this section.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section. CMS will then apply low-volume scoring adjustment described in paragraph (d)(3) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (e)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (e)(3) of this section.

(i) *Special rules for the FY 2023 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2023, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (f)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (f)(3) of this section.

(j) *Validation.* (1) Beginning with the FY 2023 program year, for the SNFRM measure, and beginning with the FY 2026 program year for all other claims-based measures, the information reported through claims are validated for accuracy by Medicare Administrative Contractors (MACs).

(2) Beginning with the FY 2026 program year, for all measures that are calculated using Payroll-Based Journal System data, information reported through the Payroll-Based Journal system is validated for accuracy by CMS and its contractors through quarterly audits.

(3) Beginning October 1, 2026, for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. CMS will request medical records as follows:

(i) On an annual basis, a CMS contractor will randomly select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if the SNF submitted at least one MDS record in the calendar year that is 3 years prior to the applicable fiscal year or was included in the SNF VBP Program in the year prior to the applicable fiscal year.

(ii) For each SNF selected under paragraph (j)(3)(i) of this section, the CMS contractor will request in writing up to 10 medical records.

(iii) A SNF that receives a request for medical records under paragraph (j)(3)(ii) of this section must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request as documented on the request.

(k) *Calculation of the Health equity adjustment (HEA) bonus points.* CMS calculates the number of HEA bonus points that are added to a SNF's point total calculated under paragraph (e)(3)(iii) of this section by:

(1) Determining for each measure whether the SNF is a top tier performing SNF and assigning two points to the SNF for each such measure;

(2) Summing the points calculated under paragraph (k)(1) of this section to calculate the measure performance scaler;

(3) Calculating the underserved multiplier for the SNF; and

(4) Multiplying the measure performance scaler calculated under paragraph (k)(2) of this section by the underserved multiplier calculated under paragraph (k)(3) of this section.

(l) *Measure selection, retention, and removal policy.* (1) The SNF VBP measure

set for each fiscal year includes the SNF readmission measure CMS has specified under section 1888(g) of the Social Security Act for application in the SNF VBP Program.

(2) Beginning with FY 2026, the SNF VBP measure set for each fiscal year may include up to nine additional measures specified by CMS. Each of these measures remains in the measure set unless CMS removes or replaces it based on one or more of the following factors:

(i) SNF performance on the measure is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(ii) Performance or improvement on a measure do not result in better resident outcomes.

(iii) A measure no longer aligns with current clinical guidelines or practices.

(iv) A more broadly applicable measure for the particular topic is available.

(v) A measure that is more proximal in time to the desired resident outcomes for the particular topic is available.

(vi) A measure that is more strongly associated with the desired resident outcomes for the particular topic is available.

(vii) The collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the Program.

(3) Upon a determination by CMS that the continued requirement for SNFs to submit data on a measure specified under paragraph (l)(2) of this section raises specific resident safety concerns, CMS may elect to immediately remove the measure from the SNF VBP Program. Upon removal of the measure, CMS will provide notice to SNFs and the public, along with a statement of the specific patient safety concern that would be raised if SNFs continued to submit data on the measure. CMS will also provide notice of the removal in the FEDERAL REGISTER.

(4) CMS uses rulemaking to make substantive updates to the specifications of measures used in the SNF VBP Program. CMS makes technical measure specification updates in a sub-regulatory manner and informs SNFs of measure specification updates through postings on the CMS website, listservs, and other educational outreach efforts to SNFs.

(m) *Extraordinary circumstances exception policy*. (1) A SNF may request and CMS may grant exceptions to the SNF Value-Based Purchasing Program's requirements under this section for one or more calendar months when there are certain extraordinary circumstances beyond the control of the SNF.

(2) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred. Prior to FY 2025, the request must be submitted in the form and manner specified by CMS on the SNF VBP website at *https://www.cms.gov/Medicare/Quality/Nursing-Home-Improvement/Value-Based-Purchasing/Extraordinary-Circumstance-Exception* and include a completed Extraordinary Circumstances Request form (available on *https://qualitynet.cms.gov/*) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients including, but not limited to, photographs and media articles. Beginning with FY 2025, a SNF may request an extraordinary circumstances exception by sending an email with the subject line ''SNF VBP Extraordinary Circumstances Exception Request'' to the SNF VBP Program Help Desk with the following information:

(i) The SNF's CMS Certification Number (CCN);

(ii) The SNF's business name and business address;

(iii) Contact information for the SNF's chief executive officer (CEO) or CEO-designated personnel, including all applicable names, email addresses, telephone numbers, and the SNF's physical mailing address (which cannot be a P.O. Box);

(iv) A description of the event, including the dates and duration of the extraordinary circumstance;

(v) Available evidence of the impact of the extraordinary circumstance on the care the SNF provided to its residents or the SNF's ability to report

SNF VBP data, including, but not limited to, photographs, media articles, and any other materials that would aid CMS in determining whether to grant the exception; and

(vi) A date proposed by the SNF for when it will again be able to fully comply with the SNF VBP Program's requirements and a justification for the proposed date.

(3) Except as provided in paragraph (m)(4) of this section, CMS will not consider an exception request unless the SNF requesting such exception has complied fully with the requirements in paragraph (m)(2) of this section.

(4) CMS may grant exceptions to SNFs without a request if it determines that an extraordinary circumstance affected an entire region or locale.

(5) CMS will calculate a SNF performance score for a fiscal year for a SNF for which it has granted an exception request that does not include its performance on a quality measure during the calendar months affected by the extraordinary circumstance.

(n) *SNF VBP performance standards.* (1) CMS announces the performance standards for each measure no later than 60 days prior to the start of the performance period that applies to the measure for the fiscal year.

(2) Beginning with FY 2021, if CMS discovers an error in the performance standard calculations subsequent to publishing their numerical values for a fiscal year, CMS will update the numerical values to correct the error. If CMS subsequently discovers one or more other errors with respect to the fiscal year, CMS will not further update the numerical values for that fiscal year.

(3) Beginning with FY 2025, CMS may update the numerical values of the performance standards for a measure if, between the time that CMS announced the performance standards for the measure for that fiscal year and the time that CMS calculates SNF performance on the measure at the conclusion of the performance period for that measure for that fiscal year, CMS has made technical updates to the specifications for the measure that affect the measure rate calculations.

[82 FR 36633, Aug. 4, 2017, as amended at 83 FR 39289, Aug. 8, 2018; 85 FR 47633, Aug. 5, 2020; 86 FR 42524, Aug. 4, 2021; 87 FR 47616, Aug. 3, 2022; 88 FR 53346, Aug. 7, 2023; 89 FR 64160, Aug. 6, 2024]

§ 413.340 Transition period.

(a) *Duration of transition period and proportions for the blended transition rate.* Beginning with an SNF's first cost reporting period beginning on or after July 1, 1998, there is a transition period covering three cost reporting periods. During this transition phase, SNFs receive a payment rate comprising a blend of the adjusted Federal rate and a facility-specific rate. For the first cost reporting period beginning on or after July 1, 1998, payment is based on 75 percent of the facility-specific rate and 25 percent of the Federal rate. For the subsequent cost reporting period, the rate is comprised of 50 percent of the facility-specific rate and 50 percent of the Federal rate. In the final cost reporting period of the transition, the rate is comprised of 25 percent of the facility-specific rate and 75 percent of the Federal rate. For all subsequent cost reporting periods, payment is based entirely on the Federal rate.

(b) *Calculation of facility-specific rate for the first cost reporting period.* The facility-specific rate is computed based on the SNF's Medicare allowable costs from its fiscal year 1995 cost report plus an estimate of the amounts payable under Part B for covered SNF services (other than those services described in § 411.15(p)(2) of this chapter) furnished during fiscal year 1995 to individuals who were residents of SNFs and receiving Part A covered services. Allowable costs associated with exceptions, as described in § 413.30(f), are included in the calculation of the facility-specific rate. Allowable costs associated with exemptions, as described in § 413.30(e)(2), are included in the calculation of the facility-specific rate but only to the extent that they do not exceed 150 percent of the routine cost limit. Low Medicare volume SNFs that were paid a prospectively determined rate under § 413.300 for their cost reporting period beginning in fiscal year 1995 will utilize that rate as the basis

for the allowable costs of routine (operating and capital-related) expenses in determining the facility-specific rate. Each SNF's allowable costs are updated to the first cost reporting period to which the payment rates apply using annual factors equal to the SNF market basket percentage minus 1 percentage point.

(c) *SNFs participating in the Multistate Nursing Home Case-Mix and Quality Demonstration.* SNFs that participated in the Multistate Nursing Home Case-Mix and Quality Demonstration in a cost reporting period that began in calendar year 1997 will utilize their allowable costs from that cost reporting period, including prospective payment amounts determined under the demonstration payment methodology.

(d) *Update of facility-specific rates for subsequent cost reporting periods.* The facility-specific rate for a cost reporting period that is subsequent to the first cost reporting period is equal to the facility-specific rate for the first cost reporting period (described in paragraph (a) of this section) updated by the market basket index.

(1) For a subsequent cost reporting period beginning in fiscal years 1998 and 1999, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage minus one percentage point.

(2) For a subsequent cost reporting period beginning in fiscal year 2000, the facility-specific rate is equal to the facility-specific rate for the previous cost reporting period updated by the applicable market basket index percentage.

(e) *SNFs excluded from the transition period.* SNFs that received their first payment from Medicare, under present or previous ownership, on or after October 1, 1995, are excluded from the transition period, and payment is made according to the Federal rates only.

§ 413.343 Resident assessment data.

(a) *Submission of resident assessment data.* SNFs are required to submit the resident assessment data described at § 483.20 of this chapter in the manner necessary to administer the payment rate methodology described in § 413.337. This provision includes the frequency, scope, and number of assessments required.

(b) *Assessment schedule.* In accordance with the methodology described in § 413.337(c) related to the adjustment of the Federal rates for case-mix, SNFs must submit assessments according to an assessment schedule. This schedule must include performance of an initial Medicare assessment with an assessment reference date that is set for no later than the 8th day of posthospital SNF care, and such other interim payment assessments as the SNF determines are necessary to account for changes in patient care needs.

(c) *Noncompliance with assessment schedule.* CMS pays a default rate for the Federal rate when a SNF fails to comply with the assessment schedule in paragraph (b) of this section. The default rate is paid for the days of a patient's care for which the SNF is not in compliance with the assessment schedule.

[63 FR 26309, May 12, 1998, as amended at 64 FR 41682, July 30, 1999; 84 FR 38832, Aug. 7, 2019]

§ 413.345 Publication of Federal prospective payment rates.

CMS publishes information pertaining to each update of the Federal payment rates in the FEDERAL REGISTER. This information includes the standardized Federal rates, the resident classification system that provides the basis for case-mix adjustment, and the factors to be applied in making the area wage adjustment. This information is published before May 1 for the fiscal year 1998 and before August 1 for the fiscal years 1999 and after.

[82 FR 36634, Aug. 4, 2017]

§ 413.348 Limitation on review.

Judicial or administrative review under sections 1869 or 1878 of the Act or otherwise is prohibited with regard to the establishment of the Federal rates. This prohibition includes the methodology used in the computation of the Federal standardized payment rates, the case-mix methodology, and the development and application of the wage index. This prohibition on judicial and

administrative review also extends to the methodology used to establish the facility-specific rates but not to determinations related to reasonable cost in the fiscal year 1995 cost reporting period used as the basis for these rates.

§ 413.350 Periodic interim payments for skilled nursing facilities receiving payment under the skilled nursing facility prospective payment system for Part A services.

(a) *General rule.* Subject to the exceptions in paragraphs (b) and (c) of this section, SNFs receiving payment under the PPS for Part A services do not receive interim payments during the cost reporting year, and receive payment only following submission of a bill. Paragraph (d) of this section provides for accelerated payments in certain circumstances.

(b) *Periodic interim payments.* (1) An SNF receiving payment under the prospective payment system may receive periodic interim payments (PIP) for Part A SNF services under the PIP method subject to the provisions of § 413.64(h). To be approved for PIP, the SNF must meet the qualifying requirements in § 413.64(h)(3). Moreover, as provided in § 413.64(h)(5), contractor approval is conditioned upon the contractor's best judgment as to whether payment can be made under the PIP method without undue risk of its resulting in an overpayment to the provider.

(2) *Frequency of payment.* The contractor estimates an SNF's prospective payments net of estimated beneficiary coinsurance and makes biweekly payments equal to 1/26 of the total estimated amount of payment for the year. If an SNF has payment experience under the prospective payment system, the contractor estimates PIP based on that payment experience, adjusted for projected changes supported by substantiated information for the current year. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final settlement.

(3) *Termination of PIP*—(i) *Request by the SNF.* An SNF receiving PIP may convert to receiving prospective payments on a non-PIP basis at any time.

(ii) *Removal by the contractor.* An contractor terminates PIP if the SNF no longer meets the requirements of § 413.64(h).

(c) *Interim payments for Medicare bad debts and for Part A costs not paid under the prospective payment system.* For Medicare bad debts and for costs of an approved education program and other costs paid outside the prospective payment system, the contractor determines the interim payments by estimating the reimbursable amount for the year based on the previous year's experience, adjusted for projected changes supported by substantiated information for the current year, and makes biweekly payments equal to 1/26 of the total estimated amount. Each payment is made 2 weeks after the end of a biweekly period of service as described in § 413.64(h)(6). The interim payments are reviewed at least twice during the reporting period and adjusted if necessary. Fewer reviews may be necessary if an SNF receives interim payments for less than a full reporting period. These payments are subject to final cost settlement.

(d) *Accelerated payments*—(1) *General rule.* Upon request, an accelerated payment may be made to an SNF that is receiving payment under the prospective payment system and is not receiving PIP under paragraph (b) of this section if the SNF is experiencing financial difficulties because of the following:

(i) There is a delay by the contractor in making payment to the SNF.

(ii) Due to an exceptional situation, there is a temporary delay in the SNF's preparation and submittal of bills to the contractor beyond its normal billing cycle.

(2) *Approval of payment.* An SNF's request for an accelerated payment must be approved by the contractor and CMS.

(3) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(4) *Recovery of payment.* Recovery of the accelerated payment is made by

recoupment as SNF bills are processed or by direct payment by the SNF.

[64 FR 41682, July 30, 1999]

§ 413.355 Additional payment: QIO reimbursement for cost of sending records electronically or by photocopy and mailing.

An additional payment is made to a skilled nursing facility in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

[85 FR 59025, Sept. 18, 2020]

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

(a) *Participation start date.* Beginning with the FY 2018 program year, a SNF must begin reporting data in accordance with paragraph (b) of this section no later than the first day of the calendar quarter subsequent to 30 days after the date on its CMS Certification Number (CCN) notification letter, which designates the SNF as operating in the CMS designated data submission system. For purposes of this section, a program year is the fiscal year in which the market basket percentage described in § 413.337(d) is reduced by two percentage points if the SNF does not report data in accordance with paragraph (b) of this section.

(b) *Data submission requirement.* (1) Except as provided in paragraph (c) of this section, and for a program year, SNFs must submit to CMS data on measures specified under sections 1899B(c)(1) and 1899B(d)(1) of the Social Security Act and standardized resident assessment data in accordance with section 1899B(b)(1) of the Social Security Act, in the form and manner, and at a time, specified by CMS.

(2) CMS may remove a quality measure from the SNF QRP based on one or more of the following factors:

(i) Measure performance among SNFs 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 resident 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 resident outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired resident outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

(c) *Exception and extension requests.* (1) A SNF may request and CMS may grant exceptions 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 SNF.

(2) A SNF may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to *SNFQRPReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) SNF CMS Certification Number (CCN).

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) SNF's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the SNF believes it will be able to again submit SNF QRP data and a justification for the proposed date.

(3) Except as provided in paragraph (c)(4) of this section, CMS will not consider an exception or extension request

unless the SNF requesting such exception or extension has complied fully with the requirements in this paragraph (c).

(4) CMS may grant exceptions or extensions to SNFs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a SNF to submit data in accordance with paragraph (b) of this section.

(d) *Reconsideration.*

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a notification of non-compliance sent through at least one of the following methods: The CMS designated data submission system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests must be submitted to CMS by sending an email to *SNFQRPReconsiderations@cms.hhs.gov* containing all of the following information:

(i) SNF CCN.

(ii) SNF Business Name.

(iii) SNF Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address. (The address must be a physical address, not a post office box.)

(v) CMS identified reason(s) for non-compliance stated in the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider a reconsideration request unless the SNF has complied fully with the requirements in paragraph (d)(2) of this section.

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following methods: CMS designated data submission system, the United States Postal Service, or via email from the CMS Medicare Administrative Contractor (MAC).

(e) *Appeals.* A SNF that is dissatisfied with CMS' decision on a request for reconsideration may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(f) *Data completion threshold.*

(1) SNFs must meet or exceed the following data completeness thresholds with respect to a program year:

(i) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the Minimum Data Set (MDS) on at least 80 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2018 through FY 2025 program years.

(ii) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the MDS on at least 90 percent of the assessments SNFs submit through the CMS designated data submission system for FY 2026 and for all subsequent payment updates.

(iii) The threshold set at 100 percent for measures data collected and submitted through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for FY 2023 and for all subsequent payment updates.

(iv) If selected for the data validation process under paragraph (g) of this section, the threshold set at 100 percent submission of medical charts.

(2) These thresholds apply to all measures and standardized patient assessment data requirements adopted into the SNF QRP.

(3) A SNF must meet or exceed each applicable threshold described in paragraph (f)(1) of this section to avoid receiving the applicable penalty for failure to report quality data set forth in § 413.337(d)(4).

(g) *Data validation process.* (1) Beginning with the FY 2027 payment year: for all measures that are calculated using Minimum Data Set (MDS) information, CMS will validate the accuracy of this information. The process by which CMS will request medical

records and by which SNFs must submit the requested medical records is as follows:

(i) On an annual basis, a CMS contractor will select up to 1,500 SNFs for validation. A SNF is eligible for selection for a year if it submitted at least one MDS record to CMS in the fiscal year that is 2 years prior to the applicable program year, and if the SNF has been randomly selected for a periodic audit for the same year under § 413.338.

(ii) For each SNF selected under this paragraph (g)(1), the CMS contractor will request up to 10 medical records. Each SNF selected will only be required to submit records once in a fiscal year, for a maximum of 10 records for each SNF selected. Each requested medical record must be the same medical record that has been requested for submission by the SNF for the same year under § 413.338. CMS will submit its request in writing to the selected SNF.

(iii) A SNF that receives a request for medical records under this paragraph (g)(1) must submit a digital or paper copy of each of the requested medical records within 45 days of the date of the request.

(2) Beginning with the FY 2027 payment year: the information reported through claims for all claims-based measures are validated for accuracy by Medicare Administrative Contractors (MACs).

[82 FR 36634, Aug. 4, 2017, as amended at 83 FR 39290, Aug. 8, 2018; 84 FR 38832, Aug. 7, 2019; 87 FR 47618, Aug. 3, 2022; 88 FR 53346, Aug. 7, 2023; 89 FR 64162, Aug. 6, 2024]

Subpart K—Payment for Acute Kidney Injury (AKI) Dialysis

SOURCE: 81 FR 77965, Nov. 4, 2016, unless otherwise noted.

§ 413.370 Scope.

This subpart implements section 1834(r) of the Act by setting forth the principles and authorities under which CMS is authorized to establish a payment amount for renal dialysis services furnished to beneficiaries with an acute kidney injury in or under the supervision of an ESRD facility that meets the conditions of coverage in part 494 of this chapter and as defined in § 413.171.

§ 413.371 Definition.

For purposes of the subpart, the following definition applies:

Individual with acute kidney injury. The term individual with acute kidney injury means an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

§ 413.372 AKI dialysis payment rate.

The amount of payment for AKI dialysis services shall be the base rate for renal dialysis services determined for such year under section 1881(b)(14), that is, the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373.

§ 413.373 Other adjustments to the AKI dialysis payment rate.

The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

§ 413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act.

(b) Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in § 413.171, but that are related to their dialysis treatment as a result of their AKI, would be separately payable, that is, drugs, biologicals, laboratory services, and

supplies that ESRD facilities are certified to furnish and that would otherwise be furnished to a beneficiary with AKI in a hospital outpatient setting.

§ 413.375 Notification of changes in rate-setting methodologies and payment rates.

(a) Changes to the methodology for payment for renal dialysis services furnished to beneficiaries with AKI as well as any adjustments to the AKI payment rate other than wage index will be adopted through notice and comment rulemaking.

(b) Annual updates in the AKI dialysis payment rate as described in § 413.372 that do not include those changes described in paragraph (a) of this section are announced by notice published in the FEDERAL REGISTER without opportunity for public comment.

(c) Effective for cost reporting periods beginning on or after January 1, 2017, on an annual basis CMS updates the AKI dialysis payment rate.

Subpart L—Payment of Organ Acquisition Costs for Transplant Hospitals. Organ Procurement Organizations, and Histocompatibility Laboratories

SOURCE: 86 FR 73515, Dec. 27, 2021, unless otherwise noted.

§ 413.400 Definitions.

As used in this subpart:

Histocompatibility laboratory means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report.

Independent organ procurement organization (IOPO) means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

(1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.

(2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

Organ, for Medicare organ acquisition payment purposes, means:

(1) A human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004, for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Organ procurement organization (OPO) means an organization defined in § 486.302 of this chapter. OPOs can be independent or hospital based.

Standard acquisition charge (SAC) means a charge as defined in § 413.404 of this chapter.

Transplant hospital (TH) means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a TH, or a TH that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the TH's Medicare cost report.

Transplant program means an organ-specific transplant program within a TH (as defined in this section).

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72287, Nov. 23, 2022]

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are allowable costs incurred in the acquisition of organs intended for transplant, including those

organs that are subsequently determined unsuitable for transplant and furnished for research from a living donor or a deceased donor by the hospital, or from a deceased donor by an OPO. Additionally, there are administrative and general costs that may be allowable and included on the cost report for an OPO or a TH.

(b) *Types of costs.* Organ acquisition costs are as follows:

(1) Tissue typing, including tissue typing furnished by independent laboratories.

(2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services (for example, intensive care unit or critical care unit services), provided to the living or deceased donor.

(4) Operating room and other inpatient ancillary services applicable to the living or deceased donor.

(5) Organ preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees, and the reasonable and necessary cost of other fees, such as the registration fees for a kidney paired exchange, to register candidates for organ transplants. These allowable registry fees must support or promote organ transplantation and must not be duplicative in nature.

(7) Surgeons' fees for excising deceased organs (currently limited to $1,250 for kidneys).

(8) Transportation of the:

(i) Excised organ to the TH; and

(ii) Deceased donor to procure organs when it is necessary to preserve clinical outcomes or to avoid loss of potentially transplantable organs.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and the costs of physicians' services.

(c) *Living donor complications.* (1) *Living kidney donor complications.* Living kidney donor complications directly related to the kidney donation, which occur after the date of the donor's discharge, must not be reported as kidney acquisition costs on the Medicare cost report.

(A) Medicare covers reasonable costs incurred for living kidney donor complications only if they are directly related to a kidney donation for a covered transplant into a Medicare beneficiary.

(B) Living kidney donor complications are paid through the claims processing system under Medicare Part A or Part B, as applicable for the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

(2) *Living non-renal donor complications.* Hospital costs incurred for living non-renal donor complications directly related to the non-renal organ donation, which occur after the date of the donor's discharge are not paid through the claims processing system but are reported as organ acquisition costs on the hospital's Medicare cost report.

(A) Medicare covers reasonable hospital costs incurred for living non-renal organ donor complications only if they are directly related to a non-renal organ donation for a covered transplant into a Medicare beneficiary.

(B) Hospital costs incurred for living non-renal organ donor complications are reported as organ acquisition costs on the Medicare cost report, and paid through the cost report on a reasonable cost basis.

(d) *Costs not related to organ acquisition.* (1) Items or services that are not related or reasonable to acquire an organ for transplantation, non-allowable administrative and general costs, or costs that are not related to patient care, are not considered organ acquisition costs.

(2) Examples of items or services that are not organ acquisition costs include, but are not limited to the following:

(i) Donor burial and funeral expenses.

(ii) Transportation costs of the deceased donor after organ procurement for funeral services or for burial.

(iii) Transportation costs for a living donor.

(iv) Fees or in-center payments for donor referrals.

(v) Costs associated with and incurred for OPO-sponsored seminars where continuing education credits are given and where the attendee is not on the OPO's staff (as described at § 486.326(b)).

(vi) Unreasonable costs incurred for administrator's duties associated with professional organizations.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

§ 413.404 Standard acquisition charge.

(a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.

(2) The SAC represents the average of the total organ acquisition costs associated with procuring either deceased donor organs or living donor organs, by organ type.

(3) When a TH/HOPO or IOPO furnishes an organ to another TH/HOPO or IOPO, it bills its SAC to the TH/HOPO or IOPO receiving the organ.

(b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).

(2) When a TH/HOPO furnishes an organ to another TH or IOPO, it must bill the receiving TH or IOPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A TH must establish SACs for living donor organs. A TH/HOPO must establish SACs for deceased donor organs.

(i) *Living donor SAC for THs–*(A) *Definition.* The living donor SAC is an average organ acquisition cost that a TH incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A TH must establish a living donor SAC before the TH bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC.—*(*1*) *Initial living donor SAC.* A TH calculates its initial living donor SAC for each living donor organ type as follows:

(*i*) By estimating the reasonable and necessary organ acquisition costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(i)(C)(*1*)(*i*) of this section by the projected number of usable living donor organs to be procured by the TH during the TH's cost reporting period.

(*2*) *Subsequent living donor SAC.* A TH calculates its subsequent years' living donor SAC for each living donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(i)(C)(*2*)(*i*) of this section by the actual number of usable living donor organs procured by the TH during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

(*1*) Costs of tissue typing services, including those furnished by independent laboratories.

(*2*) Costs of physician pre-admission transplant evaluation services.

(*3*) Registry fees as specified at § 413.402(b)(6) of this subpart.

(*4*) Costs for donor and recipient evaluations and workups furnished prior to admission for transplantation.

(*5*) Other costs associated with procurement, for example, general routine and special care services (for example, intensive care unit or critical care unit services), related to the donor.

(*6*) Costs of operating room and other inpatient ancillary services related to the donor.

(*7*) Organ preservation and perfusion costs.

(*8*) Transportation costs of the excised organ as specified in § 413.402(b)(8)(i) of this subpart.

(ii) *Deceased donor SAC for TH/HOPOs*—(A) *Definition*. The deceased donor SAC is an average cost that a TH/HOPO incurs to procure a deceased donor organ.

(B) *Calculating the deceased donor SAC—(1)—Initial deceased donor SAC*. A TH/HOPO calculates its initial deceased donor SAC for each deceased donor organ type as follows:

(*i*) By estimating the reasonable and necessary costs it expects to incur to procure deceased donor organs, combined with the expected costs of acquiring deceased donor organs from OPOs or other THs.

(*ii*) By dividing the estimated amount described in paragraph (b)(3)(ii)(B)(*1*)(*i*) of this section by the projected number of usable deceased donor organs to be procured by the TH/HOPO within the TH's cost reporting period.

(*2*) *Subsequent deceased donor SAC*. A TH/HOPO calculates its subsequent years' deceased donor SAC for each deceased donor organ type as follows:

(*i*) By using the TH's actual organ acquisition costs for the deceased donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) By dividing the costs in paragraph (b)(3)(ii)(B)(*2*)(*i*) of this section by the actual number of usable deceased donor organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the deceased donor SAC*. Costs that may be used to develop the deceased donor SAC include, but are not limited to the following:

(*1*) Costs of organs acquired from other THs or OPOs.

(*2*) Costs of transportation as specified in §413.402(b)(8).

(*3*) Surgeons' fees for excising deceased donor organs (currently limited to $1,250 for kidneys).

(*4*) Costs of tissue typing services, including those furnished by independent laboratories.

(*5*) Organ preservation and perfusion costs.

(*6*) General routine and special care service costs (for example, intensive care unit or critical care unit services related to the donor).

(*7*) Operating room and other inpatient ancillary service costs.

(c) *Independent OPO SACs*—(1) *Non-renal SAC*. An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure deceased donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of deceased donor non-renal organs the IOPO expects to procure within its cost reporting period.

(iii) An IOPO may adjust its non-renal SACs during the year if necessary to account for cost changes.

(2) *Kidney SAC*. (i) *General*. An IOPO's contractor establishes the kidney SAC based on an estimate of, initial year projected or subsequent years' actual, reasonable and necessary costs the IOPO expects to incur to procure deceased donor kidneys during the IOPO's cost reporting period, divided by the, initial year projected or subsequent years' actual, number of usable deceased donor kidneys the IOPO expects to procure.

(ii) *Initial year*. The contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) *Subsequent years*. The contractor computes the kidney SAC for subsequent years using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable deceased donor kidneys procured during that cost reporting period. The kidney SAC amount is the interim payment made by the TH or other OPO to the IOPO, as set forth in §413.420(d)(1).

(iv) *SAC adjustments*. The IOPO's contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally*. When an IOPO obtains an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The receiving IOPO uses

its SAC for each organ type and not the procuring IOPO's SAC when billing the TH receiving the organ.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72288, Nov. 23, 2022]

§ 413.406 Acquisition of pancreata for islet cell transplant.

(a) Medicare only covers and pays for reasonable costs of acquisition on or after October 1, 2004, of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

(b) Pancreata procured under paragraph (a), for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

§ 413.408 [Reserved]

§ 413.410 [Reserved]

§ 413.412 Intent to transplant, intent for research, counting en bloc, and unusable organs.

(a) *Principles for organs intended for transplant for organ acquisition payment purposes.* (1) An organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type. These costs include the costs associated with an organ intended for transplant, but subsequently determined unsuitable for transplant and furnished for research.

(3) An organ intended for transplant but subsequently determined unsuitable for transplant and instead furnished for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs.

(4) Subject to paragraph (a)(4)(iii) of this section, OPOs and THs must reduce total organ acquisition costs, when the organ is intended for transplant but determined unsuitable for transplant and instead furnished for research, as follows:

(i) By deducting the costs to furnish organs for research from total organ acquisition costs; or

(ii) By offsetting the total organ acquisition costs by the revenue received for these organs.

(iii) In no event may the reduction in total organ acquisition costs as a result of application of paragraph (a)(4) of this section exceed the costs incurred to furnish organs for research.

(5) When the costs to furnish organs for research are not included in total organ acquisition costs but are included in a non-reimbursable cost center, no offset is necessary.

(b) *Principles for organs intended for research for organ acquisition payment purposes.* (1) An organ is intended for research when the OPO or TH designates it for research

prior to the time the donor enters the hospital's operating room for surgical removal of the organ.

(2) Medicare does not share in the acquisition costs of an organ intended for research and costs to procure these organs must not be included in organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(3) An organ intended for research is not counted as a Medicare usable organ or as a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs (except pancreata for islet cell transplants as specified in § 413.406(a)).

(c) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and THs count -

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney.

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For

each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney.

(d) *Unusable organs.* (1) An organ is not counted as a Medicare usable organ or a total usable organ in the ratio used to calculate Medicare's share of organ acquisition costs if a physician determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and is therefore unusable.

(2) OPOs and THs include the cost to procure unusable organs, as described in paragraph (d)(1) of this section, in total organ acquisition costs reported on their Medicare cost report.

[87 FR 72289, Nov. 23, 2022]

§413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer to the TH that performs the transplant in certain instances. To determine whether Medicare has liability to the TH that performs the transplant as a secondary payer for organ acquisition costs, it is necessary for the TH that performs the transplant to review the TH's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the TH that performs the transplant to accept the payment from the primary insurer as payment in full, and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability to the TH that performs the transplant for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH that performs the transplant to submit a bill to its contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the TH must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The TH must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) Only the TH that performs the transplant counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72289, Nov. 23, 2022]

§413.416 Organ acquisition charges for kidney-paired exchanges.

(a) Initial living donor evaluations. When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are

matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's Medicare cost report.

(c) *Procurement and transport of a kidney*. When a donor's TH procures and furnishes a kidney to a recipient's TH all of the following are applicable:

(1) All costs must be reasonable and necessary.

(2)(i) The donor's TH bills the recipient's TH.

(ii) The donor's TH bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's TH records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs.

(4) The recipient's TH records as part of its kidney acquisition costs -

(i) The amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's TH.

(d) Donor's procurement occurs at recipient TH. In a kidney-paired exchange—

(1) When a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's TH; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]

§ 413.418 Amounts billed to organ procurement organizations for hospital services provided to deceased donors and included as organ acquisition costs.

(a) *General*. A donor community hospital (a Medicare-certified non-TH) and a TH incur costs for hospital services attributable to a deceased donor or a donor whose death is imminent. These services must not be part of medical treatment that primarily offers a medical benefit to the patient as determined by a healthcare team, must be authorized by the OPO, and are included as organ acquisition costs when:

(1) There is consent to donate; and

(2) Declaration of death has been made, or if a declaration of death has not been made, death is imminent and it is necessary that the services be provided prior to declaration of death in order to avoid compromising the viability of the organs for transplant.

(b) *Amounts billed for organ acquisition costs*. When a donor community hospital or TH incurs costs for services furnished to a deceased donor, or a donor whose death is imminent as described in paragraph (a) of this section, as authorized by the OPO, the donor community hospital or TH must bill the OPO the lesser of its customary charges that are reduced to cost by applying its most recently available hospital specific inpatient operating cost-to-charge ratio for the period in which the service was rendered, or a negotiated rate.

[87 FR 72290, Nov. 23, 2022]

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle*. (1) Covered services furnished by IOPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the TH using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by IOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions*. Definitions relevant to this section can be found in § 413.400.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with §413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate, payable by the THs for services provided by the IOPO or laboratory, and to determine Medicare's reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to THs and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) Interim reimbursement. (1) THs with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is a kidney SAC or contractor established rates, based on costs associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by THs on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all THs and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in §413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to determine the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) *Retroactive adjustment.* A retroactive adjustment in the amount paid under the interim rate is made in accordance with §413.64(f).

(ii) *Lump sum adjustment.* If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to THs, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements.* For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals.* If the amount in controversy is $1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance

with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

[86 FR 73515, Dec. 27, 2021, as amended at 87 FR 72290, Nov. 23, 2022]

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List of CFR Sections Affected

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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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403 Authority citation revised 20757, 51813

403.736 Introductory text and (b) removed; (a) revised; (c) and (d) redesignated as new (b) and (c); eff. 11-29-19 51813

403.748 (a) introductory text, (4), (b) introductory text, (c) introductory text, (d) introductory text, and (1)(ii) revised; (d)(1)(v) added; eff. 11-29-19 51813

403.800—403.822 (Subpart H) Heading revised 25675

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403.904 (c)(1), (3) introductory text, (ii), (iii), (8), (e)(2) introductory text, (xiv), (xv), (f)(1) introductory text, (i)(A) introductory text, (*1*), (*3*), (*5*), (iv), (v), (h)(5), (7), and (13) revised; (e)(2)(xi) and (xviii) added; interim 63186

403.908 (g)(2)(ii) introductory text revised; interim 63187

403.1200—403.1204 (Subpart L) Added 20757

405 Authority citation revised 19869, 47851

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405.371 (a) introductory text revised; (a)(1) and (2) amended; (a)(4) added 47852

405.425 (i) and (j) revised 47852

405.800 (c) added 47852

405.910 (c)(5) and (e)(4) amended 19869

405.926 (f) amended 19869
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405.952 (b)(4)(i) and (d) amended 19870

405.964 (b)(2) and (4) amended 19870

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405.1010 (b)(1), (3)(ii), (c)(3)(i), and (ii)(A) revised 19870

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405.1014 (a)(1)(i) and (e)(2) amended 19870

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405.1046 (a)(2)(ii) amended 19871

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405.1056 (d), (f), and (g) revised 19871

405.1110 (a) and (b)(2) amended; (e) added 19871

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405.1114 (c)(1) amended 19871
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410.41 Heading and (c)(1) revised; interim 63188
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412.87 (c) redesignated as (e); (b)(1)(i) through (v), new (c), and (d) added; new (e) revised 42611
412.88 (a)(2) and (b) revised 42612
412.101 (e) revised 42613
412.103 (g)(1)(iii), (3), and (4) added; (b)(3) and (g)(2)(iii) revised 42613
412.106 (g)(1)(iii)(C)(*6*) added 42613
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412.256 (a)(1) revised 42614
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412.523 (c)(3)(xvi) added 42614
412.560 (d)(1), (3), and (f)(1) revised 42615
412.622 (a)(3)(iv), (4)(i)(A), (iii)(A), and (5)(i) revised; (c) added 39172
412.634 (a)(1), (d)(1), (5), and (f)(1) revised 39172
413 Authority citation revised 42615
413 Technical correction 53602
413.70 (b)(5)(i)(C) revised; (b)(5)(i)(D) added 42615
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413.230 (b) and (c) revised; (d) and (e) added 60803
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413.236 Added 60805
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412.64 (e)(5) added 59020
412.82 (c) amended 59020
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412.85—412.86 Undesignated center heading added 59020
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412.87 (c)(1), (d) introductory text, (1), (e) heading, and (2) revised; (e)(3) added 59020
412.88 (a)(2)(ii)(A) introductory text amended; (a)(2)(ii)(B) introductory text and (b)(2) revised 59021
412.92 (c)(3) revised 59021
412.96 (c)(2)(iii) added 59021
412.104 (a) revised 59021
412.105 (d)(1) and (f)(1)(iii)(A) revised; interim 27621

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412.278 (b)(1) revised 59023
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412.622 (a)(3)(ii), (iv) (4)(i)(B), and (D) revised; (a)(4)(ii) removed; (a)(4)(iii) redesignated as new (a)(4)(ii); (c) amended 48462
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413.20 (d)(3) revised 59023
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413.232 (b) introductory text, (1), (e), and (g) introductory text revised; (g)(4) and (h) added 71485
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412.154 (f)(4) revised 45520
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412.168 Added 45520
412.172 (f)(4) revised 45520
412.230 (a)(1)(iii) added; (a)(5)(i) revised; interim 24739
412.278 (b)(1) amended; (f)(2)(ii) revised 45520
412.402 Amended; eff. 10-1-21 42678
412.424 (d)(1)(iii)(F) revised; eff. 10-1-21 42678
412.434 (b)(3) revised; eff. 10-1-21 42678
412.612 Regulation at 81 FR 61562 continued to 9-6-22 50263
413 Technical correction 67874, 70982
413.20 (d)(3) revised 45521
413.24 (f)(5)(i) introductory text and (A) revised 45521
413.24 Correction: (f)(5)(i) introductory text amended; (f)(5)(i)(A) revised 58039
413.177 (a) introductory text revised 62020
413.178 (h) added 62020
413.338 (d)(4)(ii) and (e)(1) revised; (g) added; eff. 10-1-21 42524

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400 Authority citation revised 66503

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400.200 Amended 66503
404 Regulation at 86 FR 5753 eff. date further delayed to 9-22-22 12399
404 Regulation at 86 FR 5753 withdrawn 32246
405.1801 (b)(2)(ii) revised 72284
405.2463 (b)(3) introductory text revised 46430
405.2463 (b)(3) introductory text revised; interim 70222
405.2469 (d) revised 46430
405.2469 (d) revised; interim 70222
406 Authority citation revised 66503
406.7 Revised 66503
406.13 (f)(2) revised 66503
406.21 (a) and (c)(3) revised 66503
406.22 (b) redesignated as (c); new (b) and (d) added; (a) introductory text amended; new (c) introductory text revised 66503
406.26 (a)(3) added; (b)(2) revised 66504
406.27 Added 66504
406.33 (a) introductory text revised; (c) redesignated as (d); new (c) added 66505
406.34 (a) introductory text revised; (e) redesignated as (f); new (e) added 66505
407 Authority citation revised 66505
407.1 (a)(6) added; (b) revised 66505
407.11 Revised 66505
407.23 Added 66505
407.25 (a), (b)(1), and (3) revised 66506
407.25 Correction: (a) and (b)(1) revised; (b)(3) added 80469
407.40 (a)(6) through (10), (c)(5), and (6) added; (b) introductory text and (c)(1) revised; (b) amended 66507
407.42 Revised 66507
407.45 Removed 66508
407.47 (a)(2), (b), (c) introductory text, and (d) introductory text revised; (g) added 66508
407.47 (f) added; eff. 1-1-24 66508
407.48 (c)(1) and (2) revised; (e) added 66508
407.55—407.62 (Subpart D) Added 66508
408 Authority citation revised 66509
408.20 (f) added 66509

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413.178 (a)(8) and (d)(2) revised; (i) added 67302
413.198 (b)(4)(ii) revised 72287
413.231 (c) and (d) added 67302
413.234 (a) amended; eff. 1-1-25 67302
413.337 (b)(4) revised; eff. 10-1-22 47616
413.338 (e) through (g) redesignated as (f) through (h); (a)(1), (4) through (17), (b), (c)(2)(i), (d) heading, (3), new (f)(1) and new (3) introductory text revised; (d)(5), (6), new (e), (f)(4), (i), and (j) added; eff. 10-1-22 47616
413.360 (b)(2) removed; (b)(3) redesignated as new (b)(2); (f) added; eff. 10-1-22 47618
413.400 Amended 72287
413.402 (a), (b)(3), (4), (7), (8)(i), (ii), and (d)(2)(ii) revised 72288
413.404 (a)(2), (b)(2), (3) introductory text, (i) heading, (A) through (C), (ii) heading, (A), (B), (C) introductory text, (1) through (3), (c)(1)(i), (ii), (2)(i) through (iv), and (3) revised 72288
413.412 Revised 72289
413.414 (a), (b), (c) introductory text, (1), (2), (3)(i), and (ii) revised 72289
413.416 (a), (b), (c) introductory text, (2) through (4), (d) introductory text, and (1) revised 72290
413.418 Revised 72290
413.420 (a), (c)(1)(ii), (iv), (v), (d), (e)(2)(i), and (ii) revised 72290

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402 Authority citation revised 70372
402 Technical correction 82787
402.1 (c) introductory text amended; (c)(20) removed; (c)(21) and (22) through (34) redesignated as (c)(20) and (23) through (35); new (c)(21) and new (22) added 70372
402.105 (b)(2) revised; (b)(3) added 70372
405 Technical correction 297
405.400 Amended 79523
405.800 (d) added 79523
405.2400 (d) added 82176

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405.2401 (b) amended 79523, 82176
405.2410 (c) added 82176
405.2411 (a)(4), (6), and (b)(2) revised 79523
405.2411 (a)(7) added 82176
405.2413 (a)(5) revised 79523
405.2415 (a) introductory text, (3), and (5) revised; (b)(6) and (7) added 79523
405.2446 (b)(5) and (6) revised 79524
405.2446 (b)(10) added 82176
405.2448 (a)(2) introductory text and (i) revised 79524
405.2450 Heading, (a) introductory text, (2), (3), and (c) revised 79524
405.2452 Heading, (a) introductory text, (3), (5), and (b) revised 79524
405.2462 (j) added 82176
405.2463 (b)(3) introductory text revised; (b)(3)(iii) redesignated as (b)(3)(v); (a)(1)(i)(I), (J), (b)(3)(iii), and (iv) added 79524
405.2463 (c)(1)(ii), (iii), and (4)(ii) revised 82176
405.2464 (c) revised 79524
405.2464 (f) added 82176
405.2468 (b)(1), (3), and (d)(2)(ii) revised 79525
405.2468 (g) added 82176
405.2469 (d) revised 79525
405.2469 (a)(1) and (2) revised; (a)(3) and (b)(4) added; (b)(3) amended 82176
406.21 (c)(5) added; eff. 11-17-23 65269
409.50 (b) amended 77874
410 Technical correction 297
410 Policy statement 2546, 27413
410.2 Amended 77874, 82177
410.3 (a)(2) revised 82177
410.10 (y) amended 77874
410.10 (c) revised 82177
410.10 (l) revised; (z) and (aa) added 79525
410.15 (a) amended 79525
410.18 (a) amended; (c)(3) redesignated as (c)(4); new (c)(3) added; (d) revised 79525
410.27 (a)(1)(iv)(B)(*1*), (2), (e) introductory text, and (g) revised 82177
410.28 (e)(2)(iii) revised 82177
410.32 (a)(2) and (b)(3)(ii) revised 79525
410.33 (g)(2) revised 79526

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410.36 (a)(3) revised; (a)(4) added 77874
410.38 (d)(4) added 77875
410.43 (a)(4)(i), (iii), and (c)(5) revised 82177
410.44 Added 82177
410.47 (a) amended; (b)(3)(ii)(A) and (d) introductory text revised; (d)(3) removed 79526
410.49 (a) amended; (b)(3)(ii) and (e) introductory text revised; (e)(3) removed 79526
410.53 Added 79526
410.54 Added 79527
410.57 (c) revised 79527
410.59 (a)(3)(ii) and (c)(2) revised 79527
410.60 (a)(3)(ii) and (c)(2) revised 79527
410.67 (b) amended 79528
410.67 (b) amended; (c)(5) and (d)(4)(i)(F) added; (d)(3), (4)(ii), and (iii) revised 82178
410.72 (d) revised 79528
410.78 (b)(2)(x) through (xii) and (e)(3) added; (b)(3)(xiv) introductory text, (4)(iv)(D), and (e)(1) revised 79528
410.79 (b) amended; (c)(1)(ii), (iii), (2)(ii), (3)(ii), (iii), (d)(2)(iii)(B), and (3)(ii) removed; (c)(1)(iv) redesignated as (c)(1)(ii); (c)(2)(i)(A), (B), (3)(i), (e)(3)(iv) introductory text, (D), (F)(*1*), and (*2*) revised 79528
410.110 (Subpart E) Heading revised 82179
410.111 Added 82179
410.130 Amended 79529
410.140 Amended 79529
410.150 (b)(21) and (22) added 79529
410.150 (b)(13) revised 82179
410.152 (b) introductory text, (h)(2), (3), (4) introductory text, and (5) revised; (m) and (n) added 79529
410.155 (b)(2)(iii) revised 82179
410.173 Added 82179
411 Technical correction 297, 68482, 68486, 77211
411.15 (p)(2)(vi) through (xviii) redesignated as (p)(2)(viii) through (xx); new (p)(2)(vi) and (vii) added; new (p)(2)(xiv) revised; eff. 1-1-24 53345

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411.15 (i)(3)(i)(A) revised; (i)(3)(i)(E) added 79530
411.353 (d) amended 59328
411.357 (s)(3) and (4) amended 59328
411.362 (a) and (b)(2) amended; (c) removed 59328
411.363 Added 59328
412 Technical correction 297, 68482, 68491, 68494, 77211
412 Policy statement 37772, 50956
412.25 (c) revised 51161
412.87 (e) redesignated as (f); new (e) added; new (f)(2) and new (3) amended 59331
412.90 (j) amended 59331
412.92 (b)(1)(v) and (2)(i) amended; (b)(2)(ii)(C) and (iv) revised; (b)(2)(vi) added 59331
412.101 (b)(2)(i), (iii), (c)(1), and (3) introductory text amended 59332
412.103 (d)(1) amended; (d)(3) added 59332
412.106 (b)(4) introductory text, (i), and (ii) revised; (b)(4)(iii) and (iv) redesignated as (b)(4)(iv) and (v); new (b)(4)(iii) added 59332
412.108 (a)(1) introductory text and (c)(2)(iii) introductory text amended 59332
412.140 (g) added 59332
412.160 Amended 59333
412.162 (b)(3) revised 59333
412.164 (b) amended; (c) added 59333
412.165 (a)(1) amended; (b)(5) redesignated as (b)(6); new (b)(5) added; new (b)(6) revised 59333
412.320 (a)(1)(iii) amended 59334
412.433 Added 51161
412.560 (f)(1) revised 59334
413 Technical correction 297, 68486
413.178 (a)(8) and (c) revised 76504
413.198 (a) and (b)(3)(iii) revised; (b)(5) and (6) added 76504
413.230 (d) and (e) revised; (f) added 76505
413.232 (b)(1), (2), and (g) introductory text revised; (g)(5) and (6) added 76505
413.234 (b)(1)(iii), (c)(1)(ii), (3), and (g) added; (c)(1)(i) revised 76506
413.235 (b) revised 76506
413.236 (b)(2) revised 76506

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413.338 (a)(1) through (17) designations removed; (a) amended; (c)(2)(i), (d)(4)(v), and (e)(2) introductory text, and (j) revised; (e)(3) and (k) added 53346
413.360 (f)(1) and (2) revised 53346
413.404 Correction: Amendatory instruction 23, (b)(3)(i)(C)(*1*)(*ii*), and (*2*)(*ii*) amended 57901
413.404 Correction: Amendatory instruction 23 revised 60346

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405 Technical correction 9002
405.1845 (a), (b), and (c) heading revised; eff. 1-1-25 69909
409 Technical correction 6019
410 Technical correction 6019, 9002
410 Notification 41324
411 Technical correction 25144
412 Policy statement 64276, 64582
412.1 (a)(1)(iv) revised 69909
412.2 (f)(11) added 69909
412.23 (e)(3)(i), (iii), and (4) revised; (e)(3)(iv) removing 69910
412.88 (a)(2)(ii)(C) and (b)(2)(iv) added 69910
412.90 (j) revised 69910
412.96 (c)(2)(ii) revised 69911

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412.101 (b)(2)(i), (iii), (c)(1), and (3) introductory text revised 69911
412.103 (a)(1) revised 69911
412.104 (b)(2) through (4) revised 69911
412.105 (f)(1)(iv)(C)(*4*) added 69911
412.106 (i)(1) revised 69911
412.108 (a)(1) introductory text and (c)(2)(iii) introductory text revised 69911
412.113 (g) added 69912
412.140 (d)(2)(ii) and (e)(2)(vii) introductory text revised 69912
412.230 (a)(5)(i) amended 69912
412.273 (c)(1)(ii) and (2) revised 69912
413 Technical correction 25144
413.75 (b) introductory text amended 69912
413.78 (e)(3)(iii) and (f)(3)(iii) introductory text amended 69912
413.79 (d)(6), (f)(8), and (k)(2)(i) revised; (q) added 69913
413.337 (f) revised 64160
413.338 (d)(4) through (6) removed; (f)(1) through (4) redesignated as (f)(2) through (5); (a) and new (f)(4) introductory text amended; new (f)(1) and (l) through (n) added; new (f)(2), new (3), and (j)(3) revised 64160
413.360 (f)(1) introductory text and (3) revised; (f)(1)(iv) and (g) added 64162
413.404 Correction: (b)(3)(ii)(C)(*4*) through (*7*) reinstated 17287