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Title 45
Public Welfare

Parts 140 to 199

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, 45 CFR 144.101 *refers to title 45, part 144, section 101.*

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Title 1 through Title 16.....as of January 1
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OLIVER A. POTTS,
Director,
Office of the Federal Register
October 1, 2024

THIS TITLE

Title 45—PUBLIC WELFARE is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–139, 140–199, 200–499, 500–1199, and 1200 to end. Volumes one and two (parts 1–139 and parts 140–199) contain all current regulations issued under Subtitle A—Department of Health and Human Services. Volumes three through five contain all current regulations issued under Subtitle B—Regulations Relating to Public Welfare. Volume three (parts 200–499) contains all current regulations issued under Chapter II—Office of Family Assistance (Assistance Programs), Administration for Children and Families, Department of Health and Human Services, Chapter III—Office of Child Support Services, Administration of Families and Services, Department of Health and Human Services, and Chapter IV—Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services. Volume four (parts 500–1199) contains all current regulations issued under Chapter V—Foreign Claims Settlement Commission of the United States, Department of Justice, Chapter VI—National Science Foundation, Chapter VII—Commission on Civil Rights, Chapter VIII—Office of Personnel Management, Chapter IX—Denali Commission, Chapter X—Office of Community Services, Administration for Children and Families, Department of Health and Human Services, and Chapter XI—National Foundation on the Arts and the Humanities. Volume five (part 1200 to end) contains all current regulations issued under Chapter XII—Corporation for National and Community Service, Chapter XIII—Administration for Children and Families, Department of Health and Human Services, Chapter XVI—Legal Services Corporation, Chapter XVII—National Commission on Libraries and Information Science, Chapter XVIII—Harry S. Truman Scholarship Foundation, Chapter XXI—Commission of Fine Arts, Chapter XXIII—Arctic Research Commission, Chapter XXIV—James Madison Memorial Fellowship Foundation, and Chapter XXV—Corporation for National and Community Service. The contents of these volumes represent all of the current regulations codified under this title of the CFR as of October 1, 2024.

For this volume, Ann Worley was Chief Editor, aided by Tess Waroich. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

Title 45—Public Welfare

(This book contains parts 140 to 199)

Part

SUBTITLE A—Department of Health and Human Services 144

SUBTITLE A—Department of Health and Human Services

EDITORIAL NOTE: Nomenclature changes to subtitle A appear at 66 FR 39452, July 31, 2001.

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PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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AUTHORITY: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended.

SOURCE: 62 FR 16955, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 144.101 Basis and purpose.

(a) Part 146 of this subchapter implements requirements of Title XXVII of the Public Health Service Act (PHS Act, 42 U.S.C. 300gg, *et seq.*) that apply to group health plans and group health insurance issuers.

(b) Part 147 of this subchapter implements the provisions of the Patient Protection and Affordable Care Act that apply to both group health plans and health insurance issuers in the Group and Individual Markets.

(c) Part 148 of this subchapter implements Individual Health Insurance Market requirements of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain individuals who previously had group coverage, guarantee the renewability of all health insurance coverage in the individual market, and provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth, and to provide certain protections for patients who elect breast reconstruction in connection with a mastectomy.

(d) Part 149 of this subchapter implements the provisions of parts D and E of title XXVII of the PHS Act that apply to group health plans, health insurance issuers in the group and individual markets, health care providers and facilities, and providers of air ambulance services.

(e) Part 150 of this subchapter implements the enforcement provisions of sections 2723 and 2761 of the PHS Act with respect to the following:

(1) States that fail to substantially enforce one or more provisions of part 146 concerning group health insurance, one or more provisions of part 147 concerning group or individual health insurance, or the requirements of part 148 of this subchapter concerning individual health insurance.

(2) Insurance issuers in States described in paragraph (d)(1) of this section.

(3) Group health plans that are non-Federal governmental plans.

(f) Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations.

[64 FR 45795, Aug. 20, 1999, as amended at 74 FR 51688, Oct. 7, 2009; 75 FR 27137, May 13, 2010; 78 FR 13435, Feb. 27, 2013; 86 FR 36970, July 13, 2021]

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 149, all health insurance coverage is generally divided into two markets—the group market and the individual market. The group market is further divided into the large group market and the small group market.

(b) The protections afforded under 45 CFR parts 144 through 149 to individuals and employers (and other sponsors

of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market.

(c) Coverage that is provided to associations, but not related to employment, and sold to individuals is not considered group coverage under 45 CFR parts 144 through 149. If the coverage is offered to an association member other than in connection with a group health plan, the coverage is considered individual health insurance coverage for purposes of 45 CFR parts 144 through 149. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under state law. If the health insurance coverage is offered in connection with a group health plan as defined at 45 CFR 144.103, it is considered group health insurance coverage for purposes of 45 CFR parts 144 through 149.

(d) Provisions relating to CMS enforcement of parts 146, 147, 148, and 149 are contained in part 150 of this subchapter.

[86 FR 36970, July 13, 2021]

§ 144.103 Definitions.

For purposes of parts 146 (group market), 147 (group and individual market), 148 (individual market), 149 (surprise billing and transparency), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

Affiliation period means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

Applicable State authority means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of 45 CFR parts 146 and 148 for the State involved with respect to the issuer.

Beneficiary has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA), which states, ''a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit'' under the plan.

Bona fide association means, with respect to health insurance coverage offered in a State, an association that meets the following conditions:

(1) Has been actively in existence for at least 5 years.

(2) Has been formed and maintained in good faith for purposes other than obtaining insurance.

(3) Does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of any employee).

(4) Makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to the members (or individuals eligible for coverage through a member).

(5) Does not make health insurance coverage offered through the association available other than in connection with a member of the association.

(6) Meets any additional requirements that may be imposed under State law.

Church plan means a Church plan within the meaning of section 3(33) of ERISA.

COBRA definitions:

(1) *COBRA* means Title *X* of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(2) *COBRA continuation coverage* means coverage, under a group health plan, that satisfies an applicable COBRA continuation provision.

(3) *COBRA continuation provision* means sections 601–608 of the Employee Retirement Income Security Act, section 4980B of the Internal Revenue Code of 1986 (other than paragraph (f)(1) of such section 4980B insofar as it relates to pediatric vaccines), or Title XXII of the PHS Act.

(4) *Continuation coverage* means coverage under a COBRA continuation provision or a similar State program. Coverage provided by a plan that is subject to a COBRA continuation provision or similar State program, but that does not satisfy all the requirements of that provision or program, will be deemed to be continuation coverage if it allows an individual to elect

to continue coverage for a period of at least 18 months. Continuation coverage does not include coverage under a conversion policy required to be offered to an individual upon exhaustion of continuation coverage, nor does it include continuation coverage under the Federal Employees Health Benefits Program.

(5) *Exhaustion of COBRA continuation coverage* means that an individual's COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted COBRA continuation coverage if such coverage ceases—

(i) Due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives, or works in the service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other COBRA continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other COBRA continuation coverage available to the individual.

(6) *Exhaustion of continuation coverage* means that an individual's continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted continuation coverage if—

(i) Coverage ceases due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives or works in a service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other continuation coverage available to the individual.

Condition means a *medical condition*.

Creditable coverage has the meaning given the term in 45 CFR 146.113(a).

Dependent means any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.

Eligible individual, for purposes of—

(1) The group market provisions in 45 CFR part 146, subpart E, is defined in 45 CFR 146.150(b); and

(2) The individual market provisions in 45 CFR part 148, is defined in 45 CFR 148.103.

Employee has the meaning given the term under section 3(6) of ERISA, which states, ''any individual employed by an employer.''

Employer has the meaning given the term under section 3(5) of ERISA, which states, ''any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity.''

Enroll means to become covered for benefits under a group health plan (that is, when coverage becomes effective), without regard to when the individual may have completed or filed any forms that are required in order to become covered under the plan. For this purpose, an individual who has health coverage under a group health plan is enrolled in the plan regardless of whether the individual elects coverage, the individual is a dependent who becomes covered as a result of an election by a participant, or the individual becomes covered without an election.

Enrollment date means the first day of coverage or, if there is a waiting period, the first day of the waiting period. If an individual receiving benefits under a group health plan changes benefit packages, or if the plan changes group health insurance issuers, the individual's enrollment date does not change.

ERISA stands for the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*).

Excepted benefits, consistent for purposes of the—

(1) Group market provisions in 45 CFR part 146, subpart D, is defined in 45 CFR 146.145(b); and

(2) Individual market provisions in 45 CFR part 148, is defined in 45 CFR 148.220.

Federal governmental plan means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

First day of coverage means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

Genetic information has the meaning specified in §146.122(a) of this subchapter.

Governmental plan means a governmental plan within the meaning of section 3(32) of ERISA.

Group health insurance coverage means health insurance coverage offered in connection with a group health plan. Individual health insurance coverage reimbursed by the arrangements described in 29 CFR 2510.3–1(l) is not offered in connection with a group health plan, and is not group health insurance coverage, provided all the conditions in 29 CFR 2510.3–1(l) are satisfied.

Group health plan or *plan* means a group health plan within the meaning of 45 CFR 146.145(a).

Group market means the market for health insurance coverage offered in connection with a group health plan.

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited-duration insurance.

Health insurance issuer or *issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA). This term does not include a group health plan.

Health maintenance organization or *HMO* means—

(1) A Federally qualified health maintenance organization (as defined in section 1301(a) of the PHS Act);

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

Health status-related factor is any factor identified as a health factor in 45 CFR 146.121(a).

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance. Individual health insurance coverage can include dependent coverage.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan, or other than coverage offered pursuant to a contract between the health insurance issuer with the Medicaid, Children's Health Insurance Program, or Basic Health programs.

Internal Revenue Code means the Internal Revenue Code of 1986, as amended (Title 26, United States Code).

Issuer means a *health insurance issuer*.

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' In the case of an employer that was not in existence throughout

the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

Large group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer.

Late enrollee means an individual whose enrollment in a plan is a late enrollment.

Late enrollment means enrollment of an individual under a group health plan other than on the earliest date on which coverage can become effective for the individual under the terms of the plan; or through special enrollment. (For rules relating to special enrollment and limited open enrollment, see §§ 146.117 and 147.104 of this subchapter.) If an individual ceases to be eligible for coverage under a plan, and then subsequently becomes eligible for coverage under the plan, only the individual's most recent period of eligibility is taken into account in determining whether the individual is a late enrollee under the plan with respect to the most recent period of coverage. Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

Medical care means amounts paid for—

(1) The diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;

(2) Transportation primarily for and essential to medical care referred to in paragraph (1) of this definition; and

(3) Insurance covering medical care referred to in paragraphs (1) and (2) of this definition.

Medical condition or *condition* means any condition, whether physical or mental, including, but not limited to, any condition resulting from illness, injury (whether or not the injury is accidental), pregnancy, or congenital malformation. However, genetic information is not a condition.

Network plan means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

Non-Federal governmental plan means a governmental plan that is not a Federal governmental plan.

Participant has the meaning given the term under section 3(7) of ERISA, which States, ''any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of such employer or members of such organization, or whose beneficiaries may be eligible to receive any such benefit.''

PHS Act stands for the Public Health Service Act (42 U.S.C. 201 *et seq.*).

Placement, or being placed, for adoption means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's placement for adoption with such person ends upon the termination of such legal obligation.

Plan means, with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area. The product comprises all plans offered with those characteristics and the combination of the service areas for all plans offered within a product constitutes the total service area of the product. With respect to a plan that has been modified at the time of coverage renewal consistent with § 147.106 of this subchapter—

(1) The plan will be considered to be the same plan if it:

(i) Has the same cost-sharing structure as before the modification, or any variation in cost sharing is solely related to changes in cost or utilization of medical care, or is to maintain the

same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act;

(ii) Continues to cover a majority of the same service area; and

(iii) Continues to cover a majority of the same provider network. For this purpose, the plan's provider network on the first day of the plan year is compared with the plan's provider network on the first day of the preceding plan year (as applicable).

(2) The plan will not fail to be treated as the same plan to the extent the modification(s) are made uniformly and solely pursuant to applicable Federal and State requirements if—

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement;

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) A State may permit greater changes to the cost-sharing structure, or designate a lower threshold for maintenance of the same provider network or service area for a plan to still be considered the same plan.

Plan sponsor has the meaning given the term under section 3(16)(B) of ERISA, which states, ''(i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan.''

Plan year means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is—

(1) The deductible or limit year used under the plan;

(2) If the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year;

(3) If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, then the plan year is the employer's taxable year; or

(4) In any other case, the plan year is the calendar year.

Policy year means, with respect to—

(1) A grandfathered health plan offered in the individual health insurance market and student health insurance coverage, the 12-month period that is designated as the policy year in the policy documents of the health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year.

(2) A non-grandfathered health plan offered in the individual health insurance market, or in a market in which the State has merged the individual and small group risk pools, for coverage issued or renewed beginning January 1, 2014, a calendar year for which health insurance coverage provides coverage for health benefits.

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified

as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

Product means a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area. In the case of a product that has been modified, transferred, or replaced, the resulting new product will be considered to be the same as the modified, transferred, or replaced product if the changes to the modified, transferred, or replaced product meet the standards of §146.152(f), §147.106(e), or §148.122(g) of this subchapter (relating to uniform modification of coverage), as applicable.

Public health plan has the meaning given the term in 45 CFR 146.113(a)(1)(ix).

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that meets the conditions of paragraph (1) of this definition.

(1) *Short-term, limited-duration insurance* means health insurance coverage provided pursuant to a policy, certificate, or contract of insurance with an issuer that:

(i) Has an expiration date specified in the policy, certificate, or contract of insurance that is no more than 3 months after the original effective date of the policy, certificate, or contract of insurance, and taking into account any renewals or extensions, has a duration no longer than 4 months in total. For purposes of this paragraph (1)(i), a renewal or extension includes the term of a new short-term, limited-duration insurance policy, certificate, or contract of insurance issued by the same issuer, or if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, to the same policyholder within the 12-month period beginning on the original effective date of the initial policy, certificate, or contract of insurance; and

(ii) Displays prominently on the first page (in either paper or electronic form, including on a website) of the policy, certificate, or contract of insurance, and in any marketing, application, and enrollment materials (including reenrollment materials) provided to individuals at or before the time an individual has the opportunity to enroll (or reenroll) in the coverage, in at least 14-point font, the language in the following notice:

IMPORTANT: This is a short-term, limited-duration policy, NOT comprehensive health coverage

This is a temporary limited policy that has fewer benefits and Federal protections than other types of health insurance options, like those on HealthCare.gov.

This policy	Insurance on HealthCare.gov
Might not cover you due to preexisting health conditions like diabetes, cancer, stroke, arthritis, heart disease, mental health & substance use disorders	Can't deny you coverage due to preexisting health conditions
Might not cover things like prescription drugs, preventive screenings, maternity care, emergency services, hospitalization, pediatric care, physical therapy & more	Covers all essential health benefits
Might have **no limit on what you pay** out-of-pocket for care	Protects you with limits on what you pay each year out-of-pocket for essential health benefits
You **won't qualify** for Federal financial help to pay premiums & out-of-pocket costs	Many people qualify for Federal financial help
Doesn't have to meet Federal standards for comprehensive health coverage	All plans must meet Federal standards

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."

(2) For purposes of paragraph (1)(i) of this definition, the term ''controlled group'' means any group treated as a single employer under section 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended.

(3) If any provision of this definition is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid

and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of the definition and shall not affect the remainder thereof.

Significant break in coverage has the meaning given the term in 45 CFR 146.113(b)(2)(iii).

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year.

Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

Special enrollment means enrollment in a group health plan or group health insurance coverage under the rights described in 45 CFR 146.117.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands; except that for purposes of part 147, the term does not include Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

State health benefits risk pool has the meaning given the term in 45 CFR §146.113(a)(1)(vii).

Student health insurance coverage has the meaning given the term in §147.145.

Travel insurance means insurance coverage for personal risks incident to planned travel, which may include, but is not limited to, interruption or cancellation of trip or event, loss of baggage or personal effects, damages to accommodations or rental vehicles, and sickness, accident, disability, or death occurring during travel, provided that the health benefits are not offered on a stand-alone basis and are incidental to other coverage. For this purpose, the term travel insurance does not include major medical plans that provide comprehensive medical protection for travelers with trips lasting 6 months or longer, including, for example, those working overseas as an expatriate or military personnel being deployed.

Waiting period has the meaning given the term in 45 CFR 147.116(b).

[69 FR 78781, Dec. 30, 2004]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §144.103, 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—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

SOURCE: 73 FR 76968, Dec. 18, 2008, unless otherwise noted.

§ 144.200 Basis.

This subpart implements—

(a) Section 1917(b)(1)(C) (iii)(VI) of the Social Security Act, (Act) which requires the issuer of a long-term care insurance policy issued under a qualified State long-term care insurance partnership to provide specified regular reports to the Secretary.

(b) Section 1917(b)(1)(C)(v) of the Act, which specifies that the regulations of the Secretary under section 1917(b)(1)(C)(iii)(VI) of the Act shall be promulgated after consultation with the National Association of Insurance Commissioners, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and shall specify the type and format of the data to be reported and the frequency with which such reports are to be made. This section of the statute also provides that the Secretary provide copies of the reports to the States involved.

§ 144.202 Definitions.

As used in this subpart—

Partnership qualified policy refers to a qualified long-term care insurance policy issued under a qualified State long-term care insurance partnership.

Qualified long-term care insurance policy means an insurance policy that has been determined by a State insurance commissioner to meet the requirements of sections 1917(b)(1)(C)(iii)(I) through (IV) and 1917(b)(5) of the Act. It includes a certificate issued under a group insurance contract.

Qualified State long-term care insurance partnership means an approved Medicaid State plan amendment that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy that has been determined by a State insurance commissioner to meet the requirements of section 1917(b)(1)(C)(iii) of the Act.

§ 144.204 Applicability of regulations.

The regulations contained in this subpart for reporting data apply only to those insurers that have issued qualified long-term care insurance policies to individuals under a qualified State long-term care insurance partnership. They do not apply to the reporting of data by insurers for States with a Medicaid State plan amendment that established a long-term care partnership on or before May 14, 1993.

§ 144.206 Reporting requirements.

(a) *General requirement.* Any insurer that sells a qualified long-term care insurance policy under a qualified State long-term care insurance partnership must submit, in accordance with the requirements of this section, data on insured individuals, policyholders, and claimants who have active partnership qualified policies or certificates for a reporting period.

(b) *Specific requirements.* Insurers of qualified long-term care insurance policies must submit the following data to the Secretary by the deadlines specified in paragraph (c) of this section:

(1) *Registry of active individual and group partnership qualified policies or certificates.* (i) Insurers must submit data on—

(A) Any insured individual who held an active partnership qualified policy or certificate at any point during a reporting period, even if the policy or certificate was subsequently cancelled, lost partnership qualified status, or otherwise terminated during the reporting period; and

(B) All active group long-term care partnership qualified insurance policies, even if the identity of the individual policy/certificate holder is unavailable.

(ii) The data required under paragraph (b)(1)(i) of this section must cover a 6-month reporting period of January through June 30 or July 1 through December 31 of each year; and

(iii) The data must include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The name of the insurance company and issuing State;

(C) The effective date and terms of coverage under the policy.

(D) The annual premium.

(E) The coverage period.

(F) Other information, as specified by the Secretary in ''State Long-Term Care Partnership Insurer Reporting Requirements.''

(2) *Claims paid under partnership qualified policies or certificates.* Insurers must submit data on all partnership qualified policies or certificates for which the insurer paid at least one claim during the reporting period. This includes data for employer-paid core plans and buy-up plans without individual insured data. The data must—

(i) Cover a quarterly reporting period of 3 months;

(ii) Include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The type and cash amount of the benefits paid during the reporting period and lifetime to date;

(C) Remaining lifetime benefits;

(D) Other information, as specified by the Secretary in ''State Long-Term Care Partnership Insurer Reporting Requirements.''

§ 144.208 Deadlines for submission of reports.

(a) Transition provision for insurers who have issued or exchanged a qualified partnership policy prior to the effective date of these regulations.

The first reports required for these insurers will be the reports that pertain to the reporting period that begins no more than 120 days after the effective date of the final regulations.

(b) All reports on the registry of qualified long-term care insurance policies issued to individuals or individuals under group coverage specified in §144.206(b)(1)(ii) must be submitted within 30 days of the end of the 6-month reporting period.

(c) All reports on the claims paid under qualified long-term care insurance policies issued to individual and individuals under group coverage specified in §144.206(b)(2)(i) must be submitted within 30 days of the end of the 3-month quarterly reporting period.

§ 144.210 Form and manner of reports.

All reports specified in §144.206 must be submitted in the form and manner specified by the Secretary.

§ 144.212 Confidentiality of information.

Data collected and reported under the requirements of this subpart are subject to the confidentiality of information requirements specified in regulations under 42 CFR part 401, subpart B, and 45 CFR part 5, subpart F.

§ 144.214 Notifications of noncompliance with reporting requirements.

If an insurer of a qualified long-term care insurance policy does not submit the required reports by the due dates specified in this subpart, the Secretary notifies the appropriate State insurance commissioner within 45 days after the deadline for submission of the information and data specified in §144.208.

PART 145 [RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

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Sec.

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Subpart F—Exclusion of Plans and Enforcement

146.180 Treatment of non-Federal governmental plans.

AUTHORITY: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92.

SOURCE: 62 FR 16958, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 146.101 Basis and scope.

(a) *Statutory basis.* This part implements the Group Market requirements of the PHS Act. Its purpose is to improve access to group health insurance coverage, to guarantee the renewability of all coverage in the group market, and to provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth. Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations, respectively.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in this part.

(1) *Subpart B.* Subpart B of this part sets forth minimum requirements for group health plans and group health insurance issuers offering group health insurance coverage concerning certain consumer protections of the Health Insurance Portability and Accountability Act (HIPAA), as amended, including special enrollment periods, prohibiting discrimination against participants and beneficiaries based on a health factor, and additional requirements prohibiting discrimination against participants and beneficiaries based on genetic information.

(2) *Subpart C.* Subpart C of this part sets forth the requirements that apply to plans and issuers with respect to coverage for hospital stays in connection with childbirth. It also sets forth the regulations governing parity between medical/surgical benefits and mental health benefits in group health plans and health insurance coverage offered by issuers in connection with a group health plan.

(3) *Subpart D.* Subpart D of this part sets forth exceptions to the requirements of subpart B for certain plans and certain types of benefits.

(4) *Subpart E.* Subpart E of this part implements requirements relating to group health plans and issuers in the Group Health Insurance Market.

(5) *Subpart F.* Subpart F of this part addresses the treatment of non-Federal governmental plans, and sets forth enforcement procedures.

[62 FR 16958, Apr. 8, 1997, as amended at 63 FR 57559, Oct. 27, 1998; 71 FR 75046, Dec. 13, 2006; 74 FR 51688, Oct. 7, 2009, as amended at 75 FR 27138, May 13, 2010; 79 FR 10313, Feb. 24, 2014]

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

§ 146.111 Preexisting condition exclusions.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 144.103 of this subchapter.

(2) *Examples.* The rules of this paragraph (a)(1) are illustrated by the following examples:

Example 1 —(i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *S.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *T.* Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for any prosthesis if the body part was lost before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. The exclusion of benefits, therefore, is prohibited.

Example 2 —(i) *Facts.* A group health plan provides coverage for cosmetic surgery in cases of accidental injury, but only if the injury occurred while the individual was covered under the plan.

(ii) *Conclusion.* In this *Example 2*, the plan provision excluding cosmetic surgery benefits for individuals injured before enrolling

in the plan is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

Example 3 —(i) *Facts.* A group health plan provides coverage for the treatment of diabetes, generally not subject to any requirement to obtain an approval for a treatment plan. However, if an individual was diagnosed with diabetes before the effective date of coverage under the plan, diabetes coverage is subject to a requirement to obtain approval of a treatment plan in advance.

(ii) *Conclusion.* In this *Example 3,* the requirement to obtain advance approval of a treatment plan is a preexisting condition exclusion because it limits benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

Example 4 —(i) *Facts.* A group health plan provides coverage for three infertility treatments. The plan counts against the three-treatment limit benefits provided under prior health coverage.

(ii) *Conclusion.* In this *Example 4,* counting benefits for a specific condition provided under prior health coverage against a treatment limit for that condition is a preexisting condition exclusion because it operates to limit benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

Example 5 —(i) *Facts.* When an individual's coverage begins under a group health plan, the individual generally becomes eligible for all benefits. However, benefits for pregnancy are not available until the individual has been covered under the plan for 12 months.

(ii) *Conclusion.* In this *Example 5,* the requirement to be covered under the plan for 12 months to be eligible for pregnancy benefits is a subterfuge for a preexisting condition exclusion because it is designed to exclude benefits for a condition (pregnancy) that arose before the effective date of coverage. The plan provision, therefore, is prohibited.

Example 6 —(i) *Facts.* A group health plan provides coverage for medically necessary items and services, generally including treatment of heart conditions. However, the plan does not cover those same items and services when used for treatment of congenital heart conditions.

(ii) *Conclusion.* In this *Example 6,* the exclusion of coverage for treatment of congenital heart conditions is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

Example 7 —(i) *Facts.* A group health plan generally provides coverage for medically necessary items and services. However, the plan excludes coverage for the treatment of cleft palate.

(ii) *Conclusion.* In this *Example 7,* the exclusion of coverage for treatment of cleft palate is not a preexisting condition exclusion because the exclusion applies regardless of when the condition arose relative to the effective date of coverage. The plan provision, therefore, is not prohibited. (But see 45 CFR 147.150, which may require coverage of cleft palate as an essential health benefit for health insurance coverage in the individual or small group market, depending on the essential health benefits benchmark plan as defined in §156.20 of this subchapter).

Example 8 —(i) *Facts.* A group health plan provides coverage for treatment of cleft palate, but only if the individual being treated has been continuously covered under the plan from the date of birth.

(ii) *Conclusion.* In this *Example 8,* the exclusion of coverage for treatment of cleft palate for individuals who have not been covered under the plan from the date of birth operates to exclude benefits in relation to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is prohibited.

(b) *General rules. See* §147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

[69 FR 78783, Dec. 30, 2004, as amended at 75 FR 37235, June 28, 2010; 79 FR 10313, Feb. 24, 2014; 80 FR 72274, Nov. 18, 2015]

§ 146.113 Rules relating to creditable coverage.

(a) *General rules*—(1) *Creditable coverage.* For purposes of this section, except as provided in paragraph (a)(2) of this section, the term *creditable coverage* means coverage of an individual under any of the following:

(i) A group health plan as defined in §146.145(a).

(ii) Health insurance coverage as defined in §144.103 of this chapter (whether or not the entity offering the coverage is subject to the requirements of this part and 45 CFR part 148 and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

(iii) Part A or B of Title XVIII of the Social Security Act (Medicare).

(iv) Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under section 1928 of the Social Security Act

(the program for distribution of pediatric vaccines).

(v) Title 10 U.S.C. Chapter 55 (medical and dental care for members and certain former members of the uniformed services, and for their dependents; for purposes of Title 10 U.S.C. Chapter 55, *uniformed services* means the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service).

(vi) A medical care program of the Indian Health Service or of a tribal organization.

(vii) A State health benefits risk pool. For purposes of this section, a *State health benefits risk pool* means—

(A) An organization qualifying under section 501(c)(26) of the Internal Revenue Code;

(B) A qualified high risk pool described in section 2744(c)(2) of the PHS Act; or

(C) Any other arrangement sponsored by a State, the membership composition of which is specified by the State and which is established and maintained primarily to provide health coverage for individuals who are residents of such State and who, by reason of the existence or history of a medical condition—

(*1*) Are unable to acquire medical care coverage for such condition through insurance or from an HMO, or

(*2*) Are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization.

(viii) A health plan offered under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefits Program).

(ix) A public health plan. For purposes of this section, a *public health plan* means any plan established or maintained by a State, the U.S. government, a foreign country, or any political subdivision of a State, the U.S. government, or a foreign country that provides health coverage to individuals who are enrolled in the plan.

(x) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

(xi) Title XXI of the Social Security Act (State Children's Health Insurance Program).

(2) *Excluded coverage.* Creditable coverage does not include coverage of solely excepted benefits (described in §146.145).

(b) *Counting creditable coverage rules superseded by prohibition on preexisting condition exclusion. See* §147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

[69 FR 78788, Dec. 30, 2004, as amended at 79 FR 10314, Feb. 24, 2014]

§146.115 Certification and disclosure of previous coverage.

(a) *In general.* The rules for providing certificates of creditable coverage and demonstrating creditable coverage have been superseded by the prohibition on preexisting condition exclusions. *See* §147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

(b) *Applicability.* The provisions of this section apply beginning December 31, 2014.

[79 FR 10314, Feb. 24, 2014]

§146.117 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage*—(1) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, is required to permit current employees and dependents (as defined in §144.103 of this chapter) who are described in paragraph (a)(2) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(3) of this section are satisfied. The special enrollment rights under this paragraph (a) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment*—(i) *When employee loses coverage.* A current employee and any dependents (including the employee's spouse) each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(A) The employee and the dependents are otherwise eligible to enroll in the benefit package;

(B) When coverage under the plan was previously offered, the employee had coverage under any group health plan or health insurance coverage; and

(C) The employee satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(ii) *When dependent loses coverage.* (A) A dependent of a current employee (including the employee's spouse) and the employee each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(*1*) The dependent and the employee are otherwise eligible to enroll in the benefit package;

(*2*) When coverage under the plan was previously offered, the dependent had coverage under any group health plan or health insurance coverage; and

(*3*) The dependent satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(B) However, the plan or issuer is not required to enroll any other dependent unless that dependent satisfies the criteria of this paragraph (a)(2)(ii), or the employee satisfies the criteria of paragraph (a)(2)(i) of this section.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1 —(i) *Facts.* Individual *A* works for Employer *X*. *A*, *A*'s spouse, and *A*'s dependent children are eligible but not enrolled for coverage under *X*'s group health plan. *A*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *A* was enrolled in coverage under *Y*'s plan. Then, *A* loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion.* In this *Example 1*, because *A* satisfies the conditions for special enrollment under paragraph (a)(2)(i) of this section, *A*, *A*'s spouse, and *A*'s dependent children are eligible for special enrollment under *X*'s plan.

Example 2 —(i) *Facts.* Individual *A* and *A*'s spouse are eligible but not enrolled for coverage under Group Health Plan *P* maintained by *A*'s employer. When *A* was first presented with an opportunity to enroll *A* and *A*'s spouse, they did not have other coverage. Later, *A* and *A*'s spouse enroll in Group Health Plan *Q* maintained by the employer of *A*'s spouse. During a subsequent open enrollment period in *P*, *A* and *A*'s spouse did not enroll because of their coverage under *Q*. They then lose eligibility for coverage under *Q*.

(ii) *Conclusion.* In this *Example 2*, because *A* and *A*'s spouse were covered under *Q* when they did not enroll in *P* during open enrollment, they satisfy the conditions for special enrollment under paragraphs (a)(2)(i) and (ii) of this section. Consequently, *A* and *A*'s spouse are eligible for special enrollment under *P*.

Example 3 —(i) *Facts.* Individual *B* works for Employer *X*. *B* and *B*'s spouse are eligible but not enrolled for coverage under *X*'s group health plan. *B*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *B*'s spouse was enrolled in self-only coverage under *Y*'s group health plan. Then, *B*'s spouse loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion.* In this *Example 3*, because *B*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *B* and *B*'s spouse are eligible for special enrollment under *X*'s plan.

Example 4 —(i) *Facts.* Individual *A* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *A* enrolls for self-only coverage in the HMO option. *A*'s spouse works for Employer *Y* and was enrolled for self-only coverage under *Y*'s plan at the time coverage was offered under *X*'s plan. Then, *A*'s spouse loses coverage under *Y*'s plan. *A* requests special enrollment for *A* and *A*'s spouse under the plan's indemnity option.

(ii) *Conclusion.* In this *Example 4*, because *A*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *A* and *A*'s spouse can enroll in either benefit package under *X*'s plan. Therefore, if *A* requests enrollment in accordance with the requirements of this section, the plan must allow *A* and *A*'s spouse to enroll in the indemnity option.

(3) *Conditions for special enrollment*—(i) *Loss of eligibility for coverage.* In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(i) are satisfied at the time the coverage is terminated as a result of loss of eligibility (regardless of whether the individual is eligible for or elects COBRA continuation coverage). Loss of eligibility under this paragraph (a)(3)(i) does not include a loss due to the failure of the employee or dependent to pay premiums on a

timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). Loss of eligibility for coverage under this paragraph (a)(3)(i) includes (but is not limited to)—

(A) Loss of eligibility for coverage as a result of legal separation, divorce, cessation of dependent status (such as attaining the maximum age to be eligible as a dependent child under the plan), death of an employee, termination of employment, reduction in the number of hours of employment, and any loss of eligibility for coverage after a period that is measured by reference to any of the foregoing;

(B) In the case of coverage offered through an HMO, or other arrangement, in the individual market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual);

(C) In the case of coverage offered through an HMO, or other arrangement, in the group market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual), and no other benefit package is available to the individual; and

(D) A situation in which a plan no longer offers any benefits to the class of similarly situated individuals (as described in §146.121(d)) that includes the individual.

(ii) *Termination of employer contributions.* In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(ii) are satisfied at the time employer contributions towards the employee's or dependent's coverage terminate. Employer contributions include contributions by any current or former employer that was contributing to coverage for the employee or dependent.

(iii) *Exhaustion of COBRA continuation coverage.* In the case of an employee or dependent who has coverage that is COBRA continuation coverage, the conditions of this paragraph (a)(3)(iii) are satisfied at the time the COBRA continuation coverage is exhausted. For purposes of this paragraph (a)(3)(iii), an individual who satisfies the conditions for special enrollment of paragraph (a)(3)(i) of this section, does not enroll, and instead elects and exhausts COBRA continuation coverage satisfies the conditions of this paragraph (a)(3)(iii). (*Exhaustion of COBRA continuation coverage* is defined in §144.103 of this chapter.)

(iv) *Written statement.* A plan may require an employee declining coverage (for the employee or any dependent of the employee) to state in writing whether the coverage is being declined due to other health coverage only if, at or before the time the employee declines coverage, the employee is provided with notice of the requirement to provide the statement (and the consequences of the employee's failure to provide the statement). If a plan requires such a statement, and an employee does not provide it, the plan is not required to provide special enrollment to the employee or any dependent of the employee under this paragraph (a)(3). A plan must treat an employee as having satisfied the plan requirement permitted under this paragraph (a)(3)(iv) if the employee provides a written statement that coverage was being declined because the employee or dependent had other coverage; a plan cannot require anything more for the employee to satisfy the plan's requirement to provide a written statement. (For example, the plan cannot require that the statement be notarized.)

(v) The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* enrolls in a group health plan maintained by Employer *Y*. At the time *D* enrolls, *Y* pays 70 percent of the cost of employee coverage and *D* pays the rest. *Y* announces that beginning January 1, *Y* will no longer make employer contributions towards the coverage. Employees may maintain coverage, however, if they pay the total cost of the coverage.

(ii) *Conclusion.* In this *Example 1*, employer contributions towards *D*'s coverage ceased on January 1 and the conditions of paragraph (a)(3)(ii) of this section are satisfied on this

date (regardless of whether *D* elects to pay the total cost and continue coverage under *Y*'s plan).

Example 2. (i) *Facts.* A group health plan provides coverage through two options—Option 1 and Option 2. Employees can enroll in either option only within 30 days of hire or on January 1 of each year. Employee *A* is eligible for both options and enrolls in Option 1. Effective July 1 the plan terminates coverage under Option 1 and the plan does not create an immediate open enrollment opportunity into Option 2.

(ii) *Conclusion.* In this *Example 2*, A has experienced a loss of eligibility for coverage that satisfies paragraph (a)(3)(i) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. Therefore, if *A* satisfies the other conditions of this paragraph (a), the plan must permit *A* to enroll in Option 2 as a special enrollee. (*A* may also be eligible to enroll in another group health plan, such as a plan maintained by the employer of *A*'s spouse, as a special enrollee.) The outcome would be the same if Option 1 was terminated by an issuer and the plan made no other coverage available to *A*.

Example 3. (i) *Facts.* Individual *C* is covered under a group health plan maintained by Employer *X*. While covered under *X*'s plan, *C* was eligible for but did not enroll in a plan maintained by Employer Z, the employer of *C*'s spouse. *C* terminates employment with *X* and loses eligibility for coverage under *X*'s plan. *C* has a special enrollment right to enroll in *Z*'s plan, but *C* instead elects COBRA continuation coverage under *X*'s plan. *C* exhausts COBRA continuation coverage under *X*'s plan and requests special enrollment in *Z*'s plan.

(ii) *Conclusion.* In this *Example 3*, *C* has satisfied the conditions for special enrollment under paragraph (a)(3)(iii) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. The special enrollment right that *C* had into *Z*'s plan immediately after the loss of eligibility for coverage under *X*'s plan was an offer of coverage under *Z*'s plan. When *C* later exhausts COBRA coverage under *X*'s plan, *C* has a second special enrollment right in *Z*'s plan.

(4) *Applying for special enrollment and effective date of coverage.* (i) A plan or issuer must allow an employee a period of at least 30 days after an event described in paragraph (a)(3) of this section to request enrollment (for the employee or the employee's dependent).

(ii) Coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(b) *Special enrollment with respect to certain dependent beneficiaries*—(1) *General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, that makes coverage available with respect to dependents is required to permit individuals described in paragraph (b)(2) of this section to be enrolled for coverage in a benefit package under the terms of the plan. Paragraph (b)(3) of this section describes the required special enrollment period and the date by which coverage must begin. The special enrollment rights under this paragraph (b) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment.* An individual is described in this paragraph (b)(2) if the individual is otherwise eligible for coverage in a benefit package under the plan and if the individual is described in paragraph (b)(2)(i), (ii), (iii), (iv), (v), or (vi) of this section.

(i) *Current employee only.* A current employee is described in this paragraph (b)(2)(i) if a person becomes a dependent of the individual through marriage, birth, adoption, or placement for adoption.

(ii) *Spouse of a participant only.* An individual is described in this paragraph (b)(2)(ii) if either—

(A) The individual becomes the spouse of a participant; or

(B) The individual is a spouse of a participant and a child becomes a dependent of the participant through birth, adoption, or placement for adoption.

(iii) *Current employee and spouse.* A current employee and an individual who is or becomes a spouse of such an employee, are described in this paragraph (b)(2)(iii) if either—

(A) The employee and the spouse become married; or

(B) The employee and spouse are married and a child becomes a dependent of the employee through birth, adoption, or placement for adoption.

(iv) *Dependent of a participant only.* An individual is described in this paragraph (b)(2)(iv) if the individual is a dependent (as defined in §144.103 of this

chapter) of a participant and the individual has become a dependent of the participant through marriage, birth, adoption, or placement for adoption.

(v) *Current employee and a new dependent.* A current employee and an individual who is a dependent of the employee, are described in this paragraph (b)(2)(v) if the individual becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(vi) *Current employee, spouse, and a new dependent.* A current employee, the employee's spouse, and the employee's dependent are described in this paragraph (b)(2)(vi) if the dependent becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(3) *Applying for special enrollment and effective date of coverage*—(i) *Request.* A plan or issuer must allow an individual a period of at least 30 days after the date of the marriage, birth, adoption, or placement for adoption (or, if dependent coverage is not generally made available at the time of the marriage, birth, adoption, or placement for adoption, a period of at least 30 days after the date the plan makes dependent coverage generally available) to request enrollment (for the individual or the individual's dependent).

(ii) *Reasonable procedures for special enrollment.* [Reserved]

(iii) *Date coverage must begin*—(A) *Marriage.* In the case of marriage, coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(B) *Birth, adoption, or placement for adoption.* Coverage must begin in the case of a dependent's birth on the date of birth and in the case of a dependent's adoption or placement for adoption no later than the date of such adoption or placement for adoption (or, if dependent coverage is not made generally available at the time of the birth, adoption, or placement for adoption, the date the plan makes dependent coverage available).

(4) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer maintains a group health plan that offers all employees employee-only coverage, employee-plus-spouse coverage, or family coverage. Under the terms of the plan, any employee may elect to enroll when first hired (with coverage beginning on the date of hire) or during an annual open enrollment period held each December (with coverage beginning the following January 1). Employee *A* is hired on September 3. *A* is married to *B*, and they have no children. On March 15 in the following year a child *C* is born to *A* and *B*. Before that date, *A* and *B* have not been enrolled in the plan.

(ii) *Conclusion.* In this *Example 1*, the conditions for special enrollment of an employee with a spouse and new dependent under paragraph (b)(2)(vi) of this section are satisfied. If *A* satisfies the conditions of paragraph (b)(3) of this section for requesting enrollment timely, the plan will satisfy this paragraph (b) if it allows *A* to enroll either with employee-only coverage, with employee-plus-spouse coverage (for *A* and *B*), or with family coverage (for *A*, *B*, and *C*). The plan must allow whatever coverage is chosen to begin on March 15, the date of *C*'s birth.

Example 2. (i) *Facts.* Individual *D* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *D* enrolls for self-only coverage in the HMO option. Then, a child, *E*, is placed for adoption with *D*. Within 30 days of the placement of *E* for adoption, *D* requests enrollment for *D* and *E* under the plan's indemnity option.

(ii) *Conclusion.* In this *Example 2*, *D* and *E* satisfy the conditions for special enrollment under paragraphs (b)(2)(v) and (b)(3) of this section. Therefore, the plan must allow *D* and *E* to enroll in the indemnity coverage, effective as of the date of the placement for adoption.

(c) *Notice of special enrollment.* At or before the time an employee is initially offered the opportunity to enroll in a group health plan, the plan must furnish the employee with a notice of special enrollment that complies with the requirements of this paragraph (c).

(1) *Description of special enrollment rights.* The notice of special enrollment must include a description of special enrollment rights. The following model language may be used to satisfy this requirement:

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance or group health plan coverage, you may be able to enroll yourself and your dependents in

this plan if you or your dependents lose eligibility for that other coverage (or if the employer stops contributing towards your or your dependents' other coverage). However, you must request enrollment within [insert ''30 days'' or any longer period that applies under the plan] after your or your dependents' other coverage ends (or after the employer stops contributing toward the other coverage).

In addition, if you have a new dependent as a result of marriage, birth, adoption, or placement for adoption, you may be able to enroll yourself and your dependents. However, you must request enrollment within [insert ''30 days'' or any longer period that applies under the plan] after the marriage, birth, adoption, or placement for adoption.

To request special enrollment or obtain more information, contact [insert the name, title, telephone number, and any additional contact information of the appropriate plan representative].

(2) *Additional information that may be required.* The notice of special enrollment must also include, if applicable, the notice described in paragraph (a)(3)(iv) of this section (the notice required to be furnished to an individual declining coverage if the plan requires the reason for declining coverage to be in writing).

(d) *Treatment of special enrollees.* (1) If an individual requests enrollment while the individual is entitled to special enrollment under either paragraph (a) or (b) of this section, the individual is a special enrollee, even if the request for enrollment coincides with a late enrollment opportunity under the plan. Therefore, the individual cannot be treated as a late enrollee.

(2) Special enrollees must be offered all the benefit packages available to similarly situated individuals who enroll when first eligible. For this purpose, any difference in benefits or cost-sharing requirements for different individuals constitutes a different benefit package. In addition, a special enrollee cannot be required to pay more for coverage than a similarly situated individual who enrolls in the same coverage when first eligible.

(3) The rules of this section are illustrated by the following example:

Example. (i) *Facts.* Employer *Y* maintains a group health plan that has an enrollment period for late enrollees every November 1 through November 30 with coverage effective the following January 1. On October 18, Individual *B* loses coverage under another group health plan and satisfies the requirements of paragraphs (a)(2), (3), and (4) of this section. *B* submits a completed application for coverage on November 2.

(ii) *Conclusion.* In this *Example*, *B* is a special enrollee. Therefore, even though *B*'s request for enrollment coincides with an open enrollment period, *B*'s coverage is required to be made effective no later than December 1 (rather than the plan's January 1 effective date for late enrollees).

[69 FR 78794, Dec. 30, 2004, as amended at 79 FR 10314, Feb. 24, 2014]

§ 146.119 HMO affiliation period as an alternative to a preexisting condition exclusion.

The rules for HMO affiliation periods have been superseded by the prohibition on preexisting condition exclusions. *See* § 147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

[79 FR 10314, Feb. 24, 2014]

§ 146.120 Interaction with the Family and Medical Leave Act. [Reserved]

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *Health factors.* (1) The term *health factor* means, in relation to an individual, any of the following health status-related factors:

(i) Health status;

(ii) Medical condition (including both physical and mental illnesses), as defined in § 144.103 of this chapter;

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information, as defined in § 146.122(a) of this subchapter;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes—

(i) Conditions arising out of acts of domestic violence; and

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However,

under §146.117, a plan or issuer must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general.* As used in this part, unless the context indicates otherwise—

(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

(E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b)(2) and (b)(3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) *Conclusion.* In this *Example 1,* the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 2. (i) *Facts.* Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) *Conclusion.* In this *Example 2,* the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) *Facts.* Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) *Conclusion.* In this *Example 3,* excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 4. (i) *Facts.* A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual *A* is an employee of the employer maintaining the plan. *A* and *A*'s dependents have a history of high health claims. Based on the information about *A* and *A*'s dependents, the issuer excludes *A* and *A*'s dependents from the group policy it offers to the employer.

(ii) *Conclusion.* In this *Example 4,* the issuer's exclusion of A and A's dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer

under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

(2) *Application to benefits*—(i) *General rule.* (A) Under this section, a group health plan or group health insurance issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a wellness program. (Whether any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under ERISA, the Affordable Care Act (including the requirements related to essential health benefits), the Americans with Disabilities Act, or any other law, whether State or Federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan applies a $10,000 annual limit on a specific covered benefit that is not an essential health benefit to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, the limit does not violate this paragraph (b)(2)(i) because coverage of the specific, non-essential health benefit up to $10,000 is available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* A group health plan has a $500 deductible on all benefits for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $2,000 deductible on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* The facts of this *Example 2* strongly suggest that the plan modification is directed at *B* based on *B*'s claim. Absent outweighing evidence to the contrary, the plan violates this paragraph (b)(2)(i).

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C*'s adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C*

has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) *Conclusion.* In this *Example 3*, the issuer violates this paragraph (b)(2)(i) because benefits for *C*'s condition are available to other individuals in the group of similarly situated individuals that includes *C* but are not available to *C*. Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates this paragraph (b)(2)(i).

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, the limit does not violate this paragraph (b)(2)(i) because $2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries. (However, applying a lifetime limit on TMJ may violate §147.126 of this subchapter, if TMJ coverage is an essential health benefit, depending on the essential health benefits benchmark plan as defined in §156.20 of this subchapter. This example does not address whether the plan provision is permissible under any other applicable law, including PHS Act section 2711 or the Americans with Disabilities Act.)

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5*, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals. Additionally, this plan provision is prohibited under §147.126 of this subchapter because it imposes a lifetime limit on essential health benefits.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6*, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) *Facts.* Under a group health plan, doctor visits are generally subject to a $250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 7*, imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Exception for wellness programs.* A group health plan or group health insurance issuer may vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(iii) *Specific rule relating to source-of-injury exclusions.* (A) If a group health plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions). This rule applies in the case of an injury resulting from a medical condition even if the condition is not diagnosed before the injury.

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or

injuries sustained in connection with attempted suicide. Because of depression, Individual D attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Under the exclusion, the plan denies *D* benefits for treatment of the injuries.

(ii) *Conclusion.* In this Example 1, the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of D's injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) *Facts.* A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant E sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for *E*'s head injury.

(ii) *Conclusion.* In this *Example 2*, the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow E to enroll in the plan (or applied different rules for eligibility to *E*) because *E* frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(c) *Prohibited discrimination in premiums or contributions*—(1) *In general.* (i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan or group health insurance coverage based on any health factor that relates to the individual or a dependent of the individual.

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But *see* §146.122(b) of this part, which prohibits adjustments in group premium or contribution rates based on genetic information.

(ii) *List billing based on a health factor prohibited.* However, a group health insurance issuer, or a group health plan, may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience. (However, if the issuer used genetic information in computing the group rate, it would violate §146.122(b) of this part.)

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the issuer quotes the employer a higher premium rate for *F*, because of *F*'s claims experience, than for a similarly situated individual.

(ii) *Conclusion.* In this *Example 2*, the issuer violates this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for *F* than for a similarly situated individual, the issuer would still violate this paragraph (c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) *Exception for wellness programs.* Notwithstanding paragraphs (c)(1) and (c)(2) of this section, a plan or issuer may vary the amount of premium or contribution it requires similarly situated individuals to pay based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(d) *Similarly situated individuals.* The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan or issuer may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) *Participants.* Subject to paragraph (d)(3) of this section, a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) *Beneficiaries.* (i) Subject to paragraph (d)(3) of this section, a plan or issuer may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (for example, as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.

(3) *Discrimination directed at individuals.* Notwithstanding paragraphs (d)(1) and (d)(2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.

(4) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the

employer's usual business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* Under a group health plan, coverage is made available to employees, their spouses, and their children. However, coverage is made available to a child only if the child is under age 26 (or under age 29 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this Example 2, treating spouses and children differently by imposing an age limitation on children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat children who are under age 26 (or full-time students under age 29) as a group of similarly situated individuals separate from those who are age 26 or older (or age 29 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) *Facts.* A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 3*, the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) *Facts.* An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but Employee *G* has a different job title and different responsibilities. After *G* files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with *G*'s job title receive a different benefit package that includes a higher deductible than in the benefit package made available to the other six employees.

(ii) *Conclusion.* Under the facts of this *Example 5*, changing the coverage classification for *G* based on the existing employment classification for *G* is not permitted under this paragraph (d) because the creation of the new coverage classification for *G* is directed at *G* based on one or more health factors.

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule.* Under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (e)(3) of this section (permitting plans and

issuers, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) *Examples.* The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) *Conclusion.* In this *Example 1*, the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) *Facts.* In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer *M*. However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer *N*. Under Issuer *N*'s policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) *Conclusion.* In this *Example 2*, Issuer *N* violates this paragraph (e)(1) because the group health insurance coverage restricts benefits (a rule for eligibility under paragraph (b)(1)) based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits clause from a previous issuer. State law cannot change the obligation of Issuer *N* under this section. However, under State law Issuer *M* may also be responsible for providing benefits to such a dependent. In a case in which Issuer *N* has an obligation under this section to provide benefits and Issuer *M* has an obligation under State law to provide benefits, any State laws designed to prevent more than 100% reimbursement, such as State coordination-of-benefits laws, continue to apply.

(2) *Actively-at-work and continuous service provisions*—(i) *General rule.* (A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan or health insurance coverage, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) *Conclusion.* In this *Example 1*, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) *Facts.* Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) *Conclusion.* In this Example 2, the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service. (In addition, any eligibility provision that is time-based must comply with the requirements of PHS Act section 2708 and its implementing regulations.)

(ii) *Exception for the first day of work.* (A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual *H* is scheduled to begin work on August 3. However, *H* is unable to begin work on that day because of illness. *H* begins working on August 4, and *H*'s coverage is effective on August 4.

(ii) *Conclusion.* In this *Example 1*, the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) *Facts.* Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual *J* is scheduled to begin work on March 24. However, *J* is unable to begin work on March 24 because of illness. *J* begins working on April 7 and *J*'s coverage is effective May 1.

(ii) *Conclusion.* In this *Example 2*, the plan provision does not violate this section. However, as in *Example 1*, if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) *Relationship to plan provisions defining similarly situated individuals.* (i) Notwithstanding the rules of paragraphs (e)(1) and (e)(2) of this section, a plan or issuer may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan or issuer may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other Federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) *Conclusion.* In this *Example 1*, the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) *Facts.* To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2*, the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment

and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 3*, the plan provision terminating *B*'s coverage upon *B*'s termination of employment does not violate this section.

Example 4. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee *C* is laid off for three months. When the layoff begins, *C*'s coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 4*, the plan provision terminating *C*'s coverage upon the cessation of *C*'s performance of services does not violate this section.

(f) *Nondiscriminatory wellness programs—in general.* A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f).

(1) *Definitions.* The definitions in this paragraph (f)(1) govern in applying the provisions of this paragraph (f).

(i) *Reward.* Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(ii) *Participatory wellness programs.* If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program. Examples of participatory wellness programs are:

(A) A program that reimburses employees for all or part of the cost for membership in a fitness center.

(B) A diagnostic testing program that provides a reward for participation in that program and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, §147.130 of this subchapter requires benefits for certain preventive health services without the imposition of cost sharing.)

(D) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(E) A program that provides a reward to employees for attending a monthly, no-cost health education seminar.

(F) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (*See also* §146.122 for rules prohibiting collection of genetic information.)

(iii) *Health-contingent wellness programs.* A health-contingent wellness program is a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). A health-contingent wellness program may be

an activity-only wellness program or an outcome-based wellness program.

(iv) *Activity-only wellness programs.* An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome. Examples include walking, diet, or exercise programs, which some individuals may be unable to participate in or complete (or have difficulty participating in or completing) due to a health factor, such as severe asthma, pregnancy, or a recent surgery. *See* paragraph (f)(3) of this section for requirements applicable to activity-only wellness programs.

(v) *Outcome-based wellness programs.* An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. To comply with the rules of this paragraph (f), an outcome-based wellness program typically has two tiers. That is, for individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. This alternative pathway, however, does not mean that the overall program, which has an outcome-based component, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program. For example, if a wellness program tests individuals for specified medical conditions or risk factors (including biometric screening such as testing for high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to individuals identified as within a normal or healthy range for these medical conditions or risk factors, while requiring individuals who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, complying with a walking or exercise program, or complying with a health care provider's plan of care) to obtain the same reward, the program is an outcome-based wellness program. *See* paragraph (f)(4) of this section for requirements applicable to outcome-based wellness programs.

(2) *Requirement for participatory wellness programs.* A participatory wellness program, as described in paragraph (f)(1)(ii) of this section, does not violate the provisions of this section only if participation in the program is made available to all similarly situated individuals, regardless of health status.

(3) *Requirements for activity-only wellness programs.* A health-contingent wellness program that is an activity-only wellness program, as described in paragraph (f)(1)(iv) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the activity-only wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the activity-only wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iv), a reward under an activity-only wellness program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(*1*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(*2*) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iv)(A)(*1*) or (*2*) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an activity-only wellness program, it must comply with the requirements of this paragraph (f)(3) in the same manner as if it were an initial program standard. (Thus, for example, if a plan or issuer provides a walking program as a reasonable alternative standard to a running program, individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program (or for whom it is medically inadvisable to attempt to complete the walking program) must be provided a reasonable alternative standard to the walking program.) To the extent that a reasonable alternative standard under an activity-only wellness program is, itself, an outcome-based wellness program, it must comply with the requirements of paragraph (f)(4) of this section, including paragraph (f)(4)(iv)(D).

(E) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from

an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard of an activity-only wellness program. Plans and issuers may seek verification with respect to requests for a reasonable alternative standard for which it is reasonable to determine that medical judgment is required to evaluate the validity of the request.

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an activity-only wellness program the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Example.* The provisions of this paragraph (f)(3) are illustrated by the following example:

Example. (i) *Facts.* A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to attempt to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) *Conclusion.* In this *Example,* the program satisfies the requirements of paragraph (f)(3)(iii) of this section because the walking program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the reward under the program is available to all similarly situated individuals. It accommodates individuals for whom it is unreasonably difficult to participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them with the reward even if they do not participate in the walking program (that is, by waiving the condition). The plan also complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

(4) *Requirements for outcome-based wellness programs.* A health-contingent wellness program that is an outcome-based wellness program, as described in paragraph (f)(1)(v) of this section, does not violate the provisions of this section only if all of the following requirements are satisfied:

(i) *Frequency of opportunity to qualify.* The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) *Size of reward.* The reward for the outcome-based wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage (as defined in paragraph (f)(5) of this section) of the total cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(4)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(iii) *Reasonable design.* The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To ensure that an outcome-based wellness program is reasonably designed to improve health and

does not act as a subterfuge for underwriting or reducing benefits based on a health factor, a reasonable alternative standard to qualify for the reward must be provided to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor, as explained in paragraph (f)(4)(iv) of this section.

(iv) *Uniform availability and reasonable alternative standards.* The full reward under the outcome-based wellness program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(4)(iv), a reward under an outcome-based wellness program is not available to all similarly situated individuals for a period unless the program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual who does not meet the initial standard based on the measurement, test, or screening, as described in this paragraph (f)(4)(iv).

(B) While plans and issuers are not required to determine a particular reasonable alternative standard in advance of an individual's request for one, if an individual is described in paragraph (f)(4)(iv)(A) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived.

(C) All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(*1*) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available or assist the employee in finding such a program (instead of requiring an individual to find such a program unassisted), and may not require an individual to pay for the cost of the program.

(*2*) The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

(*3*) If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.

(*4*) If an individual's personal physician states that a plan standard (including, if applicable, the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(D) To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, an activity-only wellness program, it must comply with the requirements of paragraph (f)(3) of this section in the same manner as if it were an initial program standard. To the extent that a reasonable alternative standard under an outcome-based wellness program is, itself, another outcome-based wellness program, it must comply with the requirements of this paragraph (f)(4), subject to the following special rules:

(*1*) The reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. However, if the initial standard is to achieve a BMI less than 30, a reasonable alternative standard for the individual could be to reduce the individual's BMI by a small amount or small percentage, over a realistic period of time, such as within a year.

(*2*) An individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan or issuer, but only if the physician joins in the request. The

individual can make a request to involve a personal physician's recommendations at any time and the personal physician can adjust the physician's recommendations at any time, consistent with medical appropriateness.

(E) It is not reasonable to seek verification, such as a statement from an individual's personal physician, under an outcome-based wellness program that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard as a condition of providing a reasonable alternative to the initial standard. However, if a plan or issuer provides an alternative standard to the otherwise applicable measurement, test, or screening that involves an activity that is related to a health factor, then the rules of paragraph (f)(3) of this section for activity-only wellness programs apply to that component of the wellness program and the plan or issuer may, if reasonable under the circumstances, seek verification that it is unreasonably difficult due to a medical condition for an individual to perform or complete the activity (or it is medically inadvisable to attempt to perform or complete the activity). (For example, if an outcome-based wellness program requires participants to maintain a certain healthy weight and provides a diet and exercise program for individuals who do not meet the targeted weight, a plan or issuer may seek verification, as described in paragraph (f)(3)(iv)(D) of this section, if reasonable under the circumstances, that a second reasonable alternative standard is needed for certain individuals because, for those individuals, it would be unreasonably difficult due to a medical condition to comply, or medically inadvisable to attempt to comply, with the diet and exercise program, due to a medical condition.)

(v) *Notice of availability of reasonable alternative standard.* The plan or issuer must disclose in all plan materials describing the terms of an outcome-based wellness program, and in any disclosure that an individual did not satisfy an initial outcome-based standard, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including contact information for obtaining a reasonable alternative standard and a statement that recommendations of an individual's personal physician will be accommodated. If plan materials merely mention that such a program is available, without describing its terms, this disclosure is not required. Sample language is provided in paragraph (f)(6) of this section, as well as in certain examples of this section.

(vi) *Examples.* The provisions of this paragraph (f)(4) are illustrated by the following examples:

Example 1—Cholesterol screening with reasonable alternative standard to work with personal physician. (i) *Facts.* A group health plan offers a reward to participants who achieve a count under 200 on a total cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan allows the participant to develop an alternative cholesterol action plan in conjunction with the participant's personal physician that may include recommendations for medication and additional screening. The plan allows the physician to modify the standards, as medically necessary, over the year. (For example, if a participant develops asthma or depression, requires surgery and convalescence, or some other medical condition or consideration makes completion of the original action plan inadvisable or unreasonably difficult, the physician may modify the original action plan.) All plan materials describing the terms of the program include the following statement: ''Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your total cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you and your doctor to find a Health Smart program that is right for you.'' In addition, when any individual participant receives notification that his or her cholesterol count is 200 or higher, the notification includes the following statement: ''Your plan offers a Health Smart program under which we will work with you and your doctor to try to lower your cholesterol. If you complete this program, you will qualify for a reward. Please contact us at [contact information] to get started.''

(ii) *Conclusion.* In this *Example 1,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health

outcome (a certain cholesterol level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because the cholesterol program is reasonably designed to promote health and prevent disease. The program satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes available to all participants who do not meet the cholesterol standard a reasonable alternative standard to qualify for the reward. Lastly, the plan also discloses in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard the availability of a reasonable alternative standard (including contact information and the individual's ability to involve his or her personal physician), as required by paragraph (f)(4)(v) of this section. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 2—Cholesterol screening with plan alternative and no opportunity for personal physician involvement. (i) *Facts.* Same facts as *Example 1,* except that the wellness program's physician or nurse practitioner (rather than the individual's personal physician) determines the alternative cholesterol action plan. The plan does not provide an opportunity for a participant's personal physician to modify the action plan if it is not medically appropriate for that individual.

(ii) *Conclusion.* In this *Example 2,* the wellness program does not satisfy the requirements of paragraph (f)(4)(iii) of this section because the program does not accommodate the recommendations of the participant's personal physician with regard to medical appropriateness, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and is not available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice also does not provide all the content required under paragraph (f)(4)(v) of this section.

Example 3—Cholesterol screening with plan alternative that can be modified by personal physician. (i) *Facts.* Same facts as *Example 2,* except that if a participant's personal physician disagrees with any part of the action plan, the personal physician may modify the action plan at any time, and the plan discloses this to participants.

(ii) *Conclusion.* In this *Example 3,* the wellness program satisfies the requirements of paragraph (f)(4)(iii) of this section because the participant's personal physician may modify the action plan determined by the wellness program's physician or nurse practitioner at any time if the physician states that the recommendations are not medically appropriate, as required under paragraph (f)(4)(iv)(C)(*3*) of this section. Thus, the program is reasonably designed under paragraph (f)(4)(iii) of this section and is available to all similarly situated individuals under paragraph (f)(4)(iv) of this section. The notice, which includes a statement that recommendations of an individual's personal physician will be accommodated, also complies with paragraph (f)(4)(v) of this section.

Example 4—BMI screening with walking program alternative. (i) *Facts.* A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the participant satisfies an alternative standard that is reasonable taking into consideration the participant's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: ''Fitness is Easy! Start Walking! Your health plan cares about your health. If you are considered overweight because you have a BMI of over 26, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn't right for you, that's okay too. We will work with you (and, if you wish, your own doctor) to develop a wellness program that is.)'' Participant *E* is unable to achieve a BMI that is 26 or lower within the plan's timeframe and receives notification that complies with paragraph (f)(4)(v) of this section. Nevertheless, it is unreasonably difficult due to a medical condition for *E* to comply with the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the same discount available to *E* that is available to other participants in the BMI program or the alternative walking program, but only if *E* actually follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4,* the program is an outcome-based wellness program because the initial standard requires an individual to attain or maintain a specific health outcome (a certain BMI level) to obtain a reward. The program satisfies the requirements of paragraph (f)(4)(iii) of this section because it is reasonably designed to promote health and prevent disease. The program also satisfies the requirements of paragraph (f)(4)(iv) of this section because it makes

available to all individuals who do not satisfy the BMI standard a reasonable alternative standard to qualify for the reward (in this case, a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the walking program is, itself, an activity-only standard and the plan complies with the requirements of paragraph (f)(3) of this section (including the requirement of paragraph (f)(3)(iv) that, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provide a reasonable alternative to those individuals). Moreover, the plan satisfies the requirements of paragraph (f)(4)(v) of this section because it discloses, in all materials describing the terms of the program and in any disclosure that an individual did not satisfy the initial outcome-based standard, the availability of a reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician) to qualify for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 5—BMI screening with alternatives available to either lower BMI or meet personal physician's recommendations. (i) *Facts.* Same facts as *Example 4* except that, with respect to any participant who does not meet the target BMI, instead of a walking program, the participant is expected to reduce BMI by one point. At any point during the year upon request, any individual can obtain a second reasonable alternative standard, which is compliance with the recommendations of the participant's personal physician regarding weight, diet, and exercise as set forth in a treatment plan that the physician recommends or to which the physician agrees. The participant's personal physician is permitted to change or adjust the treatment plan at any time and the option of following the participant's personal physician's recommendations is clearly disclosed.

(ii) *Conclusion.* In this *Example 5*, the reasonable alternative standard to qualify for the reward (the alternative BMI standard requiring a one-point reduction) does not make the program unreasonable under paragraph (f)(4)(iii) or (iv) of this section because the program complies with paragraph (f)(4)(iv)(C)(*4*) of this section by allowing a second reasonable alternative standard to qualify for the reward (compliance with the recommendations of the participant's personal physician, which can be changed or adjusted at any time). Accordingly, the program continues to satisfy the applicable requirements of paragraph (f) of this section.

Example 6—Tobacco use surcharge with smoking cessation program alternative. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: ''Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge.'' The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances, and discloses contact information and the individual's option to involve his or her personal physician. The plan pays for the cost of participation in the smoking cessation program. Any participant can avoid the surcharge for the plan year by participating in the program, regardless of whether the participant stops smoking, but the plan can require a participant who wants to avoid the surcharge in a subsequent year to complete the smoking cessation program again.

(ii) *Conclusion.* In this *Example 6*, the premium differential satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v). The program is an outcome-based wellness program because the initial standard for obtaining a reward is dependent on the results of a health risk assessment (a measurement, test, or screening). The program is reasonably designed under paragraph (f)(4)(iii) because the plan provides a reasonable alternative standard (as required under paragraph (f)(4)(iv) of this section) to qualify for the reward to all tobacco users (a smoking cessation program). The plan discloses, in all materials describing the terms of the program, the availability of the reasonable alternative standard (including contact information and the individual's option to involve his or her personal physician). Thus, the program satisfies the requirements of paragraphs (f)(4)(iii), (iv), and (v) of this section.

Example 7—Tobacco use surcharge with alternative program requiring actual cessation. (i) *Facts.* Same facts as *Example 6*, except the plan does not provide participant *F* with the reward in subsequent years unless *F* actually stops smoking after participating in the tobacco cessation program.

(ii) *Conclusion.* In this *Example 7*, the program is not reasonably designed under paragraph (f)(4)(iii) of this section and does not provide a reasonable alternative standard as required under paragraph (f)(4)(iv) of this section. The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking

after participating in a smoking cessation program. The plan must continue to offer a reasonable alternative standard whether it is the same or different (such as a new recommendation from *F*'s personal physician or a new nicotine replacement therapy).

Example 8—Tobacco use surcharge with smoking cessation program alternative that is not reasonable. (i) *Facts.* Same facts as *Example 6*, except the plan does not facilitate participant *F*'s enrollment in a smoking cessation program. Instead the plan advises *F* to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) *Conclusion.* In this *Example 8*, the requirement for *F* to find and pay for *F*'s own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(4)(iii) and (iv) of this section and the program fails to satisfy the requirements of paragraph (f) of this section.

(5) *Applicable percentage.* (i) For purposes of this paragraph (f), the applicable percentage is 30 percent, except that the applicable percentage is increased by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(ii) The rules of this paragraph (f)(5) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program with several components, focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) *Conclusion.* In this *Example 1*, the reward for the wellness program, $600, does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 × 30% = $1,800.)

Example 2. (i) *Facts.* Same facts as *Example 1*, except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) *Conclusion.* In this *Example 2*, the reward for the wellness program (absence of a $1,000 surcharge), does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 × 50% = $3,000.)

Example 3. (i) *Facts.* Same facts as *Example 1*, except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) *Conclusion.* In this *Example 3*, the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed the applicable percentage of 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage ($1,800).

Example 4. (i) *Facts.* An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program, with an opportunity to earn a $1,500 reward.

(ii) *Conclusion.* In this *Example 4*, even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds the applicable percentage of 30 percent of the cost of the annual premium for employee-only coverage ($5,000 × 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(5) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account.) Accordingly, the health-contingent wellness program offers a reward that does not exceed the applicable percentage of 30 percent of the total annual cost of employee-only coverage.

(6) *Sample language.* The following language, or substantially similar language, can be used to satisfy the notice requirement of paragraphs (f)(3)(v) or (f)(4)(v) of this section: ''Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think

you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and, if you wish, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status.''

(g) *More favorable treatment of individuals with adverse health factors permitted*—(1) *In rules for eligibility*. (i) Nothing in this section prevents a group health plan or group health insurance issuer from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan or issuer from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 26. However, dependent children who are disabled are eligible for coverage beyond age 26.

(ii) *Conclusion.* In this Example 1, the plan provision allowing coverage for disabled dependent children beyond age 26 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) *Facts.* An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees $50 per month for employee-only coverage and $125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee $100 per month for employee-only coverage and $250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 2*, the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) *Facts.* To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) *Conclusion.* In this *Example 3*, the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) *In premiums or contributions.* (i) Nothing in this section prevents a group health plan or group health insurance issuer from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) *Facts.* Under a group health plan, employees are generally required to pay $50 per month for employee-only coverage and $125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) *Conclusion.* In this *Example*, the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the PHS Act (including the COBRA continuation provisions) or any other State or Federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other Federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(i) *Applicability dates*—(1) *Generally.* This section applies for plan years beginning on or after July 1, 2007.

(2) *Special rule for self-funded nonfederal governmental plans exempted under 45 CFR 146.180.* (i) If coverage has been denied to any individual because the sponsor of a self-funded nonfederal governmental plan has elected under §146.180 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan—

(A) Must notify the individual that the plan will be coming into compliance with the requirements of this section, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees);

(B) Must give the individual an opportunity to enroll that continues for at least 30 days;

(C) Must permit coverage to be effective as of the first day of plan coverage for which an exemption election under §146.180 of this part (with regard to this section) is no longer in effect; and

(D) May not treat the individual as a late enrollee or a special enrollee.

(ii) For purposes of this paragraph (i)(2), an individual is considered to have been denied coverage if the individual failed to apply for coverage because, given an exemption election under §146.180 of this part, it was reasonable to believe that an application for coverage would have been denied based on a health factor.

(iii) The rules of this paragraph (i)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* was hired by a nonfederal governmental employer in June 1999. The employer maintains a self-funded group health plan with a plan year beginning on October 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section for the plan year beginning October 1, 2005, and renewed the exemption election for the plan year beginning October 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual could enroll effective October 1 of any plan year if the individual could pass a physical examination. The evidence-of-good-health requirement for late enrollees, absent an exemption election under §146.180 of this part, would have been in violation of this section. *D* chose not to enroll for coverage when first hired. In February of 2006, *D* was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 2006, because *D* assumed *D* could not meet the evidence-of-good-health requirement. With the plan year beginning October 1, 2007 the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. The plan notifies individual *D* (and all other

employees) that it will be coming into compliance with the requirements of this section. The notice specifies that the effective date of compliance will be October 1, 2007, explains the applicable enrollment restrictions that will apply under the plan, states that individuals will have at least 30 days to enroll, and explains that coverage for those who choose to enroll will be effective as of October 1, 2007. Individual *D* timely requests enrollment in the plan, and coverage commences under the plan on October 1, 2007.

(ii) *Conclusion*. In this *Example 1*, the plan complies with this paragraph (i)(2).

Example 2. (i) *Facts*. Individual *E* was hired by a nonfederal governmental employer in February 1999. The employer maintains a self-funded group health plan with a plan year beginning on September 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section and ''§146.111 (limitations on preexisting condition exclusion periods) for the plan year beginning September 1, 2002, and renews the exemption election for the plan years beginning September 1, 2003, September 1, 2004, September 1, 2005, and September 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declined to enroll when first eligible, the individual could enroll effective September 1 of any plan year if the individual could pass a physical examination. Also under the terms of the plan, all enrollees were subject to a 12-month preexisting condition exclusion period, regardless of whether they had creditable coverage. *E* chose not to enroll for coverage when first hired. In June of 2006, *E* is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2007, the plan sponsor chooses to bring the plan into compliance with this section, but renews its exemption election with regard to limitations on preexisting condition exclusion periods. The plan notifies *E* of her opportunity to enroll, without a physical examination, effective September 1, 2007. The plan gives *E* 30 days to enroll. *E* is subject to a 12-month preexisting condition exclusion period with respect to any treatment *E* receives that is related to *E*'s MS, without regard to any prior creditable coverage *E* may have. Beginning September 1, 2008, the plan will cover treatment of *E*'s MS.

(ii) *Conclusion*. In this *Example 2*, the plan complies with the requirements of this section. (The plan is not required to comply with the requirements of §146.111 because the plan continues to be exempted from those requirements in accordance with the plan sponsor's election under §146.180.)

[71 FR 75046, Dec. 13, 2006, as amended at 74 FR 51688, Oct. 7, 2009; 78 FR 33187, June 3, 2013; 79 FR 10314, Feb. 24, 2014]

§ 146.122 Additional requirements prohibiting discrimination based on genetic information.

(a) *Definitions*. Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

(1) *Collect* means, with respect to information, to request, require, or purchase such information.

(2) *Family member* means, with respect to an individual—

(i) A dependent (as defined in §144.103 of this part) of the individual; or

(ii) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a

disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

(A) With respect to a pregnant woman (or a family member of the pregnant woman), genetic information of any fetus carried by the pregnant woman; and

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means —

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* is a newborn covered under a group health plan. *A* undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in *A*'s blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion.* In this *Example*, the PKU screening is a genetic test with respect to *A* because the screening is an analysis of metabolites that detects a genetic mutation.

(6)(i) *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this section, a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* has a family medical history of diabetes. *A* begins to experience excessive sweating, thirst, and fatigue. *A*'s physician examines *A* and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, *A*'s symptoms, and test results that show elevated levels of blood glucose, *A*'s physician diagnoses *A* as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion.* In this *Example 1*, *A* has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to *A*.

Example 2. (i) *Facts.* Individual *B* has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). *B*'s physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that *B* undergo a targeted genetic test to look for the specific mutation found in *B* 's relative to determine if *B* has an elevated risk for cancer. The genetic test with respect to *B* showed that *B* also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. *B* has a colonoscopy which indicates no signs of disease, and *B* has no symptoms.

(ii) *Conclusion.* In this *Example 2*, because *B* has no signs or symptoms of colorectal cancer, *B* has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to *B*.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *B*'s colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, *B*'s physician makes a diagnosis of HNPCC.

(ii) *Conclusion.* In this *Example 3*, HNPCC is manifested with respect to *B* because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts.* Individual *C* has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that *C* has the Huntington's Disease gene variant. At age 42, *C* begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. *C* is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion.* In this *Example 4*, *C* is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to *C*.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that *C* exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to *C*.

(ii) *Conclusion.* In this *Example 5*, *C* could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to *C*.

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not adjust premium or contribution amounts for the plan, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in §146.121(d) of this part.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for a group health plan or a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for a group health plan or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-participant rate because of both the genetic information and the higher claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the provisions of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of this section (nor would it violate the requirements of paragraph (c) of §146.121 of this part, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered

under the plan and other health status information of the individuals, including genetic information. The issuer finds that Employee *A* has made claims for treatment of polycystic kidney disease. *A* also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both *A*'s claims experience and the family medical history of *A*'s children (that is, the fact that *A* has the disease).

(ii) *Conclusion.* In this *Example 2*, the issuer violates the provisions of this paragraph (b) because, by taking the likelihood that *A*'s children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in *A*'s children. However, it is permissible for the issuer to increase the premium based on *A*'s claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (c)(1) and (2) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* goes to a physician for a routine physical examination. The physician reviews *A*'s family medical history and *A* informs the physician that *A*'s mother has been diagnosed with Huntington's Disease. The physician advises *A* that Huntington's Disease is hereditary and recommends that *A* undergo a genetic test.

(ii) *Conclusion.* In this *Example 1*, the physician is a health care professional who is providing health care services to *A*. Therefore, the physician's recommendation that *A* undergo the genetic test does not violate this paragraph (c).

Example 2. (i) *Facts.* Individual *B* is covered by a health maintenance organization (HMO). *B* is a child being treated for leukemia. *B*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *B*'s physician recommends that *B* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion.* In this *Example 2*, even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *B*. Therefore, the physician's recommendation that *B* undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment*—(i) *In general.* As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan or issuer from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in §164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan or issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan or issuer is permitted to condition payment for the item or service on the outcome of a genetic test. The plan or issuer may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation.* A plan or issuer is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in §164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (c)(1) of this section, a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local*

law or regulations. The plan or issuer makes the request pursuant to research, as defined in §46.102(d) of this subtitle, that complies with part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The plan or issuer makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in §146.121(b)(1) of this part) or premium or contribution amounts.

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies.* The plan or issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information*—(1) *For underwriting purposes*—(i) *General rule.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in §146.121(b)(1)(ii) of this part (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan or health insurance coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan or issuer conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan or issuer is permitted to condition the benefit on the genetic information. A plan or issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan or issuer may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment*—(i) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in

connection with a group health plan, must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan or coverage, nor in connection with the rules for eligibility (as defined in §146.121(b)(1)(ii) of this part) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception*—(A) *In general.* If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples.* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion.* In this *Example 1*, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

Example 2. (i) *Facts.* The same facts as *Example 1*, except there is no premium reduction or any other reward for completing the health risk assessment.

(ii) *Conclusion.* In this *Example 2*, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 3. (i) *Facts.* A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the health risk assessment.

(ii) *Conclusion.* In this *Example 3*, because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

Example 4. (i) *Facts.* The facts are the same as in *Example 1*, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) *Conclusion.* In this *Example 4*, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results

of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion.* In this *Example 5*, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts.* A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion.* In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6*, except that the last question goes on to state, ''In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.''

(ii) *Conclusion.* In this *Example 7*, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

Example 8. (i) *Facts.* Issuer *M* acquires Issuer *N*. *M* requests *N*'s records, stating that *N* should not provide genetic information and should review the records to excise any genetic information. *N* assembles the data requested by *M* and, although *N* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *M* receives genetic information about some of *N*'s covered individuals.

(ii) *Conclusion.* In this *Example 8*, *M*'s request for health information explicitly stated that genetic information should not be provided. Therefore, the collection of genetic information was within the incidental collection exception. However, *M* may not use the genetic information it obtained incidentally for underwriting purposes.

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan or issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* group health plan covers genetic testing for celiac disease for individuals who have family members with this condition. After *A*'s son is diagnosed with celiac disease, *A* undergoes a genetic test and promptly submits a claim for the test to *A*'s issuer for reimbursement. The issuer asks *A* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion.* In this *Example 1*, under the rules of paragraph (c)(4) of this section the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of *A*'s claim, the issuer's request for the results of the genetic test violates paragraph (c) of this section.

Example 2. (i) *Facts.* Individual *B*'s group health plan covers a yearly mammogram for participants and beneficiaries starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *B* is 33 years old and has the BRCA2 mutation. *B* undergoes a mammogram and promptly submits a claim to *B*'s plan for reimbursement. Following an established policy, the plan asks *B* for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer, before the claim for the mammogram is paid. This policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum

amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C*'s physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C*'s group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3*, the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C*'s undergoing a genetic test to determine what genetic markers *C* has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C*.

Example 4. (i) *Facts.* A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion.* In this *Example 4*, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion.* In this *Example 5*, the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts.* Same facts as *Example 4*, except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion.* In this *Example 6*, because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Applicability date.* This section applies for plan years beginning on or after December 7, 2009.

[74 FR 51688, Oct. 7, 2009]

§ 146.123 Special rule allowing integration of Health Reimbursement Arrangements (HRAs) and other account-based group health plans with individual health insurance coverage and Medicare and prohibiting discrimination in HRAs and other account-based group health plans.

(a) *Scope.* This section applies to health reimbursement arrangements (HRAs) and other account-based group health plans, as defined in §147.126(d)(6)(i) of this subchapter. For ease of reference, the term ''HRA'' is used in this section to include other account-based group health plans. For related regulations, see 26 CFR 1.36B–

2(c)(3)(i) and (c)(5), 29 CFR 2510.3–1(l), and 45 CFR 155.420.

(b) *Purpose.* This section provides the conditions that an HRA must satisfy in order to be integrated with individual health insurance coverage for purposes of Public Health Service Act (PHS Act) sections 2711 and 2713 and §147.126(d)(4) of this subchapter (referred to as an individual coverage HRA). This section also allows an individual coverage HRA to be integrated with Medicare for purposes of PHS Act sections 2711 and 2713 and §147.126(d)(4) of this subchapter, subject to the conditions provided in this section (see paragraph (e) of this section). Some of the conditions set forth in this section specifically relate to compliance with PHS Act sections 2711 and 2713 and some relate to the effect of having or being offered an individual coverage HRA on eligibility for the premium tax credit under section 36B of the Internal Revenue Code (Code). In addition, this section provides conditions that an individual coverage HRA must satisfy in order to comply with the nondiscrimination provisions in PHS Act section 2705 and that are consistent with the provisions of the Patient Protection and Affordable Care Act, Public Law 111–148 (124 Stat. 119 (2010)), and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152 (124 Stat. 1029 (2010)), each as amended, that are designed to create a competitive individual market. These conditions are intended to prevent an HRA plan sponsor from intentionally or unintentionally, directly or indirectly, steering any participants or dependents with adverse health factors away from its traditional group health plan, if any, and toward individual health insurance coverage.

(c) *General rule.* An HRA will be considered to be integrated with individual health insurance coverage for purposes of PHS Act sections 2711 and 2713 and §147.126(d)(4) of this subchapter and will not be considered to discriminate in violation of PHS Act section 2705 solely because it is integrated with individual health insurance coverage, provided that the conditions of this paragraph (c) are satisfied. See paragraph (e) of this section for how these conditions apply to an individual coverage HRA integrated with Medicare. For purposes of this section, medical care expenses means medical care expenses as defined in §147.126(d)(6)(ii) of this subchapter and Exchange means Exchange as defined in §155.20 of this subchapter.

(1) *Enrollment in individual health insurance coverage*—(i) *In general.* The HRA must require that the participant and any dependent(s) are enrolled in individual health insurance coverage that is subject to and complies with the requirements in PHS Act sections 2711 (and §147.126(a)(2) of this subchapter) and PHS Act section 2713 (and §147.130(a)(1) of this subchapter), for each month that the individual(s) are covered by the HRA. For purposes of this paragraph (c), all individual health insurance coverage, except for individual health insurance coverage that consists solely of excepted benefits, is treated as being subject to and complying with PHS Act sections 2711 and 2713. References to individual health insurance coverage in this paragraph (c) do not include individual health insurance coverage that consists solely of excepted benefits.

(ii) *Forfeiture.* The HRA must provide that if any individual covered by the HRA ceases to be covered by individual health insurance coverage, the HRA will not reimburse medical care expenses that are incurred by that individual after the individual health insurance coverage ceases. In addition, if the participant and all dependents covered by the participant's HRA cease to be covered by individual health insurance coverage, the participant must forfeit the HRA. In either case, the HRA must reimburse medical care expenses incurred by the individual prior to the cessation of individual health insurance coverage to the extent the medical care expenses are otherwise covered by the HRA, but the HRA may limit the period to submit medical care expenses for reimbursement to a reasonable specified time period. If a participant or dependent loses coverage under the HRA for a reason other than cessation of individual health insurance coverage, COBRA and other continuation coverage requirements may apply.

(iii) *Grace periods and retroactive termination of individual health insurance coverage.* In the event an individual is initially enrolled in individual health insurance coverage and subsequently timely fails to pay premiums for the coverage, with the result that the individual is in a grace period, the individual is considered to be enrolled in individual health insurance coverage for purposes of this paragraph (c)(1) and the individual coverage HRA must reimburse medical care expenses incurred by the individual during that time period to the extent the medical care expenses are otherwise covered by the HRA. If the individual fails to pay the applicable premium(s) by the end of the grace period and the coverage is cancelled or terminated, including retroactively, or if the individual health insurance coverage is cancelled or terminated retroactively for some other reason (for example, a rescission), an individual coverage HRA must require that a participant notify the HRA that coverage has been cancelled or terminated and the date on which the cancellation or termination is effective. After the individual coverage HRA has received the notice of cancellation or termination, the HRA may not reimburse medical care expenses incurred on and after the date the individual health insurance coverage was cancelled or terminated, which is considered to be the date of termination of coverage under the HRA.

(2) *No traditional group health plan may be offered to same participants.* To the extent a plan sponsor offers any class of employees (as defined in paragraph (d) of this section) an individual coverage HRA, the plan sponsor may not also offer a traditional group health plan to the same class of employees, except as provided in paragraph (d)(5) of this section. For purposes of this section, a traditional group health plan is any group health plan other than either an account-based group health plan or a group health plan that consists solely of excepted benefits. Therefore, a plan sponsor may not offer a choice between an individual coverage HRA or a traditional group health plan to any participant or dependent.

(3) *Same terms requirement*—(i) *In general.* If a plan sponsor offers an individual coverage HRA to a class of employees described in paragraph (d) of this section, the HRA must be offered on the same terms to all participants within the class, except as provided in paragraphs (c)(3)(ii) through (vi) and (d)(5) of this section.

(ii) *Carryover amounts, salary reduction arrangements, and transfer amounts.* Amounts that are not used to reimburse medical care expenses for any plan year that are made available to participants in later plan years are disregarded for purposes of determining whether an HRA is offered on the same terms, provided that the method for determining whether participants have access to unused amounts in future years, and the methodology and formula for determining the amounts of unused funds which they may access in future years, is the same for all participants in a class of employees. In addition, the ability to pay the portion of the premium for individual health insurance coverage that is not covered by the HRA, if any, by using a salary reduction arrangement under section 125 of the Code is considered to be a term of the HRA for purposes of this paragraph (c)(3). Therefore, an HRA is not provided on the same terms unless the salary reduction arrangement, if made available to any participant in a class of employees, is made available on the same terms to all participants (other than former employees, as defined in paragraph (c)(3)(iv) of this section) in the class of employees. Further, to the extent that a participant in an individual coverage HRA was previously covered by another HRA and the current individual coverage HRA makes available amounts that were not used to reimburse medical care expenses under the prior HRA (transferred amounts), the transferred amounts are disregarded for purposes of determining whether the HRA is offered on the same terms, provided that if the HRA makes available transferred amounts, it does so on the same terms for all participants in the class of employees.

(iii) *Permitted variation.* An HRA does not fail to be provided on the same terms solely because the maximum

dollar amount made available to participants in a class of employees to reimburse medical care expenses for any plan year increases in accordance with paragraph (c)(3)(iii)(A) or (B) of this section.

(A) *Variation due to number of dependents.* An HRA does not fail to be provided on the same terms to participants in a class of employees solely because the maximum dollar amount made available to those participants to reimburse medical care expenses for any plan year increases as the number of the participant's dependents who are covered under the HRA increases, so long as the same maximum dollar amount attributable to the increase in family size is made available to all participants in that class of employees with the same number of dependents covered by the HRA.

(B) *Variation due to age.* An HRA does not fail to be provided on the same terms to participants in a class of employees solely because the maximum dollar amount made available under the terms of the HRA to those participants to reimburse medical care expenses for any plan year increases as the age of the participant increases, so long as the requirements in paragraphs (c)(3)(iii)(B)(*1*) and (*2*) of this section are satisfied. For the purpose of this paragraph (c)(3)(iii)(B), the plan sponsor may determine the age of the participant using any reasonable method for a plan year, so long as the plan sponsor determines each participant's age for the purpose of this paragraph (c)(3)(iii)(B) using the same method for all participants in the class of employees for the plan year and the method is determined prior to the plan year.

(*1*) The same maximum dollar amount attributable to the increase in age is made available to all participants who are the same age.

(*2*) The maximum dollar amount made available to the oldest participant(s) is not more than three times the maximum dollar amount made available to the youngest participant(s).

(iv) *Former employees.* An HRA does not fail to be treated as provided on the same terms if the plan sponsor offers the HRA to some, but not all, former employees within a class of employees. However, if a plan sponsor offers the HRA to one or more former employees within a class of employees, the HRA must be offered to the former employee(s) on the same terms as to all other employees within the class, except as provided in paragraph (c)(3)(ii) of this section. For purposes of this section, a former employee is an employee who is no longer performing services for the employer.

(v) *New employees or new dependents.* For a participant whose coverage under the HRA becomes effective later than the first day of the plan year, the HRA does not fail to be treated as being provided on the same terms to the participant if the maximum dollar amount made available to the participant either is the same as the maximum dollar amount made available to participants in the participant's class of employees whose coverage became effective as of the first day of the plan year, or is pro-rated consistent with the portion of the plan year in which the participant is covered by the HRA. Similarly, if the HRA provides for variation in the maximum amount made available to participants in a class of employees based on the number of a participant's dependents covered by the HRA, and the number of a participant's dependents covered by the HRA changes during a plan year (either increasing or decreasing), the HRA does not fail to be treated as being provided on the same terms to the participant if the maximum dollar amount made available to the participant either is the same as the maximum dollar amount made available to participants in the participant's class of employees who had the same number of dependents covered by the HRA on the first day of the plan year or is pro-rated for the remainder of the plan year after the change in the number of the participant's dependents covered by the HRA consistent with the portion of the plan year in which that number of dependents are covered by the HRA. The method the HRA uses to determine amounts made available for participants whose coverage under the HRA is effective later than the first day of the plan year or who have changes in the number of dependents covered by the HRA during a plan year must be the

same for all participants in the class of employees and the method must be determined prior to the beginning of the plan year.

(vi) *HSA-compatible HRAs.* An HRA does not fail to be treated as provided on the same terms if the plan sponsor offers participants in a class of employees a choice between an HSA-compatible individual coverage HRA and an individual coverage HRA that is not HSA compatible, provided both types of HRAs are offered to all participants in the class of employees on the same terms. For the purpose of this paragraph (c)(3)(vi), an HSA-compatible individual coverage HRA is an individual coverage HRA that is limited in accordance with applicable guidance under section 223 of the Code such that an individual covered by such an HRA is not disqualified from being an eligible individual under section 223 of the Code.

(vii) *Examples.* The following examples illustrate the provisions of this paragraph (c)(3), without taking into account the provisions of paragraph (d) of this section. In each example, the HRA is an individual coverage HRA that has a calendar year plan year and may reimburse any medical care expenses, including premiums for individual health insurance coverage (except as provided in paragraph (c)(3)(vii)(E) of this section (*Example 5*)). Further, in each example, assume the HRA is offered on the same terms, except as otherwise specified in the example and that no participants or dependents are Medicare beneficiaries.

(A) *Example 1: Carryover amounts permitted—(1) Facts.* For 2020 and again for 2021, Plan Sponsor A offers all employees $7,000 each in an HRA, and the HRA provides that amounts that are unused at the end of a plan year may be carried over to the next plan year, with no restrictions on the use of the carryover amounts compared to the use of newly available amounts. At the end of 2020, some employees have used all of the funds in their HRAs, while other employees have balances remaining that range from $500 to $1,750 that are carried over to 2021 for those employees.

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(A) (*Example 1*) for 2020 because Plan Sponsor A offers all employees the same amount, $7,000, in an HRA for that year. The same terms requirement is also satisfied for 2021 because Plan Sponsor A again offers all employees the same amount for that year, and the carryover amounts that some employees have are disregarded in applying the same terms requirement because the amount of the carryover for each employee (that employee's balance) and each employee's access to the carryover amounts is based on the same terms.

(B) *Example 2: Employees hired after the first day of the plan year—(1) Facts.* For 2020, Plan Sponsor B offers all employees employed on January 1, 2020, $7,000 each in an HRA for the plan year. Employees hired after January 1, 2020, are eligible to enroll in the HRA with an effective date of the first day of the month following their date of hire, as long as they have enrolled in individual health insurance coverage effective on or before that date, and the amount offered to these employees is pro-rated based on the number of months remaining in the plan year, including the month which includes their coverage effective date.

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(B) (*Example 2*) for 2020 because Plan Sponsor B offers all employees employed on the first day of the plan year the same amount, $7,000, in an HRA for that plan year and all employees hired after January 1, 2020, a pro-rata amount based on the portion of the plan year during which they are enrolled in the HRA.

(C) *Example 3: HRA amounts offered vary based on number of dependents—(1) Facts.* For 2020, Plan Sponsor C offers its employees the following amounts in an HRA: $1,500, if the employee is the only individual covered by the HRA; $3,500, if the employee and one dependent are covered by the HRA; and $5,000, if the employee and more than one dependent are covered by the HRA.

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(C) (*Example 3*) because paragraph (c)(3)(iii)(A) of this section allows the

maximum dollar amount made available in an HRA to increase as the number of the participant's dependents covered by the HRA increases and Plan Sponsor C makes the same amount available to each employee with the same number of dependents covered by the HRA.

(D) *Example 4: HRA amounts offered vary based on increases in employees' ages—(1) Facts.* For 2020, Plan Sponsor D offers its employees the following amounts in an HRA: $1,000 each for employees age 25 to 35; $2,000 each for employees age 36 to 45; $2,500 each for employees age 46 to 55; and $4,000 each for employees over age 55.

(*2*) *Conclusion.* The same terms requirement of this paragraph (c)(3) is not satisfied in this paragraph (c)(3)(vii)(D) (*Example 4*) because the terms of the HRA provide the oldest participants (those over age 55) with more than three times the amount made available to the youngest participants (those ages 25 to 35), in violation of paragraph (c)(3)(iii)(B)(*2*) of this section.

(E) *Example 5: Application of same terms requirement to premium only HRA—(1) Facts.* For 2020, Plan Sponsor E offers its employees an HRA that reimburses only premiums for individual health insurance coverage, up to $10,000 for the year. Employee A enrolls in individual health insurance coverage with a $5,000 premium for the year and is reimbursed $5,000 from the HRA. Employee B enrolls in individual health insurance coverage with an $8,000 premium for the year and is reimbursed $8,000 from the HRA.

(*2*) [Reserved]

Conclusion. The same terms requirement of this paragraph (c)(3) is satisfied in this paragraph (c)(3)(vii)(E) (*Example 5*) because Plan Sponsor E offers the HRA on the same terms to all employees, notwithstanding that some employees receive a greater amount of reimbursement than others based on the cost of the individual health insurance coverage selected by the employee.

(4) *Opt out.* Under the terms of the HRA, a participant who is otherwise eligible for coverage must be permitted to opt out of and waive future reimbursements on behalf of the participant and all dependents eligible for the HRA from the HRA once, and only once, with respect to each plan year. The HRA may establish timeframes for enrollment in (and opting out of) the HRA but, in general, the opportunity to opt out must be provided in advance of the first day of the plan year. For participants who become eligible to participate in the HRA on a date other than the first day of the plan year (or who become eligible fewer than 90 days prior to the plan year or for whom the notice under paragraph (c)(6) of this section is required to be provided as set forth in paragraph (c)(6)(i)(C) of this section), or for a dependent who newly becomes eligible during the plan year, this opportunity must be provided during the applicable HRA enrollment period(s) established by the HRA for these individuals. Further, under the terms of the HRA, upon termination of employment, for a participant who is covered by the HRA, either the remaining amounts in the HRA must be forfeited or the participant must be permitted to permanently opt out of and waive future reimbursements from the HRA on behalf of the participant and all dependents covered by the HRA.

(5) *Reasonable procedures for coverage substantiation*—(i) *Substantiation of individual health insurance coverage for the plan year.* The HRA must implement, and comply with, reasonable procedures to substantiate that participants and each dependent covered by the HRA are, or will be, enrolled in individual health insurance coverage for the plan year (or for the portion of the plan year the individual is covered by the HRA, if applicable). The HRA may establish the date by which this substantiation must be provided, but, in general, the date may be no later than the first day of the plan year. However, for a participant who is not eligible to participate in the HRA on the first day of the plan year (or who becomes eligible fewer than 90 days prior to the plan year or for whom the notice under paragraph (c)(6) of this section is required to be provided as set forth in paragraph (c)(6)(i)(C) of this section), the HRA may establish the date by which this substantiation must be provided, but that date may be no later

than the date the HRA coverage begins. Similarly, for a participant who adds a new dependent during the plan year, the HRA may establish the date by which this substantiation must be provided, but the date may be no later than the date the HRA coverage for the new dependent begins; however, to the extent the dependent's coverage under the HRA is effective retroactively, the HRA may establish a reasonable time by which this substantiation is required, but must require it be provided before the HRA will reimburse any medical care expense for the newly added dependent. The reasonable procedures an HRA may use to implement the substantiation requirement set forth in this paragraph (c)(5)(i) may include a requirement that a participant substantiate enrollment by providing either:

(A) A document from a third party (for example, the issuer or an Exchange) showing that the participant and any dependents covered by the HRA are, or will be, enrolled in individual health insurance coverage (for example, an insurance card or an explanation of benefits document pertaining to the relevant time period or documentation from the Exchange showing that the individual has completed the application and plan selection); or

(B) An attestation by the participant stating that the participant and dependent(s) covered by the HRA are, or will be, enrolled in individual health insurance coverage, the date coverage began or will begin, and the name of the provider of the coverage.

(ii) *Coverage substantiation with each request for reimbursement of medical care expenses.* Following the initial substantiation of coverage, with each new request for reimbursement of an incurred medical care expense for the same plan year, the HRA may not reimburse a participant for any medical care expenses unless, prior to each reimbursement, the participant substantiates that the individual on whose behalf medical care expenses are requested to be reimbursed continues to be enrolled in individual health insurance coverage for the month during which the medical care expenses were incurred. The HRA must implement, and comply with, reasonable procedures to satisfy this requirement. This substantiation may be in the form of a written attestation by the participant, which may be part of the form used to request reimbursement, or a document from a third party (for example, a health insurance issuer) showing that the participant or the dependent, if applicable, are or were enrolled in individual health insurance coverage for the applicable month.

(iii) *Reliance on substantiation.* For purposes of this paragraph (c)(5), an HRA may rely on the participant's documentation or attestation unless the HRA, its plan sponsor, or any other entity acting in an official capacity on behalf of the HRA has actual knowledge that any individual covered by the HRA is not, or will not be, enrolled in individual health insurance coverage for the plan year (or applicable portion of the plan year) or the month, as applicable.

(6) *Notice requirement*—(i) *Timing.* The HRA must provide a written notice to each participant:

(A) At least 90 calendar days before the beginning of each plan year for any participant who is not described in either paragraph (c)(6)(i)(B) or (C) of this section;

(B) No later than the date on which the HRA may first take effect for the participant, for any participant who is not eligible to participate at the beginning of the plan year (or is not eligible to participate at the time the notice is provided at least 90 calendar days before the beginning of the plan year pursuant to paragraph (c)(6)(i)(A) of this section); or

(C) No later than the date on which the HRA may first take effect for the participant, for any participant who is employed by an employer that is first established less than 120 days before the beginning of the first plan year of the HRA; this paragraph (c)(6)(i)(C) applies only with respect to the first plan year of the HRA.

(ii) *Content.* The notice must include all the information described in this paragraph (c)(6)(ii) (and may include any additional information that does not conflict with that information). To the extent that the Departments of the Treasury, Labor and Health and Human Services provide model notice

language for certain elements of this required notice, HRAs are permitted, but not required, to use the model language.

(A) A description of the terms of the HRA, including the maximum dollar amount available for each participant (including the self-only HRA amount available for the plan year (or the maximum dollar amount available for the plan year if the HRA provides for reimbursements up to a single dollar amount regardless of whether a participant has self-only or other than self-only coverage)), any rules regarding the proration of the maximum dollar amount applicable to any participant (or dependent, if applicable) who is not eligible to participate in the HRA for the entire plan year, whether (and which of) the participant's dependents are eligible for the HRA, a statement that there are different kinds of HRAs (including a qualified small employer health reimbursement arrangement) and the HRA being offered is an individual coverage HRA, a statement that the HRA requires the participant and any covered dependents to be enrolled in individual health insurance coverage (or Medicare Part A and B or Medicare Part C, if applicable), a statement that the coverage in which the participant and any covered dependents must be enrolled cannot be short-term, limited-duration insurance or consist solely of excepted benefits, if the HRA is subject to the Employee Retirement Income Security Act (ERISA), a statement that individual health insurance coverage in which the participant and any covered dependents are enrolled is not subject to ERISA, if the conditions under 29 CFR 2510.3–1(l) are satisfied, the date as of which coverage under the HRA may first become effective (both for participants whose coverage will become effective on the first day of the plan year and for participants whose HRA coverage may become effective at a later date), the dates on which the HRA plan year begins and ends, and the dates on which the amounts newly made available under the HRA will be made available.

(B) A statement of the right of the participant to opt out of and waive future reimbursements from the HRA, as set forth under paragraph (c)(4) of this section.

(C) A description of the potential availability of the premium tax credit if the participant opts out of and waives future reimbursements from the HRA and the HRA is not affordable for one or more months under 26 CFR 1.36B–2(c)(5), a statement that even if the participant opts out of and waives future reimbursements from an HRA, the offer will prohibit the participant (and, potentially, the participant's dependents) from receiving a premium tax credit for the participant's coverage (or the dependent's coverage, if applicable) on an Exchange for any month that the HRA is affordable under 26 CFR 1.36B–2(c)(5), a statement describing how the participant may find assistance with determining affordability, a statement that, if the participant is a former employee, the offer of the HRA does not render the participant (or the participant's dependents, if applicable) ineligible for the premium tax credit regardless of whether it is affordable under 26 CFR 1.36B–2(c)(5), and a statement that if the participant or dependent is enrolled in Medicare, he or she is ineligible for the premium tax credit without regard to the offer or acceptance of the HRA;

(D) A statement that if the participant accepts the HRA, the participant may not claim a premium tax credit for the participant's Exchange coverage for any month the HRA may be used to reimburse medical care expenses of the participant, and a premium tax credit may not be claimed for the Exchange coverage of the participant's dependents for any month the HRA may be used to reimburse medical care expenses of the dependents.

(E) A statement that the participant must inform any Exchange to which the participant applies for advance payments of the premium tax credit of the availability of the HRA; the self-only HRA amount available for the HRA plan year (or the maximum dollar amount available for the plan year if the HRA provides for reimbursements up to a single dollar amount regardless of whether a participant has self-only or other than self-only coverage) as set

forth in the written notice in accordance with paragraph (c)(6)(ii)(A) of this section; whether the HRA is also available to the participant's dependents and if so, which ones; the date as of which coverage under the HRA may first become effective; the date on which the plan year begins and the date on which it ends; and whether the participant is a current employee or former employee.

(F) A statement that the participant should retain the written notice because it may be needed to determine whether the participant is allowed a premium tax credit on the participant's individual income tax return.

(G) A statement that the HRA may not reimburse any medical care expense unless the substantiation requirement set forth in paragraph (c)(5)(ii) of this section is satisfied and a statement that the participant must also provide the substantiation required by paragraph (c)(5)(i) of this section.

(H) A statement that if the individual health insurance coverage (or coverage under Medicare Part A and B or Medicare Part C) of a participant or dependent ceases, the HRA will not reimburse any medical care expenses that are incurred by the participant or dependent, as applicable, after the coverage ceases, and a statement that the participant must inform the HRA if the participant's or dependent's individual health insurance coverage (or coverage under Medicare Part A and B or Medicare Part C) is cancelled or terminated retroactively and the date on which the cancellation or termination is effective.

(I) The contact information (including a phone number) for an individual or a group of individuals who participants may contact in order to receive additional information regarding the HRA. The plan sponsor may determine which individual or group of individuals is best suited to be the specified contact.

(J) A statement of availability of a special enrollment period to enroll in or change individual health insurance coverage, through or outside of an Exchange, for the participant and any dependents who newly gain access to the HRA and are not already covered by the HRA.

(d) *Classes of employees*—(1) *In general.* This paragraph (d) sets forth the rules for determining classes of employees. Paragraph (d)(2) of this section sets forth the specific classes of employees; paragraph (d)(3) of this section sets forth a minimum class size requirement that applies in certain circumstances; paragraph (d)(4) of this section sets forth rules regarding the definition of ''full-time employees,'' ''part-time employees,'' and ''seasonal employees''; paragraph (d)(5) of this section sets forth a special rule for new hires; and paragraph (d)(6) of this section addresses student premium reduction arrangements. For purposes of this section, including determining classes under this paragraph (d), the employer is the common law employer and is determined without regard to the rules under sections 414(b), (c), (m), and (o) of the Code that would treat the common law employer as a single employer with certain other entities.

(2) *List of classes.* Participants may be treated as belonging to a class of employees based on whether they are, or are not, included in the classes described in this paragraph (d)(2). If the individual coverage HRA is offered to former employees, former employees are considered to be in the same class in which they were included immediately before separation from service. Before each plan year, a plan sponsor must determine for the plan year which classes of employees it intends to treat separately and the definition of the relevant class(es) it will apply, to the extent these regulations permit a choice. After the classes and the definitions of the classes are established for a plan year, a plan sponsor may not make changes to the classes of employees or the definitions of those relevant classes with respect to that plan year.

(i) Full-time employees, defined at the election of the plan sponsor to mean either full-time employees under section 4980H of the Code (and 26 CFR 54.4980H–1(a)(21)) or employees who are not part-time employees (as described in 26 CFR 1.105–11(c)(2)(iii)(C));

(ii) Part-time employees, defined at the election of the plan sponsor to mean either employees who are not

full-time employees under section 4980H of the Code (and under 26 CFR 54.4980H–1(a)(21) (which defines full-time employee)) or employees who are part-time employees as described in 26 CFR 1.105–11(c)(2)(iii)(C);

(iii) Employees who are paid on a salary basis;

(iv) Non-salaried employees (such as, for example, hourly employees);

(v) Employees whose primary site of employment is in the same rating area as defined in §147.102(b) of this subchapter;

(vi) Seasonal employees, defined at the election of the plan sponsor to mean seasonal employees as described in either 26 CFR 54.4980H–1(a)(38) or 26 CFR 1.105–11(c)(2)(iii)(C);

(vii) Employees included in a unit of employees covered by a particular collective bargaining agreement (or an appropriate related participation agreement) in which the plan sponsor participates (as described in 26 CFR 1.105–11(c)(2)(iii)(D));

(viii) Employees who have not satisfied a waiting period for coverage (if the waiting period complies with §147.116 of this subchapter);

(ix) Non-resident aliens with no U.S.-based income (as described in 26 CFR 1.105–11(c)(2)(iii)(E));

(x) Employees who, under all the facts and circumstances, are employees of an entity that hired the employees for temporary placement at an entity that is not the common law employer of the employees and that is not treated as a single employer with the entity that hired the employees for temporary placement under section 414(b), (c), (m), or (o) of the Code; or

(xi) A group of participants described as a combination of two or more of the classes of employees set forth in paragraphs (d)(2)(i) through (x) of this section.

(3) *Minimum class size requirement*—(i) *In general.* If a class of employees is subject to the minimum class size requirement as set forth in this paragraph (d)(3), the class must consist of at least a minimum number of employees (as described in paragraphs (d)(3)(iii) and (iv) of this section), otherwise, the plan sponsor may not treat that class as a separate class of employees. Paragraph (d)(3)(ii) of this section sets forth the circumstances in which the minimum class size requirement applies to a class of employees, paragraph (d)(3)(iii) of this section sets forth the rules for determining the applicable class size minimum, and paragraph (d)(3)(iv) of this section sets forth the rules for a plan sponsor to determine if it satisfies the minimum class size requirement with respect to a class of employees.

(ii) *Circumstances in which minimum class size requirement applies.* (A) The minimum class size requirement applies only if a plan sponsor offers a traditional group health plan to one or more classes of employees and offers an individual coverage HRA to one or more other classes of employees.

(B) The minimum class size requirement does not apply to a class of employees offered a traditional group health plan or a class of employees offered no coverage.

(C) The minimum class size requirement applies to a class of employees offered an individual coverage HRA if the class is full-time employees, part-time employees, salaried employees, non-salaried employees, or employees whose primary site of employment is in the same rating area (described in paragraph (d)(2)(i), (ii), (iii), (iv), or (v) of this section, respectively, and referred to collectively as the applicable classes or individually as an applicable class), except that:

(*1*) In the case of the class of employees whose primary site of employment is in the same rating area (as described in paragraph (d)(2)(v) of this section), the minimum class size requirement does not apply if the geographic area defining the class is a State or a combination of two or more entire States; and

(*2*) In the case of the classes of employees that are full-time employees and part-time employees (as described in paragraphs (d)(2)(i) and (ii) of this section, respectively), the minimum class size requirement applies only to those classes (and the classes are only applicable classes) if the employees in one such class are offered a traditional group health plan while the employees in the other such class are offered an individual coverage HRA. In such a

case, the minimum class size requirement applies only to the class offered an individual coverage HRA.

(D) A class of employees offered an individual coverage HRA is also subject to the minimum class size requirement if the class is a class of employees created by combining at least one of the applicable classes (as defined in paragraph (d)(3)(ii)(C) of this section) with any other class, except that the minimum class size requirement shall not apply to a class that is the result of a combination of one of the applicable classes and a class of employees who have not satisfied a waiting period (as described in paragraph (d)(2)(viii) of this section).

(iii) *Determination of the applicable class size minimum*—(A) *In general.* The minimum number of employees that must be in a class of employees that is subject to the minimum class size requirement (the applicable class size minimum) is determined prior to the beginning of the plan year for each plan year of the individual coverage HRA and is:

(*1*) 10, for an employer with fewer than 100 employees;

(*2*) A number, rounded down to a whole number, equal to 10 percent of the total number of employees, for an employer with 100 to 200 employees; and

(*3*) 20, for an employer with more than 200 employees.

(B) *Determining employer size.* For purposes of this paragraph (d)(3), the number of employees of an employer is determined in advance of the plan year of the HRA based on the number of employees that the employer reasonably expects to employ on the first day of the plan year.

(iv) *Determining if a class satisfies the applicable class size minimum.* For purposes of this paragraph (d)(3), whether a class of employees satisfies the applicable class size minimum for a plan year of the individual coverage HRA is based on the number of employees in the class offered the individual coverage HRA as of the first day of the plan year. Therefore, this determination is not based on the number of employees that actually enroll in the individual coverage HRA, and this determination is not affected by changes in the number of employees in the class during the plan year.

(4) *Consistency requirement.* For any plan year, a plan sponsor may define ''full-time employee,'' ''part-time employee,'' and ''seasonal employee'' in accordance with the relevant provisions of sections 105(h) or 4980H of the Code, as set forth in paragraphs (d)(2)(i), (ii), and (vi) of this section, if:

(i) To the extent applicable under the HRA for the plan year, each of the three classes of employees are defined in accordance with section 105(h) of the Code or each of the three classes of employees are defined in accordance with section 4980H of the Code for the plan year; and

(ii) The HRA plan document sets forth the applicable definitions prior to the beginning of the plan year to which the definitions will apply.

(5) *Special rule for new hires*—(i) *In general.* Notwithstanding paragraphs (c)(2) and (3) of this section, a plan sponsor that offers a traditional group health plan to a class of employees may prospectively offer the employees in that class of employees who are hired on or after a certain future date (the new hire date) an individual coverage HRA (with this group of employees referred to as the new hire subclass), while continuing to offer employees in that class of employees who are hired before the new hire date a traditional group health plan (with the rule set forth in this sentence referred to as the special rule for new hires). For the new hire subclass, the individual coverage HRA must be offered on the same terms to all participants within the subclass, in accordance with paragraph (c)(3) of this section. In accordance with paragraph (c)(2) of this section, a plan sponsor may not offer a choice between an individual coverage HRA or a traditional group health plan to any employee in the new hire subclass or to any employee in the class who is not a member of the new hire subclass.

(ii) *New hire date.* A plan sponsor may set the new hire date for a class of employees prospectively as any date on or after January 1, 2020. A plan sponsor may set different new hire dates prospectively for separate classes of employees.

(iii) *Discontinuation of use of special rule for new hires and multiple applications of the special rule for new hires.* A plan sponsor may discontinue use of the special rule for new hires at any time for any class of employees. In that case, the new hire subclass is no longer treated as a separate subclass of employees. In the event a plan sponsor applies the special rule for new hires to a class of employees and later discontinues use of the rule to the class of employees, the plan sponsor may later apply the rule if the application of the rule would be permitted under the rules for initial application of the special rule for new hires. If a plan sponsor, in accordance with the requirements for the special rule for new hires, applies the rule to a class of employees subsequent to any prior application and discontinuance of the rule to that class, the new hire date must be prospective.

(iv) *Application of the minimum class size requirement under the special rule for new hires.* The minimum class size requirement set forth in paragraph (d)(3) of this section does not apply to the new hire subclass. However, if a plan sponsor subdivides the new hire subclass subsequent to creating the new hire subclass, the minimum class size requirement set forth in paragraph (d)(3) of this section applies to any class of employees created by subdividing the new hire subclass, if the minimum class size requirement otherwise applies.

(6) *Student employees offered student premium reduction arrangements.* For purposes of this section, if an institution of higher education (as defined in the Higher Education Act of 1965) offers a student employee a student premium reduction arrangement, the employee is not considered to be part of the class of employees to which the employee would otherwise belong. For the purpose of this paragraph (d)(6) and paragraph (f)(1) of this section, a student premium reduction arrangement is defined as any program offered by an institution of higher education under which the cost of insured or self-insured student health coverage is reduced for certain students through a credit, offset, reimbursement, stipend or similar arrangement. A student employee offered a student premium reduction arrangement is also not counted for purposes of determining the applicable class size minimum under paragraph (d)(3)(iii) of this section. If a student employee is not offered a student premium reduction arrangement (including if the student employee is offered an individual coverage HRA instead), the student employee is considered to be part of the class of employees to which the employee otherwise belongs and is counted for purposes of determining the applicable class size minimum under paragraph (d)(3)(iii) of this section.

(e) *Integration of Individual Coverage HRAs with Medicare*—(1) *General rule.* An individual coverage HRA will be considered to be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713 and §147.126(d)(4) of this subchapter), provided that the conditions of paragraph (c) of this section are satisfied, subject to paragraph (e)(2) of this section. Nothing in this section requires that a participant and his or her dependents all have the same type of coverage; therefore, an individual coverage HRA may be integrated with Medicare for some individuals and with individual health insurance coverage for others, including, for example, a participant enrolled in Medicare Part A and B or Part C and his or her dependents enrolled in individual health insurance coverage.

(2) *Application of conditions in paragraph (c) of this section*—(i) *In general.* Except as provided in paragraph (e)(2)(ii) of this section, in applying the conditions of paragraph (c) of this section with respect to integration with Medicare, a reference to ''individual health insurance coverage'' is deemed to refer to coverage under Medicare Part A and B or Part C. References in this section to integration of an HRA with Medicare refer to integration of an individual coverage HRA with Medicare Part A and B or Part C.

(ii) *Exceptions.* For purposes of the statement regarding ERISA under the notice content element under paragraph (c)(6)(ii)(A) of this section and the statement regarding the availability of a special enrollment period under the notice content element

under paragraph (c)(6)(ii)(J) of this section, the term individual health insurance coverage means only individual health insurance coverage and does not also mean coverage under Medicare Part A and B or Part C.

(f) *Examples*—(1) *Examples regarding classes and the minimum class size requirement*. The following examples illustrate the provisions of paragraph (c)(3) of this section, taking into account the provisions of paragraphs (d)(1) through (4) and (d)(6) of this section. In each example, the HRA is an individual coverage HRA that may reimburse any medical care expenses, including premiums for individual health insurance coverage and it is assumed that no participants or dependents are Medicare beneficiaries.

(i) *Example 1: Collectively bargained employees offered traditional group health plan; non-collectively bargained employees offered HRA*—(A) *Facts*. For 2020, Plan Sponsor A offers its employees covered by a collective bargaining agreement a traditional group health plan (as required by the collective bargaining agreement) and all other employees (non-collectively bargained employees) each an HRA on the same terms.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(i) (*Example 1*) because collectively bargained and non-collectively bargained employees may be treated as different classes of employees, one of which may be offered a traditional group health plan and the other of which may be offered an individual coverage HRA, and Plan Sponsor A offers the HRA on the same terms to all participants who are non-collectively bargained employees. The minimum class size requirement does not apply to this paragraph (f)(1)(i) (*Example 1*) even though Plan Sponsor A offers one class a traditional group health plan and one class the HRA because collectively bargained and non-collectively bargained employees are not applicable classes that are subject to the minimum class size requirement.

(ii) *Example 2: Collectively bargained employees in one unit offered traditional group health plan and in another unit offered HRA*—(A) *Facts*. For 2020, Plan Sponsor B offers its employees covered by a collective bargaining agreement with Local 100 a traditional group health plan (as required by the collective bargaining agreement), and its employees covered by a collective bargaining agreement with Local 200 each an HRA on the same terms (as required by the collective bargaining agreement).

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(ii) (*Example 2*) because the employees covered by the collective bargaining agreements with the two separate bargaining units (Local 100 and Local 200) may be treated as two different classes of employees and Plan Sponsor B offers an HRA on the same terms to the participants covered by the agreement with Local 200. The minimum class size requirement does not apply to this paragraph (f)(1)(ii) (*Example 2*) even though Plan Sponsor B offers the Local 100 employees a traditional group health plan and the Local 200 employees an HRA because collectively bargained employees are not applicable classes that are subject to the minimum class size requirement.

(iii) *Example 3: Employees in a waiting period offered no coverage; other employees offered an HRA*—(A) *Facts*. For 2020, Plan Sponsor C offers its employees who have completed a waiting period that complies with the requirements for waiting periods in §147.116 of this subchapter each an HRA on the same terms and does not offer coverage to its employees who have not completed the waiting period.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(iii) (*Example 3*) because employees who have completed a waiting period and employees who have not completed a waiting period may be treated as different classes and Plan Sponsor C offers the HRA on the same terms to all participants who have completed the waiting period. The minimum class size requirement does not apply to this paragraph (f)(1)(iii) (*Example 3*) because Plan Sponsor C does not offer at least one class of employees a traditional group health plan and because the class

of employees who have not completed a waiting period and the class of employees who have completed a waiting period are not applicable classes that are subject to the minimum class size requirement.

(iv) *Example 4: Employees in a waiting period offered an HRA; other employees offered a traditional group health plan*—(A) *Facts*. For 2020, Plan Sponsor D offers its employees who have completed a waiting period that complies with the requirements for waiting periods in § 147.116 of this subchapter a traditional group health plan and offers its employees who have not completed the waiting period each an HRA on the same terms.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(iv) (*Example 4*) because employees who have completed a waiting period and employees who have not completed a waiting period may be treated as different classes and Plan Sponsor D offers an HRA on the same terms to all participants who have not completed the waiting period. The minimum class size requirement does not apply to this paragraph (f)(1)(iv) (*Example 4*) even though Plan Sponsor D offers employees who have completed a waiting period a traditional group health plan and employees who have not completed a waiting period an HRA because the class of employees who have not completed a waiting period is not an applicable class that is subject to the minimum class size requirement (nor is the class made up of employees who have completed the waiting period).

(v) *Example 5: Staffing firm employees temporarily placed with customers offered an HRA; other employees offered a traditional group health plan*—(A) *Facts*. Plan Sponsor E is a staffing firm that places certain of its employees on temporary assignments with customers that are not the common law employers of Plan Sponsor E's employees or treated as a single employer with Plan Sponsor E under section 414(b), (c), (m), or (o) of the Code (unrelated entities); other employees work in Plan Sponsor E's office managing the staffing business (non-temporary employees). For 2020, Plan Sponsor E offers its employees who are on temporary assignments with customers each an HRA on the same terms. All other employees are offered a traditional group health plan.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(v) (*Example 5*) because the employees who are hired for temporary placement at an unrelated entity and non-temporary employees of Plan Sponsor E may be treated as different classes of employees and Plan Sponsor E offers an HRA on the same terms to all participants temporarily placed with customers. The minimum class size requirement does not apply to this paragraph (f)(1)(v) (*Example 5*) even though Plan Sponsor E offers one class a traditional group health plan and one class the HRA because the class of employees hired for temporary placement is not an applicable class that is subject to the minimum class size requirement (nor is the class made up of non-temporary employees).

(vi) *Example 6: Staffing firm employees temporarily placed with customers in rating area 1 offered an HRA; other employees offered a traditional group health plan*—(A) *Facts*. The facts are the same as in paragraph (f)(1)(v) of this section (*Example 5*), except that Plan Sponsor E has work sites in rating area 1 and rating area 2, and it offers its 10 employees on temporary assignments with a work site in rating area 1 an HRA on the same terms. Plan Sponsor E has 200 other employees in rating areas 1 and 2, including its non-temporary employees in rating areas 1 and 2 and its employees on temporary assignments with a work site in rating area 2, all of whom are offered a traditional group health plan.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(vi) (*Example 6*) because, even though the employees who are temporarily placed with customers generally may be treated as employees of a different class, because Plan Sponsor E is also using a rating area to identify the class offered the HRA (which is an applicable class for the minimum class size requirement) and is offering one class the HRA and another class the traditional group

health plan, the minimum class size requirement applies to the class offered the HRA, and the class offered the HRA fails to satisfy the minimum class size requirement. Because Plan Sponsor E employs 210 employees, the applicable class size minimum is 20, and the HRA is offered to only 10 employees.

(vii) *Example 7: Employees in State 1 offered traditional group health plan; employees in State 2 offered HRA*—(A) *Facts*. Plan Sponsor F employs 45 employees whose work site is in State 1 and 7 employees whose primary site of employment is in State 2. For 2020, Plan Sponsor F offers its 45 employees in State 1 a traditional group health plan, and each of its 7 employees in State 2 an HRA on the same terms.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(vii) (*Example 7*) because Plan Sponsor F offers the HRA on the same terms to all employees with a work site in State 2 and that class is a permissible class under paragraph (d) of this section. This is because employees whose work sites are in different rating areas may be considered different classes and a plan sponsor may create a class of employees by combining classes of employees, including by combining employees whose work site is in one rating area with employees whose work site is in a different rating area, or by combining all employees whose work site is in a state. The minimum class size requirement does not apply to this paragraph (f)(1)(vii) (*Example 7*) because the minimum class size requirement does not apply if the geographic area defining a class of employees is a state or a combination of two or more entire states.

(viii) *Example 8: Full-time seasonal employees offered HRA; all other full-time employees offered traditional group health plan; part-time employees offered no coverage*—(A) *Facts*. Plan Sponsor G employs 6 full-time seasonal employees, 75 full-time employees who are not seasonal employees, and 5 part-time employees. For 2020, Plan Sponsor G offers each of its 6 full-time seasonal employees an HRA on the same terms, its 75 full-time employees who are not seasonal employees a traditional group health plan, and offers no coverage to its 5 part-time employees.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(viii) (*Example 8*) because full-time seasonal employees and full-time employees who are not seasonal employees may be considered different classes and Plan Sponsor G offers the HRA on the same terms to all full-time seasonal employees. The minimum class size requirement does not apply to the class offered the HRA in this paragraph (f)(1)(viii) (*Example 8*) because part-time employees are not offered coverage and full-time employees are not an applicable class subject to the minimum class size requirement if part-time employees are not offered coverage.

(ix) *Example 9: Full-time employees in rating area 1 offered traditional group health plan; full-time employees in rating area 2 offered HRA; part-time employees offered no coverage*—(A) *Facts*. Plan Sponsor H employs 17 full-time employees and 10 part-time employees whose work site is in rating area 1 and 552 full-time employees whose work site is in rating area 2. For 2020, Plan Sponsor H offers its 17 full-time employees in rating area 1 a traditional group health plan and each of its 552 full-time employees in rating area 2 an HRA on the same terms. Plan Sponsor H offers no coverage to its 10 part-time employees in rating area 1. Plan Sponsor H reasonably expects to employ 569 employees on the first day of the HRA plan year.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(ix) (*Example 9*) because employees whose work sites are in different rating areas may be considered different classes and Plan Sponsor H offers the HRA on the same terms to all full-time employees in rating area 2. The minimum class size requirement applies to the class offered the HRA in this paragraph (f)(1)(ix) (*Example 9*) because the minimum class size requirement applies to a class based on a geographic area unless the geographic area is a state or a combination of two or more entire states. However, the minimum class size requirement applies only to

the class offered the HRA, and Plan Sponsor H offers the HRA to the 552 full-time employees in rating area 2 on the first day of the plan year, satisfying the minimum class size requirement (because the applicable class size minimum for Plan Sponsor H is 20).

(x) *Example 10: Employees in rating area 1 offered HRA; employees in rating area 2 offered traditional group health plan*—(A) *Facts.* The facts are the same as in paragraph (f)(1)(ix) of this section (*Example 9*) except that Plan Sponsor H offers its 17 full-time employees in rating area 1 the HRA and offers its 552 full-time employees in rating area 2 the traditional group health plan.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(x) (*Example 10*) because, even though employees whose work sites are in different rating areas generally may be considered different classes and Plan Sponsor H offers the HRA on the same terms to all participants in rating area 1, the HRA fails to satisfy the minimum class size requirement. Specifically, the minimum class size requirement applies to this paragraph (f)(1)(x) (*Example 10*) because the minimum class size requirement applies to a class based on a geographic area unless the geographic area is a state or a combination of two or more entire states. Further, the applicable class size minimum for Plan Sponsor H is 20 employees, and the HRA is only offered to the 17 full-time employees in rating area 1 on the first day of the HRA plan year.

(xi) *Example 11: Employees in State 1 and rating area 1 of State 2 offered HRA; employees in all other rating areas of State 2 offered traditional group health plan*—(A) *Facts.* For 2020, Plan Sponsor I offers an HRA on the same terms to a total of 200 employees it employs with work sites in State 1 and in rating area 1 of State 2. Plan Sponsor I offers a traditional group health plan to its 150 employees with work sites in other rating areas in State 2. Plan Sponsor I reasonably expects to employ 350 employees on the first day of the HRA plan year.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xi) (*Example 11*). Plan Sponsor I may treat all of the employees with a work site in State 1 and rating area 1 of State 2 as a class of employees because employees whose work sites are in different rating areas may be considered different classes and a plan sponsor may create a class of employees by combining classes of employees, including by combining employees whose work site is in one rating area with a class of employees whose work site is in a different rating area. The minimum class size requirement applies to the class of employees offered the HRA (made up of employees in State 1 and in rating area 1 of State 2) because the minimum class size requirement applies to a class based on a geographic area unless the geographic area is a state or a combination of two or more entire states. In this case, the class is made up of a state plus a rating area which is not the entire state. However, this class satisfies the minimum class size requirement because the applicable class size minimum for Plan Sponsor I is 20, and Plan Sponsor I offered the HRA to 200 employees on the first day of the plan year.

(xii) *Example 12: Salaried employees offered a traditional group health plan; hourly employees offered an HRA*—(A) *Facts.* Plan Sponsor J has 163 salaried employees and 14 hourly employees. For 2020, Plan Sponsor J offers its 163 salaried employees a traditional group health plan and each of its 14 hourly employees an HRA on the same terms. Plan Sponsor J reasonably expects to employ 177 employees on the first day of the HRA plan year.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(xii) (*Example 12*) because, even though salaried and hourly employees generally may be considered different classes and Plan Sponsor J offers the HRA on the same terms to all hourly employees, the HRA fails to satisfy the minimum class size requirement. Specifically, the minimum class size requirement applies in this paragraph (f)(1)(xii) (*Example 12*) because employees who are paid on a salaried basis and employees who are not paid on a salaried basis are applicable classes subject to the minimum class size

requirement. Because Plan Sponsor J reasonably expects to employ between 100 and 200 employees on the first day of the plan year, the applicable class size minimum is 10 percent, rounded down to a whole number. Ten percent of 177 total employees, rounded down to a whole number is 17, and the HRA is offered to only 14 hourly employees.

(xiii) *Example 13: Part-time employees and full-time employees offered different HRAs; no traditional group health plan offered*—(A) *Facts*. Plan Sponsor K has 50 full-time employees and 7 part-time employees. For 2020, Plan Sponsor K offers its 50 full-time employees $2,000 each in an HRA otherwise provided on the same terms and each of its 7 part-time employees $500 in an HRA otherwise provided on the same terms. Plan Sponsor K reasonably expects to employ 57 employees on the first day of the HRA plan year.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xiii) (*Example 13*) because full-time employees and part-time employees may be treated as different classes and Plan Sponsor K offers an HRA on the same terms to all the participants in each class. The minimum class size requirement does not apply to either the full-time class or the part-time class because (although in certain circumstances the minimum class size requirement applies to a class of full-time employees and a class of part-time employees) Plan Sponsor K does not offer any class of employees a traditional group health plan, and the minimum class size requirement applies only when, among other things, at least one class of employees is offered a traditional group health plan while another class is offered an HRA.

(xiv) *Example 14: No employees offered an HRA*—(A) *Facts*. The facts are the same facts as in paragraph (f)(1)(xiii) of this section (*Example 13*), except that Plan Sponsor K offers its full-time employees a traditional group health plan and does not offer any group health plan (either a traditional group health plan or an HRA) to its part-time employees.

(B) *Conclusion*. The regulations set forth under this section do not apply to Plan Sponsor K because Plan Sponsor K does not offer an individual coverage HRA to any employee.

(xv) *Example 15: Full-time employees offered traditional group health plan; part-time employees offered HRA*—(A) *Facts*. The facts are the same as in paragraph (f)(1)(xiii) of this section (*Example 13*), except that Plan Sponsor K offers its full-time employees a traditional group health plan and offers each of its part-time employees $500 in an HRA and otherwise on the same terms.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(xv) (*Example 15*) because, even though the full-time employees and the part-time employees generally may be treated as different classes, in this paragraph (f)(1)(xv) (*Example 15*), the minimum class size requirement applies to the part-time employees, and it is not satisfied. Specifically, the minimum class size requirement applies to the part-time employees because that requirement applies to an applicable class offered an HRA when one class is offered a traditional group health plan while another class is offered an HRA, and to the part-time and full-time employee classes when one of those classes is offered a traditional group health plan while the other is offered an HRA. Because Plan Sponsor K reasonably expects to employ fewer than 100 employees on the first day of the HRA plan year, the applicable class size minimum for Plan Sponsor K is 10 employees, but Plan Sponsor K offered the HRA only to its 7 part-time employees.

(xvi) *Example 16: Satisfying minimum class size requirement based on employees offered HRA*—(A) *Facts*. Plan Sponsor L employs 78 full-time employees and 12 part-time employees. For 2020, Plan Sponsor L offers its 78 full-time employees a traditional group health plan and each of its 12 part-times employees an HRA on the same terms. Only 6 part-time employees enroll in the HRA. Plan Sponsor L reasonably expects to employ fewer than 100 employees on the first day of the HRA plan year.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xvi) (*Example 16*) because full-time employees and part-time employees

may be treated as different classes, Plan Sponsor L offers an HRA on the same terms to all the participants in the part-time class, and the minimum class size requirement is satisfied. Specifically, whether a class of employees satisfies the applicable class size minimum is determined as of the first day of the plan year based on the number of employees in a class that is offered an HRA, not on the number of employees who enroll in the HRA. The applicable class size minimum for Plan Sponsor L is 10 employees, and Plan Sponsor L offered the HRA to its 12 part-time employees.

(xvii) *Example 17: Student employees offered student premium reduction arrangements and same terms requirement*—(A) *Facts*. Plan Sponsor M is an institution of higher education that offers each of its part-time employees an HRA on the same terms, except that it offers its part-time employees who are student employees a student premium reduction arrangement, and the student premium reduction arrangement provides different amounts to different part-time student employees.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(1)(xvii) (*Example 17*) because Plan Sponsor M offers the HRA on the same terms to its part-time employees who are not students and because the part-time student employees offered a student premium reduction arrangement (and their varying HRAs) are not taken into account as part-time employees for purposes of determining whether a class of employees is offered an HRA on the same terms.

(xiii) *Example 18: Student employees offered student premium reduction arrangements and minimum class size requirement*—(A) *Facts*. Plan Sponsor N is an institution of higher education with 25 hourly employees. Plan Sponsor N offers 15 of its hourly employees, who are student employees, a student premium reduction arrangement and it wants to offer its other 10 hourly employees an HRA for 2022. Plan Sponsor N offers its salaried employees a traditional group health plan. Plan Sponsor N reasonably expects to have 250 employees on the first day of the 2022 HRA plan year, 15 of which will have offers of student premium reduction arrangements.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(1)(xviii) (*Example 18*). The minimum class size requirement will apply to the class of hourly employees to which Plan Sponsor N wants to offer the HRA because Plan Sponsor N offers a class of employees a traditional group health plan and another class the HRA, and the minimum class size requirement generally applies to a class of hourly employees offered an HRA. Plan Sponsor N's applicable class size minimum is 20 because Plan Sponsor N reasonably expects to employ 235 employees on the first day of the plan year (250 employees minus 15 employees receiving a student premium reduction arrangement). Plan Sponsor N may not offer the HRA to its hourly employees because the 10 employees offered the HRA as of the first day of the plan year does not satisfy the applicable class size minimum.

(2) *Examples regarding special rule for new hires*. The following examples illustrate the provisions of paragraph (c)(3) of this section, taking into account the provisions of paragraph (d) of this section, in particular the special rule for new hires under paragraph (d)(5) of this section. In each example, the HRA is an individual coverage HRA that has a calendar year plan year and may reimburse any medical care expenses, including premiums for individual health insurance coverage. The examples also assume that no participants or dependents are Medicare beneficiaries.

(i) *Example 1: Application of special rule for new hires to all employees*—(A) *Facts*. For 2021, Plan Sponsor A offers all employees a traditional group health plan. For 2022, Plan Sponsor A offers all employees hired on or after January 1, 2022, an HRA on the same terms and continues to offer the traditional group health plan to employees hired before that date. On the first day of the 2022 plan year, Plan Sponsor A has 2 new hires who are offered the HRA.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(2)(i) (*Example 1*) because, under the

special rule for new hires in paragraph (d)(5) of this section, the employees newly hired on and after January 1, 2022, may be treated as a new hire subclass, Plan Sponsor A offers the HRA on the same terms to all participants in the new hire subclass, and the minimum class size requirement does not apply to the new hire subclass.

(ii) *Example 2: Application of special rule for new hires to full-time employees*—(A) *Facts*. For 2021, Plan Sponsor B offers a traditional group health plan to its full-time employees and does not offer any coverage to its part-time employees. For 2022, Plan Sponsor B offers full-time employees hired on or after January 1, 2022, an HRA on the same terms, continues to offer its full-time employees hired before that date a traditional group health plan, and continues to offer no coverage to its part-time employees. On the first day of the 2022 plan year, Plan Sponsor B has 2 new hire, full-time employees who are offered the HRA.

(B) *Conclusion*. The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(2)(ii) (*Example 2*) because, under the special rule for new hires in paragraph (d)(5) of this section, the full-time employees newly hired on and after January 1, 2022, may be treated as a new hire subclass and Plan Sponsor B offers the HRA on the same terms to all participants in the new hire subclass. The minimum class size requirement does not apply to the new hire subclass.

(iii) *Example 3: Special rule for new hires impermissibly applied retroactively*—(A) *Facts*. For 2025, Plan Sponsor C offers a traditional group health plan to its full-time employees. For 2026, Plan Sponsor C wants to offer an HRA to its full-time employees hired on and after January 1, 2023, while continuing to offer a traditional group health plan to its full-time employees hired before January 1, 2023.

(B) *Conclusion*. The special rule for new hires under paragraph (d)(5) of this section does not apply in this paragraph (f)(2)(iii) (*Example 3*) because the rule must be applied prospectively. That is, Plan Sponsor C may not, in 2026, choose to apply the special rule for new hires retroactive to 2023. If Plan Sponsor C were to offer an HRA in this way, it would fail to satisfy the conditions under paragraphs (c)(2) and (3) of this section because the new hire subclass would not be treated as a subclass for purposes of applying those rules and, therefore, all full-time employees would be treated as one class to which either a traditional group health plan or an HRA could be offered, but not both.

(iv) *Example 4: Permissible second application of the special rule for new hires to the same class of employees*—(A) *Facts*. For 2021, Plan Sponsor D offers all of its full-time employees a traditional group health plan. For 2022, Plan Sponsor D applies the special rule for new hires and offers an HRA on the same terms to all employees hired on and after January 1, 2022, and continues to offer a traditional group health plan to full-time employees hired before that date. For 2025, Plan Sponsor D discontinues use of the special rule for new hires, and again offers all full-time employees a traditional group health plan. In 2030, Plan Sponsor D decides to apply the special rule for new hires to the full-time employee class again, offering an HRA to all full-time employees hired on and after January 1, 2030, on the same terms, while continuing to offer employees hired before that date a traditional group health plan.

(B) *Conclusion*. Plan Sponsor D has permissibly applied the special rule for new hires and is in compliance with the requirements of paragraphs (c)(2) and (3) of this section.

(v) *Example 5: Impermissible second application of the special rule for new hires to the same class of employees*—(A) *Facts*. The facts are the same as in paragraph (f)(2)(iv) of this section (*Example 4*), except that for 2025, Plan Sponsor D discontinues use of the special rule for new hires by offering all full-time employees an HRA on the same terms. Further, for 2030, Plan Sponsor D wants to continue to offer an HRA on the same terms to all full-time employees hired before January 1, 2030, and to offer all full-time employees hired on or after January 1, 2030, an HRA in a different amount.

(B) *Conclusion*. Plan Sponsor D may not apply the special rule for new hires for 2030 to the class of full-time employees being offered an HRA because

the special rule for new hires may only be applied to a class that is being offered a traditional group health plan.

(vi) *Example 6: New full-time employees offered different HRAs in different rating areas*—(A) *Facts.* Plan Sponsor E has work sites in rating area 1, rating area 2, and rating area 3. For 2021, Plan Sponsor E offers its full-time employees a traditional group health plan. For 2022, Plan Sponsor E offers its full-time employees hired on or after January 1, 2022, in rating area 1 an HRA of $3,000, its full-time employees hired on or after January 1, 2022, in rating area 2 an HRA of $5,000, and its full-time employees hired on or after January 1, 2022, in rating area 3 an HRA of $7,000. Within each class offered an HRA, Plan Sponsor E offers the HRA on the same terms. Plan Sponsor E offers its full-time employees hired prior to January 1, 2022, in each of those classes a traditional group health plan. On the first day of the 2022 plan year, there is one new hire, full-time employee in rating area 1, three new hire, full-time employees in rating area 2, and 10 new hire-full-time employees in rating area 3.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(2)(vi) (*Example 6*) because, under the special rule for new hires in paragraph (d)(5) of this section, the full-time employees in each of the three rating areas newly hired on and after January 1, 2022, may be treated as three new hire subclasses and Plan Sponsor E offers the HRA on the same terms to all participants in the new hire subclasses. Further, the minimum class size requirement does not apply to the new hire subclasses.

(vii) *Example 7: New full-time employee class subdivided based on rating area*—(A) *Facts.* Plan Sponsor F offers its full-time employees hired on or after January 1, 2022, an HRA on the same terms and it continues to offer its full-time employees hired before that date a traditional group health plan. Plan Sponsor F offers no coverage to its part-time employees. For the 2025 plan year, Plan Sponsor F wants to subdivide the full-time new hire subclass so that those whose work site is in rating area 1 will be offered the traditional group health plan and those whose work site is in rating area 2 will continue to receive the HRA. Plan Sponsor F reasonably expects to employ 219 employees on January 1, 2025. As of January 1, 2025, Plan Sponsor F has 15 full-time employees whose work site in in rating area 2 and who were hired between January 1, 2022, and January 1, 2025.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is not satisfied in this paragraph (f)(2)(vii) (*Example 7*) because the new hire subclass has been subdivided in a manner that is subject to the minimum class size requirement, and the class offered the HRA fails to satisfy the minimum class size requirement. Specifically, once the new hire subclass is subdivided the general rules for applying the minimum class size requirement apply to the employees offered the HRA in the new hire subclass. In this case, because the subdivision of the new hire full-time subclass is based on rating areas; a class based on rating areas is an applicable class subject to the minimum class size requirement; and the employees in one rating area are to be offered the HRA, while the employees in the other rating area are offered the traditional group health plan, the minimum class size requirement would apply on and after the date of the subdivision. Further, the minimum class size requirement would not be satisfied, because the applicable class size minimum for Plan Sponsor F would be 20, and only 15 employees in rating area 2 would be offered the HRA.

(viii) *Example 8: New full-time employee class subdivided based on state*—(A) *Facts.* The facts are the same as in paragraph (f)(2)(vii) of this section (*Example 7*), except that for the 2025 plan year, Plan Sponsor F intends to subdivide the new hire, full-time class so that those in State 1 will be offered the traditional group health plan and those in State 2 will each be offered an HRA on the same terms.

(B) *Conclusion.* The same terms requirement of paragraph (c)(3) of this section is satisfied in this paragraph (f)(2)(viii) (*Example 8*) because even though the new hire subclass has been subdivided, it has been subdivided in a

manner that is not subject to the minimum class size requirement as the subdivision is based on the entire state.

(ix) *Example 9: New full-time employees and part-time employees offered HRA*—(A) *Facts.* In 2021, Plan Sponsor G offers its full-time employees a traditional group health plan and does not offer coverage to its part-time employees. For the 2022 plan year, Plan Sponsor G offers its full-time employees hired on or after January 1, 2022, and all of its part-time employees, including those hired before January 1, 2022, and those hired on and after January 1, 2022, an HRA on the same terms, and it continues to offer its full-time employees hired before January 1, 2022, a traditional group health plan.

(B) *Conclusion.* The minimum class size requirement applies to the part-time employees offered the HRA in 2022 because the class is being offered an HRA; the special rule for new hires does not apply (because this class was not previously offered a traditional group health plan) and so it is not a new hire subclass exempt from the minimum class size requirement; another class of employees (that is, full-time hired before January 1, 2022) are being offered a traditional group health plan; and the part-time employee class is generally an applicable classes that is subject to the minimum class size requirement. However, because the full-time, new hire subclass is based on the special rule for new hires, the minimum class size requirement does not apply to full-time new hires offered an HRA in 2022.

(g) *Applicability date.* This section applies to plan years beginning on or after January 1, 2020.

[84 FR 29014, June 20, 2019]

§ 146.125 Applicability dates.

Section 144.103 of this subchapter and §§ 146.111 through 146.119, 146.143, and 146.145 are applicable for plan years beginning on or after July 1, 2005. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in § 144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in § 144.103 applies for coverage periods beginning on or after September 1, 2024.

[89 FR 23418, Apr. 3, 2024]

Subpart C—Requirements Related to Benefits

§ 146.130 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule.* Except as provided in paragraph (a)(5) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital.* If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital.* If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into

labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3,* the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan or issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example,* the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother

to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1*, because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health

insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, a group health plan that provides benefits for hospital lengths of stay in connection with childbirth must meet the following requirements:

(1) *Required statement.* The plan document that provides a description of plan benefits to participants and beneficiaries, or that notifies participants and beneficiaries of plan benefit changes, must disclose information that notifies participants and beneficiaries of their rights under this section.

(2) *Disclosure notice.* To meet the disclosure requirement set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, group health plans and health insurance issuers offering group health insurance coverage generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the plan or issuer may pay for a shorter stay if the attending provider (*e.g.*, your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, plans and issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, a plan or issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your plan administrator.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to each participant covered under a group health plan, and each beneficiary receiving benefits under a group health plan, not

later than 60 days after the first day of the first plan year beginning on or after January 1, 2009. Each time a plan distributes one or both of the documents described in paragraph (d)(1) to participants and beneficiaries after providing this initial notice, the disclosure notice in paragraph (d)(2) must appear in at least one of those documents.

(4) *Exceptions.* The requirements of this paragraph (d) do not apply in the following situations.

(i) *Self-insured plans that have already provided notice.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has already provided an initial notice that complies with paragraphs (d)(1) and (d)(2) of this section, the group health plan is not automatically required to provide another such notice to participants and beneficiaries who have been provided with the initial notice. However, following the effective date of these regulations, whenever such a plan provides one or both of the documents described in paragraph (d)(1) of this section to participants and beneficiaries, the disclosure notice in paragraph (d)(2) of this section must appear in at least one of those documents.

(ii) *Self-insured plans that have elected exemption from this section.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has made the election described in Sec. 146.180 to be exempted from the requirements of this section, the group health plan is not subject to this paragraph (d).

(iii) *Insured plans.* If benefits for hospital lengths of stay in connection with childbirth are provided through health insurance coverage, and the coverage is regulated under a State law described in paragraph (e) of this section, the group health plan is not subject to this paragraph (d).

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2725 of the PHS Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 2725 of the PHS Act and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 2724 (a) of the PHS Act.* The preemption provisions

contained in section 2724 (a)(1) of the PHS Act and Sec. 146.143(a) do not supersede a state law described in paragraph (e)(1) of this section.

(4) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this Example 1, the coverage is subject to state law, and the requirements of section 2725 of the PHS Act and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this Example 2, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 2725 of the PHS Act and this section.

(f) *Applicability date.* Section 2725 of the PHS Act applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 1998. This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

[73 FR 62424, Oct. 20, 2008, as amended at 75 FR 27138, May 13, 2010]

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. Any condition defined by the plan or coverage as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any condition defined by the plan or

coverage as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits.* This paragraph (b) details the application of the parity requirements with respect to aggregate lifetime and annual dollar limits. This paragraph (b) does not address the provisions of PHS Act section 2711, which prohibit imposing lifetime and annual limits on the dollar value of essential health benefits. For more information, see §147.126 of this subchapter.

(1) *General*—(i) *General parity requirement.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(5) of this section.

(ii) *Exception.* The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) *Plan with a limit on at least two-thirds of all medical/surgical benefits.* If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) *Determining one-third and two-thirds of all medical/surgical benefits.* For

purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(5) *Plan not described in paragraph (b)(2) or (b)(3) of this section*—(i) *In general.* A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(5)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting.* For purposes of this paragraph (b)(5), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(4) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(c) *Parity requirements with respect to financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits.* When reference is made in this paragraph (c) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) *Coverage unit.* When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) *General parity requirement*—(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) *Classifications of benefits used for applying rules*—(A) *In general.* If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(*1*) *Inpatient, in-network.* Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*2*) *Inpatient, out-of-network.* Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*3*) *Outpatient, in-network.* Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage. See special rules for office visits and plans with multiple network tiers in paragraph (c)(3)(iii) of this section.

(*4*) *Outpatient, out-of-network.* Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers. See special rules for office visits in paragraph (c)(3)(iii) of this section.

(*5*) *Emergency care.* Benefits for emergency care.

(*6*) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) *Application to out-of-network providers.* See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example,

the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 1,* because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) *Facts.* A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 2,* because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) *Facts.* Same facts as *Example 2,* except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3,* because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for—

(A) Benefits in the emergency care classification; and

(B) All other benefits.

Example 4. (i) *Facts.* Same facts as *Example 2,* except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this *Example 4,* because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for—

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining ''substantially all'' and ''predominant''*—(A) *Substantially all.* For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant.* (*1*) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment

limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments.* For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707(b) and Affordable Care Act section 1302(c), which establish limitations on annual deductibles for non-grandfathered health plans in the small group market and annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

(E) *Determining the dollar amount of plan payments.* Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Application to different coverage units.* If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) *Special rules*—(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for non-quantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the

rules in paragraph (c)(4)(i) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

(C) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are:

(*1*) Office visits (such as physician visits), and

(*2*) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(iv) *Examples.* The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0%	10%	15%	20%	30%	Total.
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x.
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level.	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) *Conclusion.* In this *Example 1,* the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) *Facts.* For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total.
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x.
Percent of total plan costs	20%	20%	20%	30%	10%	

Percent subject to copayments	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x + $300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) *Conclusion.* In this *Example 2*, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels—the $50 copayment, the $20 copayment, and the $15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) *Facts.* A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3*, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4 —(i) *Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as ''generic'', ''preferred brand name'', ''non-preferred brand name'', or ''specialty'' complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) *Conclusion.* In this *Example 4*, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

Example 5 —(i) *Facts.* A plan has two-tiers of network of providers: A preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section, such as accreditation, quality and performance

measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 5,* the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

Example 6 —(i) *Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(ii) *Conclusion.* In this *Example 6,* the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

Example 7 —(i) *Facts.* Same facts as *Example 6,* but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(ii) *Conclusion.* In this *Example 7,* the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

(v) *No separate cumulative financial requirements or cumulative quantitative treatment limitations.* (A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1 —(i) *Facts.* A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1,* the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2 —(i) *Facts.* A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 2,* the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3 —(i) *Facts.* A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) *Conclusion.* In this *Example 3,* the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4 —(i) *Facts.* A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits subject to deductible	Total benefits	Percent subject to deductible
Inpatient, in-network	$1,800x	$2,000x	90
Inpatient, out-of-network	1,000x	1,000x	100
Outpatient, in-network	1,400x	2,000x	70
Outpatient, out-of-network	1,880x	2,000x	94
Emergency care	300x	500x	60

(ii) *Conclusion.* In this *Example 4*, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards for provider admission to participate in a network, including reimbursement rates;

(E) Plan methods for determining usual, customary, and reasonable charges;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1 —(i) *Facts.* A plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given only for one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan.

(ii) *Conclusion.* In this Example 1, the plan violates the rules of this paragraph (c)(4) because it is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits.

Example 2 —(i) *Facts.* A plan applies concurrent review to inpatient care where there are high levels of variation in length of stay (as measured by a coefficient of variation exceeding 0.8). In practice, the application of this standard affects 60 percent of mental health conditions and substance use disorders, but only 30 percent of medical/surgical conditions.

(ii) *Conclusion.* In this *Example 2*, the plan complies with the rules of this paragraph (c)(4) because the evidentiary standard used by the plan is applied no more stringently for mental health and substance use disorder benefits than for medical/surgical benefits, even though it results in an overall difference in the application of concurrent review for mental health conditions or substance use disorders than for medical/surgical conditions.

Example 3 —(i) *Facts.* A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits and uses comparable criteria in determining whether a course of treatment is medically necessary. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) *Conclusion.* In this *Example 3,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, it is not applied in a comparable way. The penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 4 —(i) *Facts.* A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 4,* the plan complies with the rules of this paragraph (c)(4) because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 5 —(i) *Facts.* A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 5,* the plan violates the rules of this paragraph (c)(4). Although the standard for applying a nonquantitative treatment limitation is the same for both mental health and substance use disorder benefits and medical/surgical benefits—whether a drug has a black box warning—it is not applied in a comparable manner. The plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 6 —(i) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(ii) *Conclusion.* In this *Example 6,* limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

Example 7 —(i) *Facts.* Training and State licensing requirements often vary among types of providers. A plan applies a general standard that any provider must meet the highest licensing requirement related to supervised clinical experience under applicable State law in order to participate in the plan's provider network. Therefore, the plan requires master's-level mental health therapists to have post-degree, supervised clinical experience but does not impose this requirement on master's-level general medical providers because the scope of their licensure under applicable State law does require clinical experience. In addition, the plan does not require post-degree, supervised clinical experience for psychiatrists or Ph.D. level psychologists since their licensing already requires supervised training.

(ii) *Conclusion.* In this *Example 7,* the plan complies with the rules of this paragraph (c)(4). The requirement that master's-level mental health therapists must have supervised clinical experience to join the network

is permissible, as long as the plan consistently applies the same standard to all providers even though it may have a disparate impact on certain mental health providers.

Example 8 —(i) *Facts.* A plan considers a wide array of factors in designing medical management techniques for both mental health and substance use disorder benefits and medical/surgical benefits, such as cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud. Based on application of these factors in a comparable fashion, prior authorization is required for some (but not all) mental health and substance use disorder benefits, as well as for some medical/surgical benefits, but not for others. For example, the plan requires prior authorization for: Outpatient surgery; speech, occupational, physical, cognitive and behavioral therapy extending for more than six months; durable medical equipment; diagnostic imaging; skilled nursing visits; home infusion therapy; coordinated home care; pain management; high-risk prenatal care; delivery by cesarean section; mastectomy; prostate cancer treatment; narcotics prescribed for more than seven days; and all inpatient services beyond 30 days. The evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan.

(ii) *Conclusion.* In this *Example 8*, the plan complies with the rules of this paragraph (c)(4). Under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Example 9 —(i) *Facts.* A plan generally covers medically appropriate treatments. The plan automatically excludes coverage for inpatient substance use disorder treatment in any setting outside of a hospital (such as a freestanding or residential treatment center). For inpatient treatment outside of a hospital for other conditions (including freestanding or residential treatment centers prescribed for mental health conditions, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the inpatient treatment is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion.* In this *Example 9*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of substance use disorder treatment in any setting outside of a hospital is not comparable to the conditional exclusion of inpatient treatment outside of a hospital for other conditions.

Example 10 —(i) *Facts.* A plan generally provides coverage for medically appropriate medical/surgical benefits as well as mental health and substance use disorder benefits. The plan excludes coverage for inpatient, out-of-network treatment of chemical dependency when obtained outside of the State where the policy is written. There is no similar exclusion for medical/surgical benefits within the same classification.

(ii) *Conclusion.* In this Example 10, the plan violates the rules of this paragraph (c)(4). The plan is imposing a nonquantitative treatment limitation that restricts benefits based on geographic location. Because there is no comparable exclusion that applies to medical/surgical benefits, this exclusion may not be applied to mental health or substance use disorder benefits.

Example 11 —(i) *Facts.* A plan requires prior authorization for all outpatient mental health and substance use disorder services after the ninth visit and will only approve up to five additional visits per authorization. With respect to outpatient medical/surgical benefits, the plan allows an initial visit without prior authorization. After the initial visit, the plan pre-approves benefits based on the individual treatment plan recommended by the attending provider based on that individual's specific medical condition. There is no explicit, predetermined cap on the amount of additional visits approved per authorization.

(ii) *Conclusion.* In this *Example 11*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—prior authorization to determine medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits for outpatient services, it is not applied in a comparable way. While the plan is more generous with respect to the number of visits initially provided without pre-authorization for mental health benefits, treating all mental health conditions and substance use disorders in the same manner, while providing for individualized treatment of medical conditions, is not a comparable application of this nonquantitative treatment limitation.

(5) *Exemptions.* The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) *Availability of plan information*—(1) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) *Reason for any denial.* The reason for any denial under a group health plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary. For this purpose, a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) that provides the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans complies with the requirements of this paragraph (d)(2).

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (d)(2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, §147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) upon appeal of an adverse benefit determination (or a final internal adverse benefit determination) to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan.

(e) *Applicability*—(1) *Group health plans.* The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) *Health insurance issuers.* The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) *Scope.* This section does not—

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group

health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan or health insurance coverage under this section to provide benefits for any other mental health condition or substance use disorder;

(ii) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides coverage for mental health or substance use disorder benefits only to the extent required under PHS Act section 2713 to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(iii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the provisions of this section to satisfy the requirement to provide essential health benefits.

(f) *Small employer exemption*—(1) *In general.* The requirements of this section do not apply to a group health plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer (as defined in section 2791 of the PHS Act).

(2) *Rules in determining employer size.* For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) *Increased cost exemption*—(1) *In general.* If the application of this section to a group health plan (or health insurance coverage offered in connection with such plans) results in an increase for the plan year involved of the actual total cost of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits as determined and certified under paragraph (g)(3) of this section by an amount that exceeds the applicable percentage described in paragraph (g)(2) of this section of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for one plan year. An employer or issuer may elect to continue to provide mental health and substance use disorder benefits in compliance with this section with respect to the plan or coverage involved regardless of any increase in total costs.

(2) *Applicable percentage.* With respect to a plan or coverage, the applicable percentage described in this paragraph (g) is—

(i) 2 percent in the case of the first plan year in which this section is applied to the plan or coverage; and

(ii) 1 percent in the case of each subsequent plan year.

(3) *Determinations by actuaries*—(i) Determinations as to increases in actual costs under a plan or coverage that are attributable to implementation of the requirements of this section shall be made and certified by a qualified and licensed actuary who is a member in

good standing of the American Academy of Actuaries. All such determinations must be based on the formula specified in paragraph (g)(4) of this section and shall be in a written report prepared by the actuary.

(ii) The written report described in paragraph (g)(3)(i) of this section shall be maintained by the group health plan or health insurance issuer, along with all supporting documentation relied upon by the actuary, for a period of six years following the notification made under paragraph (g)(6) of this section.

(4) *Formula.* The formula to be used to make the determination under paragraph (g)(3)(i) of this section is expressed mathematically as follows:

$$[(E_1 - E_0) / T_0] - D > k$$

(i) E_1 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the base period, including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits consistent with the requirements of this section.

(ii) E_0 is the actual total cost of coverage with respect to mental health and substance use disorder benefits for the length of time immediately before the base period (and that is equal in length to the base period), including claims paid by the plan or issuer with respect to mental health and substance use disorder benefits and administrative costs (amortized over time) attributable to providing these benefits.

(iii) T_0 is the actual total cost of coverage with respect to all benefits during the base period.

(iv) k is the applicable percentage of increased cost specified in paragraph (g)(2) of this section that will be expressed as a fraction for purposes of this formula.

(v) D is the average change in spending that is calculated by applying the formula $(E_1 - E_0)/T_0$ to mental health and substance use disorder spending in each of the five prior years and then calculating the average change in spending.

(5) *Six month determination.* If a group health plan or health insurance issuer seeks an exemption under this paragraph (g), determinations under paragraph (g)(3) of this section shall be made after such plan or coverage has complied with this section for at least the first 6 months of the plan year involved.

(6) *Notification.* A group health plan or health insurance issuer that, based on the certification described under paragraph (g)(3) of this section, qualifies for an exemption under this paragraph (g), and elects to implement the exemption, must notify participants and beneficiaries covered under the plan, the Secretary, and the appropriate State agencies of such election.

(i) *Participants and beneficiaries*—(A) *Content of notice.* The notice to participants and beneficiaries must include the following information:

(*1*) A statement that the plan or issuer is exempt from the requirements of this section and a description of the basis for the exemption.

(*2*) The name and telephone number of the individual to contact for further information.

(*3*) The plan or issuer name and plan number (PN).

(*4*) The plan administrator's name, address, and telephone number.

(*5*) For single-employer plans, the plan sponsor's name, address, and telephone number (if different from paragraph (g)(6)(i)(A)(*3*) of this section) and the plan sponsor's employer identification number (EIN).

(*6*) The effective date of such exemption.

(*7*) A statement regarding the ability of participants and beneficiaries to contact the plan administrator or health insurance issuer to see how benefits may be affected as a result of the plan's or issuer's election of the exemption.

(*8*) A statement regarding the availability, upon request and free of charge, of a summary of the information on which the exemption is based (as required under paragraph (g)(6)(i)(D) of this section).

(B) *Use of summary of material reductions in covered services or benefits.* A plan or issuer may satisfy the requirements of paragraph (g)(6)(i)(A) of this section by providing participants and beneficiaries (in accordance with paragraph (g)(6)(i)(C) of this section) with a

summary of material reductions in covered services or benefits consistent with 29 CFR 2520.104b–3(d) that also includes the information specified in paragraph (g)(6)(i)(A) of this section. However, in all cases, the exemption is not effective until 30 days after notice has been sent.

(C) *Delivery*. The notice described in this paragraph (g)(6)(i) is required to be provided to all participants and beneficiaries. The notice may be furnished by any method of delivery that satisfies the requirements of section 104(b)(1) of ERISA (29 U.S.C. 1024(b)(1)) and its implementing regulations (for example, first-class mail). If the notice is provided to the participant and any beneficiaries at the participant's last known address, then the requirements of this paragraph (g)(6)(i) are satisfied with respect to the participant and all beneficiaries residing at that address. If a beneficiary's last known address is different from the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(D) *Availability of documentation*. The plan or issuer must make available to participants and beneficiaries (or their representatives), on request and at no charge, a summary of the information on which the exemption was based. (For purposes of this paragraph (g), an individual who is not a participant or beneficiary and who presents a notice described in paragraph (g)(6)(i) of this section is considered to be a representative. A representative may request the summary of information by providing the plan a copy of the notice provided to the participant under paragraph (g)(6)(i) of this section with any personally identifiable information redacted.) The summary of information must include the incurred expenditures, the base period, the dollar amount of claims incurred during the base period that would have been denied under the terms of the plan or coverage absent amendments required to comply with paragraphs (b) and (c) of this section, the administrative costs related to those claims, and other administrative costs attributable to complying with the requirements of this section. In no event should the summary of information include any personally identifiable information.

(ii) *Federal agencies*—(A) *Content of notice*. The notice to the Secretary must include the following information:

(*1*) A description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost exemption under this paragraph (g) by such plan (or coverage);

(*2*) For both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical/surgical benefits and mental health and substance use disorder benefits; and

(*3*) For both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(B) *Reporting by health insurance coverage offered in connection with a church plan*. See 26 CFR 54.9812(g)(6)(ii)(B) for delivery with respect to church plans.

(C) *Reporting by health insurance coverage offered in connection with a group health plans subject to Part 7 of Subtitle B of Title I of ERISA*. See 29 CFR 2590.712(g)(6)(ii) for delivery with respect to group health plans subject to ERISA.

(D) *Reporting with respect to non-Federal governmental plans and health insurance issuers in the individual market*. A group health plan that is a non-Federal governmental plan, or a health insurance issuer offering health insurance coverage in the individual market, claiming the exemption of this paragraph (g) for any benefit package must provide notice to the Department of Health and Human Services. This requirement is satisfied if the plan or issuer sends a copy, to the address designated by the Secretary in generally applicable guidance, of the notice described in paragraph (g)(6)(ii)(A) of this section identifying the benefit package to which the exemption applies.

(iii) *Confidentiality*. A notification to the Secretary under this paragraph

(g)(6) shall be confidential. The Secretary shall make available, upon request and not more than on an annual basis, an anonymous itemization of each notification that includes—

(A) A breakdown of States by the size and type of employers submitting such notification; and

(B) A summary of the data received under paragraph (g)(6)(ii) of this section.

(iv) *Audits.* The Secretary may audit the books and records of a group health plan or a health insurance issuer relating to an exemption, including any actuarial reports, during the 6 year period following notification of such exemption under paragraph (g)(6) of this section. A State agency receiving a notification under paragraph (g)(6) of this section may also conduct such an audit with respect to an exemption covered by such notification.

(h) *Sale of nonparity health insurance coverage.* A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) *Applicability dates*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, this section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after July 1, 2014. Until the applicability date, plans and issuers are required to continue to comply with the corresponding sections of §146.136 contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2013.

(2) *Special effective date for certain collectively-bargained plans.* For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the date on which the last of the collective bargaining agreements terminates (determined without regard to any extension agreed to after October 3, 2008).

[78 FR 68286, Nov. 13, 2013]

EFFECTIVE DATE NOTE: At 89 FR 77735, Sept. 23, 2024, §146.136 was amended, effective Nov. 22, 2024, by:

1. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);
2. In newly redesignated paragraph (a)(2):
i. Revising the introductory text;
ii. Adding the definitions of ''DSM,'' ''Evidentiary standards,'' ''Factors,'' and ''ICD'' in alphabetical order;
iii. Revising the definitions of ''Medical/surgical benefits'' and ''Mental health benefits'';
iv. Adding the definitions of ''Processes'' and ''Strategies'' in alphabetical order;
v. Revising the definitions of ''Substance use disorder benefits'' and ''Treatment limitations'';
3. Revising paragraphs (c)(1)(ii), (c)(2)(i), (c)(2)(ii)(A) introductory text, (c)(2)(ii)(C), and (c)(3)(i)(A), (C), and (D);
4. In paragraph (c)(3)(iii), adding introductory text.
5. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and by
6. Adding paragraph (j).

For the convenience of the user, the added and revised text is set forth as follows:

§146.136 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms*—(1) *Purpose.* This section and §146.137 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under PHS Act section 2726. A fundamental purpose of PHS Act section 2726, this section, and §146.137 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and §146.137. Accordingly, in complying with the provisions of PHS Act section 2726, this section, and §146.137, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or

substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of PHS Act section 2726, this section, and §146.137 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and §146.137, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of November 22, 2024, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the ''usual, customary and reasonable'' rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through §162.1002 of this subtitle. For the purpose of this definition, the most current version of the ICD as of November 22, 2024, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through §162.1002 of this subtitle after November 22, 2024, will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current

medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a

waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures. For purposes of this paragraph (c)(2)(ii)(A), a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the

permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to the examples in this paragraph (c)(2)(ii)(C), references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(*1*) *Example 1—*(*i*) *Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*1*) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(*2*) *Example 2—*(*i*) *Facts.* A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*2*) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(*3*) *Example 3—*(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*3*) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(*4*) *Example 4—*(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*2*)(*i*) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*4*) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(*5*) *Example 5—*(*i*) *Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*5*) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(*6*) *Example 6—*(*i*) *Facts.* Same facts as in paragraph (c)(2)(ii)(C)(*5*) of this section (*Example 5*), except that the plan is an HMO that does not cover the full range of medical/surgical benefits including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under PHS Act

sections 2799A–1 and 2799A–2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*6*) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A–1 and 2799A–2), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(*7*) *Example 7—*(*i*) *Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*7*) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(*8*) *Example 8—*(*i*) *Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(*ii*) *Conclusion.* In this paragraph (c)(2)(ii)(C)(*8*) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not

been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. The rules of this paragraph (c)(3)(i)(D) apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (*i*) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

TABLE 1 TO PARAGRAPH (c)(3)(iv)(A)(*1*)(*i*)

Coinsurance rate	0%	10%	15%	20%	30%	Total.
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x.
Percent of total plan costs.	20%	10%	45%	10%	15%.	
Percent subject to coinsurance level.	N/A	12.5% (100x/800x).	56.25% (450x/800x).	12.5% (100x/800x).	18.75% (150x/800x).	

(*ii*) The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect

to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (*i*) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

TABLE 2 TO PARAGRAPH (c)(3)(iv)(B)(*1*)(*i*)

Copayment amount	$0	$10	$15	$20	$50	Total.
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x.
Percent of total plan costs.	20%	20%	20%	30%	10%.	
Percent subject to copayments.	N/A	25% (200x/800x).	25% (200x/800x).	37.5% (300x/800x).	12.5% (100x/800x).	

(*ii*) The plan projects plan costs of $800x to be subject to copayments ($200x + $200x + $300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels—the $50 copayment, the $20 copayment, and the $15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as ''generic'', ''preferred brand name'', ''non-preferred brand name'', or ''specialty'' complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

TABLE 3 TO PARAGRAPH (c)(3)(iv)(D)(*1*)

	Tier 1	Tier 2	Tier 3	Tier 4
Tier description	Generic drugs.	Preferred brand name drugs.	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives).	Specialty drugs.
Percent paid by plan.	90%	80%	60%	50%.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a $25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services).The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(*1*) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(*2*) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For purposes of this paragraph (c)(4), a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate PHS Act section 2726 (a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation*—(A) *In general.* A plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage), as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used

in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(*1*) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For purposes of this paragraph (c)(4)(i)(B)(*1*), relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(*2*) For purposes of this paragraph (c)(4)(i)(B), historical plan data or other historical information from a time when the plan or coverage was not subject to PHS Act section 2726 or was not in compliance with PHS Act section 2726 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(*3*) For purposes of this paragraph (c)(4)(i)(B), generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Required use of outcomes data*—(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a

classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's or issuer's evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(*1*) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(*2*) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(*1*) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(*3*) *Unavailability of data.* (*i*) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with this paragraph (c)(4)(iii)(A), the plan or issuer must include in its comparative analysis, as required under §146.137(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with this paragraph (c)(4)(iii)(A) as soon as practicable once relevant data becomes available.

(*ii*) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under §146.137(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with this paragraph (c)(4)(iii)(A) as soon as practicable.

(*iii*) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(*3*)(*i*) and (*ii*) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates this paragraph (c)(4).

(*1*) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with this paragraph (c)(4) and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by §146.137(c)(5)(iv).

(*2*) For purposes of this paragraph (c)(4)(iii)(B), relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(*2*), the difference

in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(*i*) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(*2*), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(*ii*) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of this paragraph (c)(4)(iii)(B). To the extent a plan or issuer attributes any differences in access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under §146.137(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(*1*) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with this paragraph (c)(4), include, but are not limited to:

(*1*) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(*2*) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(*3*) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(*4*) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under §146.137.* (A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary or applicable State authority that the plan or issuer is not in compliance with the requirements of PHS Act section 2726(a)(8) or §146.137 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary or applicable State authority may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary or applicable State authority compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (not comparable and more stringent factors for reimbursement rate methodology, in operation)—(1) Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of this paragraph (c)(4). Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)—(1) Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of this paragraph (c)(4). As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)—(1) Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's

attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe *and* irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (use of historical plan data and plan steps to correct, cure, or supplement)—*(*1*) *Facts.* A plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to PHS Act section 2726. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(*2*) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)—(1) Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of this paragraph (c)(4). The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(*3*) of this section. However, the plan must comply with other requirements in this paragraph (c)(4), as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)—(1) Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates this paragraph (c)(4). The plan does not comply with paragraph (c)(4)(iii)(A)(*3*)(*ii*) of this section because the plan did not include in its comparative analysis, as required under §146.137(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this paragraph (c)(4). Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under §146.137(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (concurrent review data collection; no material difference in access)—(1)*

Facts. A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates this paragraph (c)(4).

(H) *Example 8 (material difference in access for prior authorization requirement with reasonable action)—*(*1*) *Facts.* A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with this paragraph (c)(4) by updating

the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(*1*) of this section.

(I) *Example 9 (differences attributable to generally recognized independent professional medical or clinical standards)*—(*1*) *Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (material differences in access for standards for provider admission to a network with reasonable action)*—(*1*) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known,

or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with this paragraph (c)(4), by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with this paragraph (c)(4). The plan also documents the actions that have been and are being taken by the plan to address material differences as required by §146.137(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)—(1) Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under §146.145(b)(3)(vi)(B)(*1*) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (separate exclusion for treatment in a residential facility applicable only to*

mental health and substance use disorder benefits)—(*1*) *Facts.* A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(*1*) *Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under §146.137(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under §146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with PHS Act section 2726 (a)(8) and §146.137 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(*2*) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, §147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses

and other applicable information required by §146.137.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or §146.137(g) changes the requirements of §§147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§156.110(a)(5) and 156.115(a) of this subchapter, must comply with the requirements under section 2726 of the PHS Act and its implementing regulations in this section and §146.137 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 45 CFR 146.136, revised as of October 1, 2023.

* * * * *

(j) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§146.137 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in §146.136(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that

describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in §146.136(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under §146.136(c)(4)(i)(B)(*1*) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or

issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or

other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in §146.136(c)(4)(iii)(A)(*3*)(*i*), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in §146.136(c)(4)(iii)(A)(*3*)(*ii*), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with §146.136(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under §146.136(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under §146.136(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with §146.136(c)(4)(iii)(B)(*2*);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment

limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in §146.136(c)(4)(iii)(B)(*2*)(*ii*); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under §146.136(c)(4)(iii)(B)(*1*) to address material differences to comply, in operation, with §146.136(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in §146.136(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of §146.136(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request*—(1) *Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan or issuer complies with §146.136(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1). Any such information

must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of §146.136(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with §146.136(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance*—(i) *In general.* If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of §146.136(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: ''Attention! The Department of Health and Human Services has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.'';

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with §146.136(c)(4) or this section, including any provisions or practices identified as being in violation of §146.136(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with §146.136(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(*1*) The plan's or issuer's phone number and an email or web portal address; and

(*2*) The Centers for Medicare & Medicaid Services' phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or

issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or §146.136 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of §146.136 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in §146.136(e), to the extent the plan or issuer is not exempt under §146.136(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[89 FR 77747, Sept. 23, 2024]

EFFECTIVE DATE NOTE: At 89 FR 77747, Sept. 23, 2024, §146.137 was added, effective Nov. 22, 2024.

Subpart D—Preemption and Special Rules

§146.143 Preemption; State flexibility; construction.

(a) *Continued applicability of State law with respect to health insurance issuers.* Subject to paragraph (b) of this section and except as provided in paragraph (c) of this section, part A of title XXVII of the PHS Act is not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(b) *Continued preemption with respect to group health plans.* Nothing in part A of title XXVII of the PHS Act affects or modifies the provisions of section 514 of ERISA with respect to group health plans.

(c) *Special rules*—(1) *In general.* Subject to paragraph (c)(2) of this section, the provisions of part A of title XXVII of the PHS Act relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 2701 of the PHS Act which differs from the standards or requirements specified in section 2701 of the PHS Act.

(2) *Exceptions.* Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision requires special enrollment periods in addition to those required under section 2702 of the Act.

(d) *Definitions*—(1) *State law.* For purposes of this section the term *State law* includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia is treated as a State law rather than a law of the United States.

(2) *State.* For purposes of this section the term *State* includes a State (as defined in §144.103), any political subdivisions of a State, or any agency or instrumentality of either.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005; 79 FR 10315, Feb. 24, 2014]

§146.145 Special rules relating to group health plans.

(a) *Group health plan*—(1) *Definition.* A group health plan means an employee welfare benefit plan to the extent that the plan provides medical care (including items and services paid for as medical care) to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

(2) *Determination of number of plans.* [Reserved]

(b) *Excepted benefits*—(1) *In general.* The requirements of subparts B and C of this part do not apply to any group health plan (or any group health insurance coverage) in relation to its provision of the benefits described in paragraph (b) (2), (3), (4), or (5) of this section (or any combination of these benefits).

(2) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances—

(i) Coverage only for accident (including accidental death and dismemberment);

(ii) Disability income coverage;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Coverage issued as a supplement to liability insurance;

(v) Workers' compensation or similar coverage;

(vi) Automobile medical payment insurance;

(vii) Credit-only insurance (for example, mortgage insurance); and

(viii) Coverage for on-site medical clinics.

(ix) Travel insurance, within the meaning of §144.103 of this subchapter.

(3) *Limited excepted benefits*—(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (b)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement (health FSA) are excepted benefits if they satisfy the requirements of paragraph (b)(3)(v) of this section; benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vi) of this section; benefits provided under limited wraparound coverage are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vii) of this section; and benefits provided under a health reimbursement arrangement or other account-based group health plan, other than a health FSA, are excepted benefits if they satisfy the requirements of paragraph (b)(3)(viii) of this section.

(ii) *Not an integral part of a group health plan.* For purposes of this paragraph (b)(3), benefits are not an integral part of a group health plan (whether the benefits are provided through the same plan, a separate plan, or as the only plan offered to participants) if either paragraph (b)(3)(ii)(A) or (B) are satisfied.

(A) Participants may decline coverage. For example, a participant may decline coverage if the participant can opt out of the coverage upon request, whether or not there is a participant contribution required for the coverage.

(B) Claims for the benefits are administered under a contract separate from claims administration for any other benefits under the plan.

(iii) *Limited scope*—(A) *Dental benefits.* Limited scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth).

(B) *Vision benefits.* Limited scope vision benefits are benefits substantially

all of which are for treatment of the eye.

(iv) *Long-term care.* Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(v) *Health flexible spending arrangements.* Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) are excepted for a class of participants only if they satisfy the following two requirements—

(A) Other group health plan coverage, not limited to excepted benefits, is made available for the year to the class of participants by reason of their employment; and

(B) The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement).

(vi) *Employee assistance programs.* Benefits provided under employee assistance programs are excepted if they satisfy all of the requirements of this paragraph (b)(3)(vi).

(A) The program does not provide significant benefits in the nature of medical care. For this purpose, the amount, scope and duration of covered services are taken into account.

(B) The benefits under the employee assistance program are not coordinated with benefits under another group health plan, as follows:

(*1*) Participants in the other group health plan must not be required to use and exhaust benefits under the employee assistance program (making the employee assistance program a gatekeeper) before an individual is eligible for benefits under the other group health plan; and

(*2*) Participant eligibility for benefits under the employee assistance program must not be dependent on participation in another group health plan.

(C) No employee premiums or contributions are required as a condition of participation in the employee assistance program.

(D) There is no cost sharing under the employee assistance program.

(vii) *Limited wraparound coverage.* Limited benefits provided through a group health plan that wrap around eligible individual health insurance (or Basic Health Plan coverage described in section 1331 of the Patient Protection and Affordable Care Act); or that wrap around coverage under a Multi-State Plan described in section 1334 of the Patient Protection and Affordable Care Act, collectively referred to as ''limited wraparound coverage,'' are excepted benefits if all of the following conditions are satisfied. For this purpose, eligible individual health insurance is individual health insurance coverage that is not a grandfathered health plan (as described in section 1251 of the Patient Protection and Affordable Care Act and §147.140 of this subchapter), not a transitional individual health insurance plan (as described in the March 5, 2014 Insurance Standards Bulletin Series—Extension of Transitional Policy through October 1, 2016), and does not consist solely of excepted benefits (as defined in paragraph (b) of this section).

(A) *Covers additional benefits.* The limited wraparound coverage provides meaningful benefits beyond coverage of cost sharing under either the eligible individual health insurance, Basic Health Program coverage, or Multi-State Plan coverage. The limited wraparound coverage must not provide benefits only under a coordination-of-benefits provision and must not consist of an account-based reimbursement arrangement.

(B) *Limited in amount.* The annual cost of coverage per employee (and any covered dependents, as defined in §144.103 of this subchapter) under the limited wraparound coverage does not exceed the greater of the amount determined under either paragraph (b)(3)(vii)(B)(*1*) or (*2*) of this section. Making a determination regarding the annual cost of coverage per employee must occur on an aggregate basis relying on sound actuarial principles.

(*1*) The maximum permitted annual salary reduction contribution toward health flexible spending arrangements, indexed in the manner prescribed under section 125(i)(2) of the Internal Revenue Code. For this purpose, the cost of coverage under the limited wraparound includes both employer and employee contributions towards coverage and is determined in the same manner as the applicable premium is calculated under a COBRA continuation provision.

(*2*) Fifteen percent of the cost of coverage under the primary plan. For this purpose, the cost of coverage under the primary plan and under the limited wraparound coverage includes both employer and employee contributions towards the coverage and each is determined in the same manner as the applicable premium is calculated under a COBRA continuation provision.

(C) *Nondiscrimination.* All of the conditions of this paragraph (b)(3)(vii)(C) are satisfied.

(*1*) *No preexisting condition exclusion.* The limited wraparound coverage does not impose any preexisting condition exclusion, consistent with the requirements of section 2704 of the PHS Act and §147.108 of this subchapter.

(*2*) *No discrimination based on health status.* The limited wraparound coverage does not discriminate against individuals in eligibility, benefits, or premiums based on any health factor of an individual (or any dependent of the individual, as defined in §144.103 of this subchapter), consistent with the requirements of section 2705 of the PHS Act.

(*3*) *No discrimination in favor of highly compensated individuals.* Neither the limited wraparound coverage, nor any other group health plan coverage offered by the plan sponsor, fails to comply with section 2716 of the PHS Act or fails to be excludible from income for any individual due to the application of section 105(h) of the Internal Revenue Code (as applicable).

(D) *Plan eligibility requirements.* Individuals eligible for the wraparound coverage are not enrolled in excepted benefit coverage under paragraph (b)(3)(v) of this section (relating to health FSAs). In addition, the conditions set forth in either paragraph (b)(3)(vii)(D)(*1*) or (*2*) of this section are met.

(*1*) *Limited wraparound coverage that wraps around eligible individual insurance for persons who are not full-time employees.* Coverage that wraps around eligible individual health insurance (or that wraps around Basic Health Plan coverage) must satisfy all of the conditions of this paragraph (b)(3)(vii)(D)(*1*).

(*i*) For each year for which limited wraparound coverage is offered, the employer that is the sponsor of the plan offering limited wraparound coverage, or the employer participating in a plan offering limited wraparound coverage, offers to its full-time employees coverage that is substantially similar to coverage that the employer would need to offer to its full-time employees in order not to be subject to a potential assessable payment under the employer shared responsibility provisions of section 4980H(a) of the Internal Revenue Code, if such provisions were applicable; provides minimum value (as defined in section 36B(c)(2)(C)(ii) of the Internal Revenue Code); and is reasonably expected to be affordable (applying the safe harbor rules for determining affordability set forth in 26 CFR 54.4980H–5(e)(2)). If a plan or issuer providing limited wraparound coverage takes reasonable steps to ensure that employers disclose to the plan or issuer necessary information regarding their coverage offered and affordability information, the plan or issuer is permitted to rely on reasonable representations by employers regarding this information, unless the plan or issuer has specific knowledge to the contrary. In the event that the employer that is the

sponsor of the plan offering wraparound coverage, or the employer participating in a plan offering wraparound coverage, has no full-time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*1*)(*i*) is considered satisfied.

(*ii*) Eligibility for the limited wraparound coverage is limited to employees who are reasonably determined at the time of enrollment to not be full-time employees (and their dependents, as defined in §144.103 of this subchapter), or who are retirees (and their dependents, as defined in §144.103 of this subchapter). For this purpose, full-time employees are employees who are reasonably expected to work at least an average of 30 hours per week.

(*iii*) Other group health plan coverage, not limited to excepted benefits, is offered to the individuals eligible for the limited wraparound coverage. Only individuals eligible for the other group health plan coverage are eligible for the limited wraparound coverage.

(*2*) *Limited coverage that wraps around Multi-State Plan coverage.* Coverage that wraps around Multi-State Plan coverage must satisfy all of the conditions of this paragraph (b)(3)(vii)(D)(*2*). For this purpose, the term ''full-time employee'' means a ''full-time employee'' as defined in 26 CFR 54.4980H–1(a)(21) who is not in a limited non-assessment period for certain employees (as defined in 26 CFR 54.4980H–1(a)(26)). Moreover, if a plan or issuer providing limited wraparound coverage takes reasonable steps to ensure that employers disclose to the plan or issuer necessary information regarding their coverage offered and contribution levels for 2013 or 2014 (as applicable), and for any year in which limited wraparound coverage is offered, the plan or issuer is permitted to rely on reasonable representations by employers regarding this information, unless the plan or issuer has specific knowledge to the contrary. Consistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section, the Office of Personnel Management may verify that plans and issuers have reasonable mechanisms in place to ensure that contributing employers meet these standards.

(*i*) The limited wraparound coverage is reviewed and approved by the Office of Personnel Management, consistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section, to provide benefits in conjunction with coverage under a Multi-State Plan authorized under section 1334 of the Patient Protection and Affordable Care Act. The Office of Personnel Management may revoke approval if it determines that continued approval is inconsistent with the reporting and evaluation criteria of paragraph (b)(3)(vii)(E) of this section.

(*ii*) The employer offered coverage in the plan year that began in either 2013 or 2014 that is substantially similar to coverage that the employer would need to have offered to its full-time employees in order to not be subject to an assessable payment under the employer shared responsibility provisions of section 4980H(a) of the Internal Revenue Code, if such provisions had been applicable. In the event that a plan that offered coverage in 2013 or 2014 has no full-time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*2*)(*ii*) is considered satisfied.

(*iii*) In the plan year that began in either 2013 or 2014, the employer offered coverage to a substantial portion of full-time employees that provided minimum value (as defined in section 36B(c)(2)(C)(ii) of the Internal Revenue Code) and was affordable (applying the safe harbor rules for determining affordability set forth in 26 CFR 54.4980H–5(e)(2)). In the event that the plan that offered coverage in 2013 or 2014 has no full-time employees for any plan year limited wraparound coverage is offered, the requirement of this paragraph (b)(3)(vii)(D)(*2*)(*iii*) is considered satisfied.

(*iv*) For the duration of the pilot program, as described in paragraph (b)(3)(vii)(F) of this section, the employer's annual aggregate contributions for both primary and limited wraparound coverage are substantially the same as the employer's total contributions for coverage offered to full-time employees in 2013 or 2014.

(E) *Reporting—(1) Reporting by group health plans and group health insurance issuers.* A self-insured group health plan, or a health insurance issuer, offering or proposing to offer limited wraparound coverage in connection with Multi-State Plan coverage pursuant to paragraph (b)(3)(vii)(D)(*2*) of this section reports to the Office of Personnel Management (OPM), in a form and manner specified in guidance, information OPM reasonably requires to determine whether the plan or issuer qualifies to offer such coverage or complies with the applicable requirements of this section.

(*2*) *Reporting by group health plan sponsors.* The plan sponsor of a group health plan offering limited wraparound coverage under paragraph (b)(3)(vii) of this section, must report to the Department of Health and Human Services (HHS), in a form and manner specified in guidance, information HHS reasonably requires.

(F) *Pilot program with sunset.* The provisions of paragraph (b)(3)(vii) of this section apply to limited wraparound coverage that is first offered no earlier than January 1, 2016 and no later than December 31, 2018 and that ends no later than on the later of:

(*1*) The date that is three years after the date limited wraparound coverage is first offered; or

(*2*) The date on which the last collective bargaining agreement relating to the plan terminates after the date limited wraparound coverage is first offered (determined without regard to any extension agreed to after the date limited wraparound coverage is first offered).

(viii) *Health reimbursement arrangements (HRAs) and other account-based group health plans.* Benefits provided under an HRA or other account-based group health plan, other than a health FSA, are excepted if they satisfy all of the requirements of this paragraph (b)(3)(viii). See paragraph (b)(3)(v) of this section for the circumstances in which benefits provided under a health FSA are excepted benefits. For purposes of this paragraph (b)(3)(viii), the term ''HRA or other account-based group health plan'' has the same meaning as ''account-based group health plan'' set forth in §147.126(d)(6)(i) of this subchapter, except that the term does not include health FSAs. For ease of reference, an HRA or other account-based group health plan that satisfies the requirements of this paragraph (b)(3)(viii) is referred to as an excepted benefit HRA.

(A) *Otherwise not an integral part of the plan.* Other group health plan coverage that is not limited to excepted benefits and that is not an HRA or other account-based group health plan must be made available by the same plan sponsor for the plan year to the participant.

(B) *Benefits are limited in amount—(1) Limit on annual amounts made available.* The amounts newly made available for each plan year under the HRA or other account-based group health plan do not exceed $1,800. In the case of any plan year beginning after December 31, 2020, the dollar amount in the preceding sentence shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment. The cost of living adjustment is the percentage (if any) by which the C–CPI–U for the preceding calendar year exceeds the C–CPI–U for calendar year 2019. The term ''C–CPI–U'' means the Chained Consumer Price Index for All Urban Consumers as published by the Bureau of Labor Statistics of the Department of Labor. The C–CPI–U for any calendar year is the average of the C–CPI–U as of the close of the 12-month period ending on March 31 of such calendar year. The values of the C–CPI–U used for any calendar year shall be the latest values so published as of the date on which the Bureau publishes the initial value of the C–CPI–U for the month of March for the preceding calendar year. Any such increase that is not a multiple of $50 shall be rounded down to the next lowest multiple of $50. The Department of the Treasury and the Internal Revenue Service will publish the adjusted amount for plan years beginning in any calendar year no later than June 1 of the preceding calendar year.

(*2*) *Carryover amounts.* If the terms of the HRA or other account-based group health plan allow unused amounts to be made available to participants and dependents in later plan years, such carryover amounts are disregarded for

purposes of determining whether benefits are limited in amount.

(*3*) *Multiple HRAs or other account-based group health plans.* If the plan sponsor provides more than one HRA or other account-based group health plan to the participant for the same time period, the amounts made available under all such plans are aggregated to determine whether the benefits are limited in amount, except that HRAs or other account-based group health plans that reimburse only excepted benefits are not included in determining whether the benefits are limited in amount.

(C) *Prohibition on reimbursement of certain health insurance premiums.* The HRA or other account-based group health plan must not reimburse premiums for individual health insurance coverage, group health plan coverage (other than COBRA continuation coverage or other continuation coverage), or Medicare Part A, B, C, or D, except that the HRA or other account-based group health plan may reimburse premiums for such coverage that consists solely of excepted benefits. See also, paragraph (b)(3)(viii)(F) of this section.

(D) *Uniform availability.* The HRA or other account-based group health plan is made available under the same terms to all similarly situated individuals, as defined in §146.121(d), regardless of any health factor (as described in §146.121(a)).

(E) *Notice requirement.* For plan years beginning on or after January 11, 2021, the HRA or other account-based group health plan must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps, or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided no later than 90 days after an employee becomes a participant and annually thereafter, in a manner reasonably calculated to ensure actual receipt by participants eligible for the HRA or other account-based group health plan.

(F) *Special rule.* The HRA or other account-based group health plan must not reimburse premiums for short-term, limited-duration insurance (as defined in §144.103 of this subchapter) if the conditions of this paragraph (b)(3)(viii)(F) are satisfied.

(*1*) The HRA or other account-based group health plan is offered by a small employer (as defined in PHS Act section 2791(e)(4)).

(*2*) The other group health plan coverage offered by the employer pursuant to paragraph (b)(3)(viii)(A) of this section is either fully-insured or partially-insured.

(*3*) The Secretary makes a finding, in consultation with the Secretaries of Labor and the Treasury, that the reimbursement of premiums for short-term, limited-duration insurance by excepted benefit HRAs has caused significant harm to the small group market in the state that is the principal place of business of the small employer.

(*4*) The finding by the Secretary is made after submission of a written recommendation by the applicable state authority of such state, in a form and manner specified by HHS. The written recommendation must include evidence that the reimbursement of premiums for short-term, limited-duration insurance by excepted benefit HRAs established by insured or partially-insured small employers in the state has caused significant harm to the state's small group market, including with respect to premiums.

(*5*) The restriction shall be imposed or discontinued by publication by the Secretary of a notice in the FEDERAL REGISTER and shall apply only prospectively and with a reasonable time for plan sponsors to comply.

(4) *Noncoordinated benefits*—(i) *Excepted benefits that are not coordinated.* Coverage for only a specified disease or illness (for example, cancer-only policies) or hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the conditions specified in paragraph (b)(4)(ii) of this section. To be hospital indemnity or other fixed indemnity insurance, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.

(ii) *Conditions.* Benefits are described in paragraph (b)(4)(i) of this section only if—

(A) The benefits are provided under a separate policy, certificate, or contract of insurance;

(B) There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

(C) The benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.

(D) For plan years beginning on or after January 1, 2025, with respect to hospital indemnity or other fixed indemnity insurance:

(*1*) The plan or issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment materials that are provided to participants at or before the time participants are given the opportunity to enroll in the coverage, in at least 14-point font, the language in the following notice:

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

(*2*) If participants are required to reenroll (in either paper or electronic form) for purposes of renewal or reissuance of the insurance, the notice described in paragraph (b)(4)(ii)(D)(*1*) of this section is prominently displayed in any marketing and reenrollment materials provided at or before the time participants are given the opportunity to reenroll in coverage.

(*3*) If a plan or issuer provides a notice satisfying the requirements in paragraphs (b)(4)(ii)(D)(*1*) and (*2*) of this section to a participant, the obligation to provide the notice is considered to be satisfied for both the plan and issuer.

(iii) *Example.* The rules of this paragraph (b)(4) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage through an insurance policy. The policy provides benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum of $100 a day.

(ii) *Conclusion.* In this *Example,* even though the benefits under the policy satisfy the conditions in paragraph (b)(4)(ii) of this section, because the policy pays a percentage of expenses incurred rather than a fixed dollar amount, the benefits under the policy are not excepted benefits under this paragraph (b)(4). This is the result even if, in practice, the policy pays the maximum of $100 for every day of hospitalization.

(iv) *Severability.* If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

(5) *Supplemental benefits.* (i) The following benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance—

(A) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act; also known as Medigap or MedSupp insurance);

(B) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as TRICARE supplemental programs); and

(C) *Similar supplemental coverage provided to coverage under a group health plan.* To be similar supplemental coverage, the coverage must be specifically designed to fill gaps in the primary coverage. The preceding sentence is satisfied if the coverage is designed to fill gaps in cost sharing in the primary coverage, such as coinsurance or deductibles, or the coverage is designed to provide benefits for items and services not covered by the primary coverage and that are not essential health benefits (as defined under section 1302(b) of the Patient Protection and Affordable Care Act) in the State where the coverage is issued, or the coverage is designed to both fill such gaps in cost sharing under, and cover such benefits not covered by, the primary coverage. Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination-of-benefits provision.

(ii) The rules of this paragraph (b)(5) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage for both active employees and retirees. The coverage for retirees supplements benefits provided by Medicare, but does not meet the requirements for a supplemental policy under section 1882(g)(1) of the Social Security Act.

(ii) *Conclusion.* In this *Example,* the coverage provided to retirees does not meet the definition of supplemental excepted benefits under this paragraph (b)(5) because the coverage is not Medicare supplemental insurance as defined under section 1882(g)(1) of the Social Security Act, is not a TRICARE supplemental program, and is not supplemental to coverage provided under a group health plan.

(c) *Treatment of partnerships.* For purposes of this part:

(1) *Treatment as a group health plan.* Any plan, fund, or program that would not be (but for this paragraph (c)) an

employee welfare benefit plan and that is established or maintained by a partnership, to the extent that the plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, is treated (subject to paragraph (c)(2) of this section) as an employee welfare benefit plan that is a group health plan.

(2) *Employment relationship.* In the case of a group health plan, the term *employer* also includes the partnership in relation to any bona fide partner. In addition, the term *employee* also includes any bona fide partner. Whether or not an individual is a bona fide partner is determined based on all the relevant facts and circumstances, including whether the individual performs services on behalf of the partnership.

(3) *Participants of group health plans.* In the case of a group health plan, the term *participant* also includes any individual described in paragraph (c)(3)(i) or (ii) of this section if the individual is, or may become, eligible to receive a benefit under the plan or the individual's beneficiaries may be eligible to receive any such benefit.

(i) In connection with a group health plan maintained by a partnership, the individual is a partner in relation to the partnership.

(ii) In connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the individual is the self-employed individual.

(d) *Determining the average number of employees.* [Reserved]

[69 FR 78798, Dec. 30, 2004, as amended at 74 FR 51692, Oct. 7, 2009; 78 FR 65092, Oct. 30, 2013; 79 FR 59136, Oct. 1, 2014; 80 FR 14007, Mar. 18, 2015; 81 FR 75326, Oct. 31, 2016; 84 FR 29024, June 20, 2019; 85 FR 29259, May 14, 2020; 89 FR 23418, Apr. 3, 2024]

Subpart E—Provisions Applicable to Only Health Insurance Issuers

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

(a) *Issuance of coverage in the small group market.* Subject to paragraphs (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State must—

(1) Offer, to any small employer in the State, all products that are approved for sale in the small group market and that the issuer is actively marketing, and must accept any employer that applies for any of those products; and

(2) Accept for enrollment under the coverage every eligible individual (as defined in paragraph (b) of this section) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan, or during a special enrollment period, and may not impose any restriction on an eligible individual's being a participant or beneficiary, which is inconsistent with the nondiscrimination provisions of § 146.121.

(b) *Eligible individual defined.* For purposes of this section, the term ''eligible individual'' means an individual who is eligible—

(1) To enroll in group health insurance coverage offered to a group health plan maintained by a small employer, in accordance with the terms of the group health plan;

(2) For coverage under the rules of the health insurance issuer which are uniformly applicable in the State to small employers in the small group market; and

(3) For coverage in accordance with all applicable State laws governing the issuer and the small group market.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(i) Limit the employers that may apply for the coverage to those with eligible individuals who live, work, or reside in the service area for the network plan; and

(ii) Within the service area of the plan, deny coverage to employers if the issuer has demonstrated to the applicable State authority (if required by the State authority) that—

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees; and

(B) It is applying this paragraph (c)(1) uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies health insurance coverage to an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the small group market within the service area to any employer for a period of 180 days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable State authority (if required by the State authority) that it—

(i) Does not have the financial reserves necessary to underwrite additional coverage; and

(ii) Is applying this paragraph (d)(1) uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies group health insurance coverage to any small employer in a State under paragraph (d)(1) of this section may not offer coverage in connection with group health plans in the small group market in the State before the later of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable State authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Exception to requirement for failure to meet certain minimum participation or contribution rules.* (1) Paragraph (a) of this section does not preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) For purposes of paragraph (e)(1) of this section—

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) *Exception for coverage offered only to bona fide association members.* Paragraph (a) of this section does not apply to health insurance coverage offered by a health insurance issuer if that coverage is made available in the small group market only through one or

more bona fide associations (as defined in 45 CFR 144.103).

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[62 FR 16958, Apr. 8, 1997; 62 FR 31694, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 67 FR 48811, July 26, 2002]

§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (f) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

(b) *Exceptions.* An issuer may nonrenew or discontinue group health insurance coverage offered in the small or large group market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under §146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

(4) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under §146.150(c); provided the issuer provides notice in accordance with the requirements of paragraph (c)(1) of this section.

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered

under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with §144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with §144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(e) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage in a market (or markets) in a State as described in paragraph (d) of this section may not issue coverage in the market (or markets) and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(f) *Exception for uniform modification of coverage.* (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the following—

(i) Large group market; and

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(2) For purposes of paragraph (f)(1)(ii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) For purposes of paragraph (f)(1)(ii) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group;

(ii) The product is offered as the same product network type (for example, health maintenance organization,

preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the rate for any plan within the product within an allowable variation of ±2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (f)(3)(iii) and (iv) of this section.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to ''plan sponsor'' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

(h) *Notice of renewal of coverage.* If an issuer in the small group market is renewing grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying grandfathered coverage as described in paragraph (f) of this section, the issuer must provide to each plan sponsor written notice of the renewal at least 60 calendar days before the date the coverage will be renewed in a form and manner specified by the Secretary.

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§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See §146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that

apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

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[62 FR 16958, Apr. 8, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart F—Exclusion of Plans and Enforcement

§ 146.180 Treatment of non-Federal governmental plans.

(a) *Opt-out election for self-funded non-Federal governmental plans*—(1) *Requirements subject to exemption.* The PHS Act requirements described in this paragraph are the following:

(i) Limitations on preexisting condition exclusion periods in accordance with section 2701 of the PHS Act as codified before enactment of the Affordable Care Act.

(ii) Special enrollment periods for individuals and dependents described under section 2704(f) of the PHS Act.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status under section 2705 of the PHS Act, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from requirements under section 2705(a)(6) and 2705(c) through (f) that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns under section 2725 of the PHS Act.

(v) Parity in mental health and substance use disorder benefits under section 2726 of the PHS Act.

(vi) Required coverage for reconstructive surgery following mastectomies under section 2727 of the PHS Act.

(vii) Coverage of dependent students on a medically necessary leave of absence under section 2728 of the PHS Act.

(2) *General rule.* For plan years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is, it is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(3) *Special rule for certain collectively bargained plans.* In the case of a plan that is maintained pursuant to a collective bargaining agreement that was ratified before March 23, 2010, and whose sponsor made an election to exempt its plan from any of the requirements described in paragraphs (a)(1)(i) through (iii) of this section, the provisions of paragraph (a)(2) of this section apply for plan years beginning after the expiration of the term of the agreement.

(4) *Examples*—(i) *Example 1.* A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1 of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to five plan years, October 1, 2009 through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraph (a)(1) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section.

(5) *Limitations.* (i) An election under this section cannot circumvent a requirement of the PHS Act to the extent the requirement applied to the plan before the effective date of the election.

(A) *Example 1.* A plan is subject to requirements of section 2727 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2727 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) [Reserved]

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non-Federal governmental employer(s) with a valid election under this section are affected by the election.

(6) *Stop-loss or excess risk coverage.* For purposes of this section—

(i) Subject to paragraph (a)(6)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as ''stop-loss'' coverage or ''excess risk'' coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements described in paragraph (a)(1) of this section.

(7) *Construction.* Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election*—(1) *Election requirements.* The election must meet the following requirements:

(i) Be made in an electronic format in a form and manner as described by the Secretary in guidance.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in § 144.103 of this subchapter.

(B) The ''term of the agreement,'' as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a)(1) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(ix) In the case of a plan sponsor submitting one opt-out election for all group health plans subject to the same collective bargaining agreement, include a list of plans subject to the agreement.

(x) In the case of a plan sponsor submitting opt-out elections for more than one group health plan that is not subject to a collective bargaining agreement, submit a separate election document for each such plan.

(2) ''*Term of the agreement*'' *defined.* Except as provided in paragraphs (b)(2)(i) and (ii) of this section, for purposes of this section ''term of the agreement'' means all group health

plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the term of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) *Construction*—(i) *Dispute resolution.* Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) *Future elections not preempted.* If a plan must comply with one or more requirements described in paragraph (a)(1) of this section for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) *Filing a timely election*—(1) *Plan not governed by collective bargaining.* Subject to paragraph (c)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) *Plan governed by a collective bargaining agreement.* Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement that was ratified before March 23, 2010, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) *Special rule for timely filing.* If the latest filing date specified under paragraphs (c)(1) or (c)(2) of this section falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts filings submitted on the next business day.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (c)(1) and (2) of this section for good cause if the plan substantially complies with the requirements of paragraph (e) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (c)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (c)(1) or (2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(d) *Additional information required*—(1) *Written notification.* If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) *Timely response.* For submissions via hard copy via U.S. Mail, CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (d)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) *Failure to respond timely.* CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (d)(1) of this section.

(e) *Notice to enrollees*—(1) *Mandatory notification.* (i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of paragraph (e) of this section, if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (e)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in §144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of paragraph (e) of this section by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) *Initial notices.* (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph (b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) *Notice content.* The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non-Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(f) *Subsequent elections*—(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

(2) *Form and manner of renewal.* Except for the requirement to forward to CMS a copy of the notice to enrollees

under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under paragraph (b)(1)(viii) of this section, the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (e) of this section.

(3) *Election renewal includes provisions from which plan not previously exempted.* If an election renewal includes a requirement described in paragraph (a)(1) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (e)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) of this section from which the plan sponsor is electing to exempt the plan.

(4) *Special rules regarding renewal of an election under a collective bargaining agreement.* (i) If protracted negotiations with respect to a new agreement result in an extension of the term of the prior agreement (as provided under paragraph (b)(2)(i) of this section) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (e)(1) of this section, and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (c)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (c)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(g) *Requirements not subject to exemption*—(1) *Genetic information.* Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of §§146.111 and 146.121, the exemption election must not be construed to exempt the plan from any provisions of this part that pertain to genetic information.

(2) *Enforcement.* CMS enforces these requirements as provided under paragraph (j) of this section.

(h) *Effect of failure to comply with certification and notification requirements*—(1) *Substantial failure*—(i) *General rule.* Except as provided in paragraph (h)(1)(iii) of this section, a substantial failure to comply with paragraph (e) or (g)(1) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) *Determination of substantial failure.* CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (e) or (g)(1) of this section based on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) *Exceptions*—(A) *Multiple employers.* If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraph (e) or (g)(1) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) *Limited failure to provide notice.* If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) *Examples*—(i) *Example 1.* A self-funded, non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (e) of this section, including

providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (e) of this section with respect to these individuals. The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) *Example 2.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (e) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure, the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(i) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and States the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (c)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all requirements of this part for the specified period for which CMS has determined the election to be invalid.

(j) *Enforcement.* To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

(k) *Construction.* Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in §146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the

State from making an election under this section.

[79 FR 30336, May 27, 2014]

EFFECTIVE DATE NOTE: At 89 FR 77751, Sept. 23, 2024, §146.180 was amended, effective Nov. 22, 2024, by:

1. Revising paragraph (a)(2);
2. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8);
3. Adding new paragraph (a)(3);
4. Revising newly redesignated paragraphs (a)(5) and (a)(7)(i) and paragraph (f)(1); and
5. Adding paragraph (f)(4)(iii).

For the convenience of the user, the added and revised text is set forth as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) * * *

(2) *General rule.* For plans years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not provided through health insurance coverage (that is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, except as provided in paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(3) *Sunset of election option related to parity in mental health and substance use disorder benefits.* A sponsor of a non-Federal governmental plan may not newly elect to exempt its plans from the requirements described in paragraph (a)(1)(v) of this section on or after December 29, 2022.

* * * * *

(5) *Examples*—(i) *Example 1.* A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1st of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to 5 plan years, October 1, 2009, through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraphs (a)(1)(i) through (iii) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

* * * * *

(7) * * *

(i) Subject to paragraph (a)(7)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

* * * * *

(f) * * *

(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. Notwithstanding the previous sentence and except as provided in paragraph (f)(4)(iii) of this section, an election with respect to the requirements described in paragraph (a)(1)(v) of this section expiring on or after June 27, 2023, may not be renewed. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

* * * * *

(4) * * *

(iii) In the case of a plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to the requirements described in paragraph (a)(1)(v) of this section in effect as of December 29, 2022, that expires on or after June 27, 2023, the plan may extend such election until the date on which the term of the last such agreement expires.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

Sec.

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147.212 Transparency in coverage—requirements for public disclosure.

AUTHORITY: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

SOURCE: 75 FR 27138, May 13, 2010, unless otherwise noted.

§ 147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§ 147.102 Fair health insurance premiums.

(a) *In general.* With respect to the premium rate charged by a health insurance issuer in accordance with § 156.80 of this subchapter for health insurance coverage offered in the individual or small group market—

(1) The rate may vary with respect to the particular plan or coverage involved only by determining the following:

(i) Whether the plan or coverage covers an individual or family.

(ii) Rating area, as established in accordance with paragraph (b) of this section. For purposes of this paragraph (a), rating area is determined—

(A) In the individual market, using the primary policyholder's address.

(B) In the small group market, using the group policyholder's principal business address. For purposes of this paragraph (a)(1)(ii)(B), principal business address means the principal business address registered with the State or, if a principal business address is not registered with the State, or is registered solely for purposes of service of process and is not a substantial worksite for the policyholder's business, the business address within the State where the greatest number of employees of such policyholder works. If, for a network plan, the group policyholder's principal business address is not within the service area of such plan, and the policyholder has employees who live, reside, or work within the service area, the principal business address for purposes of the network plan is the business address within the plan's service area where the greatest number of employees work as of the beginning of the plan year. If there is no such business address, the rating area for purposes of the network plan is the rating area that reflects where the greatest number of employees within the plan's service area live or reside as of the beginning of the plan year.

(iii) Age, except that the rate may not vary by more than 3:1 for like individuals of different age who are age 21 and older and that the variation in rate must be actuarially justified for individuals under age 21, consistent with the uniform age rating curve under paragraph (e) of this section. For purposes of identifying the appropriate age adjustment under this paragraph and the age band under paragraph (d) of this section applicable to a specific enrollee, the enrollee's age as of the date of policy issuance or renewal must be used.

(iv) Subject to section 2705 of the Public Health Service Act and its implementing regulations (related to prohibiting discrimination based on health status and programs of health promotion or disease prevention) as applicable, tobacco use, except that such rate may not vary by more than 1.5:1 and may only be applied with respect to individuals who may legally use tobacco under federal and state law. For purposes of this section, tobacco use means use of tobacco on average four or more times per week within no longer than the past 6 months. This includes all tobacco products, except that tobacco use does not include religious or ceremonial use of tobacco. Further, tobacco use must be defined in terms of when a tobacco product was last used.

(2) The rate must not vary with respect to the particular plan or coverage involved by any other factor not described in paragraph (a)(1) of this section.

(b) *Rating area.* (1) A state may establish one or more rating areas within that state, as provided in paragraphs (b)(3) and (b)(4) of this section, for purposes of applying this section and the requirements of title XXVII the Public Health Service Act and title I of the Patient Protection and Affordable Care Act.

(2) If a state does not establish rating areas as provided in paragraphs (b)(3) and (b)(4) of this section or provide information on such rating areas in accordance with §147.103, or CMS determines in accordance with paragraph (b)(5) of this section that a state's rating areas under paragraph (b)(4) of this section are not adequate, the default will be one rating area for each metropolitan statistical area in the state and one rating area comprising all non-metropolitan statistical areas in the state, as defined by the Office of Management and Budget.

(3) A state's rating areas must be based on the following geographic boundaries: Counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas, as defined by the Office of Management and Budget, and will be presumed adequate if either of the following conditions are satisfied:

(i) The state established by law, rule, regulation, bulletin, or other executive action uniform rating areas for the entire state as of January 1, 2013.

(ii) The state establishes by law, rule, regulation, bulletin, or other executive action after January 1, 2013 uniform rating areas for the entire state that are no greater in number than the number of metropolitan statistical areas in the state plus one.

(4) Notwithstanding paragraph (b)(3) of this section, a state may propose to CMS for approval a number of rating areas that is greater than the number described in paragraph (b)(3)(ii) of this section, provided such rating areas are based on the geographic boundaries specified in paragraph (b)(3) of this section.

(5) In determining whether the rating areas established by each state under paragraph (b)(4) of this section are adequate, CMS will consider whether the state's rating areas are actuarially justified, are not unfairly discriminatory, reflect significant differences in health care unit costs, lead to stability in rates over time, apply uniformly to all issuers in a market, and are based on the geographic boundaries of counties, three-digit zip codes, or metropolitan statistical areas and non-metropolitan statistical areas.

(c) *Application of variations based on age or tobacco use.* With respect to family coverage under health insurance coverage, the rating variations permitted under paragraphs (a)(1)(iii) and (a)(1)(iv) of this section must be applied based on the portion of the premium attributable to each family member covered under the coverage.

(1) *Per-member rating.* The total premium for family coverage must be determined by summing the premiums for each individual family member. With respect to family members under the age of 21, the premiums for no more than the three oldest covered children must be taken into account in determining the total family premium.

(2) *Family tiers under community rating.* If a state does not permit any rating variation for the factors described in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the state may require that premiums for family coverage be determined by using uniform family tiers

and the corresponding multipliers established by the state. If a state does not establish uniform family tiers and the corresponding multipliers, the per-member-rating methodology under paragraph (c)(1) of this section will apply in that state.

(3) *Application to small group market*—(i) In the case of the small group market, the total premium charged to a group health plan is determined by summing the premiums of covered participants and beneficiaries in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(ii) Subject to paragraph (c)(3)(iii) of this section, nothing in this section prevents a state from requiring issuers to offer to a group health plan, or an issuer from voluntarily offering to a group health plan, premiums that are based on average enrollee premium amounts, provided that the total group premium established at the time of applicable enrollment at the beginning of the plan year is the same total amount derived in accordance with paragraph (c)(1) or (2) of this section, as applicable.

(iii) Effective for plan years beginning on or after January 1, 2015, an issuer that, in connection with a group health plan in the small group market, offers premiums that are based on average enrollee premium amounts under paragraph (c)(3)(ii) of this section must—

(A) Ensure an average enrollee premium amount calculated based on applicable enrollment of participants and beneficiaries at the beginning of the plan year does not vary during the plan year.

(B) Unless a state establishes and CMS approves an alternate rating methodology, calculate an average enrollee premium amount for covered individuals age 21 and older, and calculate an average enrollee premium amount for covered individuals under age 21. The premium for a given family composition is determined by summing the average enrollee premium amount applicable to each family member covered under the plan, taking into account no more than three covered children under age 21.

(C) Pursuant to applicable state law, ensure that the average enrollee premium amount calculated for any individual covered under the plan does not include any rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section. The rating variation for tobacco use permitted under paragraph (a)(1)(iv) of this section is determined based on the premium rate that would be applied on a per-member basis with respect to an individual who uses tobacco and then included in the premium charged for that individual.

(D) To the extent permitted by applicable State law and, in the case of coverage offered through a SHOP, as permitted by the SHOP, apply this paragraph (c)(3)(iii) uniformly among group health plans enrolling in that product, giving those group health plans the option to pay premiums based on average enrollee premium amounts.

(d) *Uniform age bands.* The following uniform age bands apply for rating purposes under paragraph (a)(1)(iii) of this section:

(1) *Child age bands.* (i) For plan years or policy years beginning before January 1, 2018, a single age band for individuals age 0 through 20.

(ii) For plan years or policy years beginning on or after January 1, 2018:

(A) A single age band for individuals age 0 through 14.

(B) One-year age bands for individuals age 15 through 20.

(2) *Adult age bands.* One-year age bands for individuals age 21 through 63.

(3) *Older adult age bands.* A single age band for individuals age 64 and older.

(e) *Uniform age rating curves.* Each State may establish a uniform age rating curve in the individual or small group market, or both markets, for rating purposes under paragraph (a)(1)(iii) of this section. If a State does not establish a uniform age rating curve or provide information on such age curve in accordance with §147.103, a default uniform age rating curve specified in guidance by the Secretary to reflect market patterns in the individual and small group markets will apply in that State that takes into account the rating variation permitted for age under State law.

(f) *Special rule for large group market.* If a state permits health insurance issuers that offer coverage in the large

group market in the state to offer such coverage through an Exchange starting in 2017, the provisions of this section applicable to coverage in the small group market apply to all coverage offered in the large group market in the state.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with §147.140.

[78 FR 13436, Feb. 27, 2013, as amended at 78 FR 54133, Aug. 30, 2013; 79 FR 13834, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016; 81 FR 94173, Dec. 22, 2016; 83 FR 17058, Apr. 17, 2018]

§147.103 State reporting.

(a) *2014.* If a state has adopted or intends to adopt for the 2014 plan or policy year a standard or requirement described in this paragraph, the state must submit to CMS information about such standard or requirement in a form and manner specified in guidance by the Secretary no later than March 29, 2013. A state standard or requirement is described in this paragraph if it includes any of the following:

(1) A ratio narrower than 3:1 in connection with establishing rates for individuals who are age 21 and older, pursuant to §147.102(a)(1)(iii).

(2) A ratio narrower than 1.5:1 in connection with establishing rates for individuals who use tobacco legally, pursuant to §147.102(a)(1)(iv).

(3) Geographic rating areas, pursuant to §147.102(b).

(4) In states that do not permit rating based on age or tobacco use, uniform family tiers and corresponding multipliers, pursuant to §147.102(c)(2).

(5) A requirement that that issuers in the small group market offer to a group premiums that are based on average enrollee amounts, pursuant to paragraph §147.102(c)(3).

(6) A uniform age rating curve, pursuant to §147.102(e).

(b) *Updates.* If a state adopts a standard or requirement described in paragraph (a) of this section for any plan or policy year beginning after the 2014 plan or policy year (or updates a standard or requirement that applies for the 2014 plan or policy year), the state must submit to CMS information about such standard in a form and manner specified in guidance by the Secretary.

(c) *Applicability date.* The provisions of this section apply on March 29, 2013.

[78 FR 13437, Feb. 27, 2013]

§147.104 Guaranteed availability of coverage.

(a) *Guaranteed availability of coverage in the individual and group market.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer that offers health insurance coverage in the individual, small group, or large group market in a State must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.

(b) *Enrollment periods.* A health insurance issuer may restrict enrollment in health insurance coverage to open or special enrollment periods.

(1) *Open enrollment periods*—(i) *Group market.* (A) Subject to paragraph (b)(1)(i)(B) of this section, a health insurance issuer in the group market must allow an employer to purchase health insurance coverage for a group health plan at any point during the year.

(B) In the case of a group health plan in the small group market that cannot comply with employer contribution or group participation rules for the offering of health insurance coverage, as allowed under applicable State law, and in the case of a QHP offered in the SHOP, as permitted by §156.285(e) or §156.286(e) of this subchapter, a health insurance issuer may restrict the availability of coverage to an annual enrollment period that begins November 15 and extends through December 15 of each calendar year.

(C) With respect to coverage in the small group market, and in the large group market if such coverage is offered through a SHOP in a State, for a group enrollment received on the first through the fifteenth day of any month, the coverage effective date must be no later than the first day of the following month. For a group enrollment received on the 16th through

last day of any month, the coverage effective date must be no later than the first day of the second following month. In either such case, a small employer may instead opt for a later effective date within a quarter for which small group market rates are available.

(ii) *Individual market.* A health insurance issuer in the individual market must allow an individual to purchase health insurance coverage during the initial and annual open enrollment periods described in §155.410(b) and (e) of this subchapter. Coverage must become effective consistent with the dates described in §155.410(c) and (f) of this subchapter.

(2) *Limited open enrollment periods.* (i) A health insurance issuer in the individual market must provide a limited open enrollment period for the triggering events described in §155.420(d) of this subchapter, excluding, with respect to coverage offered outside of an Exchange, the following:

(A) Section 155.420(d)(3) of this subchapter (concerning Exchange eligibility standards);

(B) Section 155.420(d)(6) of this subchapter (to the extent concerning eligibility for advance payments of the premium tax credit or change in eligibility for cost-sharing reductions other than ineligibility);

(C) Section 155.420(d)(8) of this subchapter (concerning Indians);

(D) Section 155.420(d)(9) of this subchapter (concerning exceptional circumstances);

(E) Section 155.420(d)(12) of this subchapter (concerning plan and benefit display errors);

(F) Section 155.420(d)(13) of this subchapter (concerning eligibility for insurance affordability programs or enrollment in the Exchange); and

(G) Section 155.420(d)(16) of this subchapter (concerning eligibility for advance payments of the premium tax credit and household income, as defined in 26 CFR 1.36B–1(e), that is expected to be no greater than 150 percent of the Federal poverty level).

(ii) In applying this paragraph (b)(2), a reference in §155.420 (other than in §155.420(a)(5) and (d)(4)) of this subchapter to a ''QHP'' is deemed to refer to a plan, a reference to ''the Exchange'' is deemed to refer to the applicable State authority, and a reference to a ''qualified individual'' is deemed to refer to an individual in the individual market. For purposes of §155.420(d)(4) of this subchapter, ''the Exchange'' is deemed to refer to the Exchange or the health plan, as applicable.

(iii) Notwithstanding anything to the contrary in §155.420(d) of this subchapter, §155.420(a)(4) of this subchapter does not apply to limited open enrollment periods under paragraph (b)(2) of this section.

(3) *Special enrollment periods.* A health insurance issuer in the group and individual market must establish special enrollment periods for qualifying events as defined under section 603 of the Employee Retirement Income Security Act of 1974, as amended. These special enrollment periods are in addition to any other special enrollment periods that are required under federal and state law.

(4) *Length of enrollment periods.* (i) In the group market, enrollees must be provided 30 calendar days after the date of the qualifying event described in paragraph (b)(3) of this section to elect coverage.

(ii) In the individual market, subject to §155.420(c)(5) of this subchapter, individuals must be provided 60 calendar days after the date of an event described in paragraph (b)(2) and (3) of this section to elect coverage, as well as 60 calendar days before certain triggering events as provided for in §155.420(c)(2) of this subchapter.

(5) *Effective date of coverage for limited open and special enrollment periods.* With respect to an election made under paragraph (b)(2) or (b)(3) of this section, coverage must become effective consistent with the dates described in §155.420(b) of this subchapter.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may do the following:

(i) Limit the employers that may apply for the coverage to those with eligible individuals in the group market who live, work, or reside in the service area for the network plan, and limit

the individuals who may apply for the coverage in the individual market to those who live or reside in the service area for the network plan.

(ii) Within the service area of the plan, deny coverage to employers and individuals if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees.

(B) It is applying paragraph (c)(1) of this section uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to an individual or an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the individual, small group, or large group market, as applicable, for a period of 180 calendar days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated to the applicable state authority (if required by the state authority) the following:

(i) It does not have the financial reserves necessary to offer additional coverage.

(ii) It is applying this paragraph (d)(1) uniformly to all employers or individual in the large group, small group, or individual market, as applicable, in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees, and dependents.

(2) An issuer that denies health insurance coverage to any employer or individual in a state under paragraph (d)(1) of this section may not offer coverage in the large group, small group, or individual market, as applicable, in the State before the later of either of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable state authority, if required under applicable state law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable state authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), expected length of life, degree of medical dependency, quality of life, or other health conditions.

(f) *Calendar year plans.* An issuer that offers coverage in the individual market, or in a merged market in a State

that has elected to merge the individual market and small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, must ensure that such coverage is offered on a calendar year basis with a policy year ending on December 31 of each calendar year.

(g) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(h) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with § 147.140.

(i) *Coverage denials for failure to pay premiums for prior coverage.* A health insurance issuer that denies coverage to an individual or employer due to the individual's or employer's failure to pay premium owed under a prior policy, certificate, or contract of insurance, including by attributing payment of premium for a new policy, certificate, or contract of insurance to the prior policy, certificate, or contract of insurance, violates paragraph (a) of this section.

(j) *Construction.* Nothing in this section should be construed to require an issuer to offer coverage otherwise prohibited under applicable Federal law.

[78 FR 13437, Feb. 27, 2013, as amended at 78 FR 65092, Oct. 30, 2013; 78 FR 76217, Dec. 17, 2013; 79 FR 30339, May 27, 2014; 79 FR 59138, Oct. 1, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 94173, Dec. 22, 2016; 82 FR 18381, Apr. 18, 2017; 83 FR 17058, Apr. 17, 2018; 85 FR 37247, June 19, 2020; 86 FR 24285, May 5, 2021; 86 FR 53503, Sept. 27, 2021; 87 FR 27386, May 6, 2022; 89 FR 37703, May 6, 2024]

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (e) of this section, a health insurance issuer offering health insurance coverage in the individual, small group, or large group market is required to renew or continue in force the coverage at the option of the plan sponsor or the individual, as applicable.

(b) *Exceptions.* An issuer may nonrenew or discontinue health insurance coverage offered in the group or individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor or individual, as applicable, has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor or individual, as applicable, has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* In the case of group health insurance coverage, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable state law. For purposes of this paragraph the following apply:

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries.

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(4) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (c) or (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 147.104(c)(1)(i); provided the issuer provides notice in accordance with the requirements of paragraph (c)(1) of this section.

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the bona fide association ceases, but only if the

coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the group or individual market, that product may be discontinued by the issuer in accordance with applicable state law in the applicable market only if the following occurs:

(1) The issuer provides notice in writing, in a form and manner specified by the Secretary, to each plan sponsor or individual, as applicable, provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 calendar days before the date the coverage will be discontinued.

(2) The issuer offers to each plan sponsor or individual, as applicable, provided that particular product the option, on a guaranteed availability basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage in that market.

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* (1) An issuer may elect to discontinue offering all health insurance coverage in the individual, small group, or large group market, or all markets, in a State in accordance with applicable State law only if—

(i) The issuer provides notice in writing to the applicable state authority and to each plan sponsor or individual, as applicable, (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 calendar days prior to the date the coverage will be discontinued; and

(ii) All health insurance policies issued or delivered for issuance in the state in the applicable market (or markets) are discontinued and not renewed.

(2) An issuer that elects to discontinue offering all health insurance coverage in a market (or markets) in a state as described in this paragraph (d) may not issue coverage in the applicable market (or markets) and state involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(3) For purposes of this paragraph (d), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with §144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with §144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (d)(3)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products

for purposes of the process and requirements applied pursuant to paragraph (d)(3)(ii)(B) of this section.

(4) For purposes of this section, the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(e) *Exception for uniform modification of coverage.* (1) Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan or an individual, as applicable, in the following:

(i) Large group market.

(ii) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(iii) Individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraphs (e)(1)(ii) and (iii) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) Other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product in the individual or small group market meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer is a member of a controlled group (as described in paragraph (d)(4) of this section), any other health insurance issuer that is a member of such controlled group);

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the plan-adjusted index rate (as described in §156.80(d)(2) of this subchapter) for any plan within the product within an allowable variation of ±2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (e)(3)(iii) and (iv) of this section.

(f) *Notice of renewal of coverage.* (1) If an issuer in the individual market is renewing non-grandfathered coverage as described in paragraph (a) of this section, or uniformly modifying non-grandfathered coverage as described in paragraph (e) of this section, the issuer must provide to each individual written notice of the renewal before the date of the first day of the next annual open enrollment period in a form and manner specified by the Secretary.

(2) If an issuer in the small group market is renewing coverage as described in paragraph (a) of this section, or uniformly modifying coverage as described in paragraph (e) of this section, the issuer must provide to each plan sponsor written notice of the renewal at least 60 calendar days before the date of the coverage will be renewed in a form and manner specified by the Secretary.

(g) *Notification of change of ownership.* If an issuer of a QHP, a plan otherwise subject to risk corridors, a risk adjustment covered plan, or a reinsurance-eligible plan experiences a change of ownership, as recognized by the State in which the plan is offered, the issuer

must notify HHS in a manner specified by HHS, by the latest of—

(1) The date the transaction is entered into; or

(2) The 30th day prior to the effective date of the transaction.

(h) *Construction.* (1) Nothing in this section should be construed to require an issuer to renew or continue in force coverage for which continued eligibility would otherwise be prohibited under applicable Federal law.

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

(i) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to ''plan sponsor'' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to the employer.

(j) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(k) *Grandfathered health plans.* This section does not apply to grandfathered health plans in accordance with §147.140.

[78 FR 13437, Feb. 27, 2013, as amended at 78 FR 65092, Oct. 30, 2013; 79 FR 30339, May 27, 2014; 79 FR 42985, July 24, 2014; 79 FR 53004, Sept. 5, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 94173, Dec. 22, 2016; 84 FR 17561, Apr. 25, 2019]

§147.108 Prohibition of preexisting condition exclusions.

(a) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in §144.103 of this subchapter).

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* §146.111(a)(2) of this subchapter):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N*. *N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M*. *M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in §146.111(a)(2) of this subchapter for a conclusion that *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(c) *Allowable screenings to determine eligibility for alternative coverage in the individual market*—(1) *In general.* (i) A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage options before offering a child-only policy if—

(A) The practice is permitted under State law;

(B) The screening applies to all child-only applicants, regardless of health status; and

(C) The alternative coverage options include options for which healthy children would potentially be eligible (*e.g.*, Children's Health Insurance Program (CHIP) or group health insurance).

(ii) An issuer must provide such coverage to an applicant effective on the first date that a child-only policy would have been effective had the applicant not been screened for an alternative coverage option, as provided by State law. A State may impose a reasonable time limit by when an issuer would have to enroll a child regardless of pending applications for other coverage.

(2) *Restrictions.* A health insurance issuer offering individual health insurance coverage may screen applicants

for eligibility for alternative coverage provided that:

(i) The screening process does not by its operation significantly delay enrollment or artificially engineer eligibility of a child for a program targeted to individuals with a pre-existing condition;

(ii) The screening process is not applied to offers of dependent coverage for children; or

(ii) The issuer does not consider whether an applicant is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions, as provided under 42 U.S.C. 1396a (25)(G).

(d) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72274, Nov. 18, 2015]

EDITORIAL NOTE: At 80 FR 72284, Nov. 18, 2015, §147.108 was revised to include two paragraphs (c)(2)(ii).

§ 147.110 Prohibiting discrimination against participants, beneficiaries, and individuals based on a health factor.

(a) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must comply with all the requirements under 45 CFR 146.121 applicable to a group health plan and a health insurance issuer offering group health insurance coverage. Accordingly, with respect to an issuer offering health insurance coverage in the individual market, the issuer is subject to the requirements of §146.121 to the same extent as an issuer offering group health insurance coverage, except the exception contained in §146.121(f) (concerning nondiscriminatory wellness programs) does not apply.

(b) *Applicability date.* This section is applicable to group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014. See §147.140, which provides that the rules of this section do not apply to grandfathered health plans that are individual health insurance coverage.

[78 FR 33192, June 3, 2013]

§ 147.116 Prohibition on waiting periods that exceed 90 days.

(a) *General rule.* A group health plan, and a health insurance issuer offering group health insurance coverage, must not apply any waiting period that exceeds 90 days, in accordance with the rules of this section. If, under the terms of a plan, an individual can elect coverage that would begin on a date that is not later than the end of the 90-day waiting period, this paragraph (a) is considered satisfied. Accordingly, in that case, a plan or issuer will not be considered to have violated this paragraph (a) solely because individuals take, or are permitted to take, additional time (beyond the end of the 90-day waiting period) to elect coverage.

(b) *Waiting period defined.* For purposes of this part, a waiting period is the period that must pass before coverage for an individual who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an individual enrolls as a late enrollee (as defined under §144.103 of this subchapter) or special enrollee (as described in §146.117 of this subchapter), any period before such late or special enrollment is not a waiting period.

(c) *Relation to a plan's eligibility criteria*—(1) *In general.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, being otherwise eligible to enroll under the terms of a group health plan means having met the plan's substantive eligibility conditions (such as, for example, being in an eligible job classification, achieving job-related licensure requirements specified in the plan's terms, or satisfying a reasonable and bona fide employment-based orientation period). Moreover, except as provided in paragraphs (c)(2) and (c)(3) of this section, nothing in this section requires a plan sponsor to offer coverage to any particular individual or class of individuals (including, for example, part-time employees). Instead,

this section prohibits requiring otherwise eligible individuals to wait more than 90 days before coverage is effective. *See also* section 4980H of the Code and its implementing regulations for an applicable large employer's shared responsibility to provide health coverage to full-time employees.

(2) *Eligibility conditions based solely on the lapse of time.* Eligibility conditions that are based solely on the lapse of a time period are permissible for no more than 90 days.

(3) *Other conditions for eligibility.* Other conditions for eligibility under the terms of a group health plan are generally permissible under PHS Act section 2708, unless the condition is designed to avoid compliance with the 90-day waiting period limitation, determined in accordance with the rules of this paragraph (c)(3).

(i) *Application to variable-hour employees in cases in which a specified number of hours of service per period is a plan eligibility condition.* If a group health plan conditions eligibility on an employee regularly having a specified number of hours of service per period (or working full-time), and it cannot be determined that a newly-hired employee is reasonably expected to regularly work that number of hours per period (or work full-time), the plan may take a reasonable period of time, not to exceed 12 months and beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date, to determine whether the employee meets the plan's eligibility condition. Except in cases in which a waiting period that exceeds 90 days is imposed in addition to a measurement period, the time period for determining whether such an employee meets the plan's eligibility condition will not be considered to be designed to avoid compliance with the 90-day waiting period limitation if coverage is made effective no later than 13 months from the employee's start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month.

(ii) *Cumulative service requirements.* If a group health plan or health insurance issuer conditions eligibility on an employee's having completed a number of cumulative hours of service, the eligibility condition is not considered to be designed to avoid compliance with the 90-day waiting period limitation if the cumulative hours-of-service requirement does not exceed 1,200 hours.

(iii) *Limitation on orientation periods.* To ensure that an orientation period is not used as a subterfuge for the passage of time, or designed to avoid compliance with the 90-day waiting period limitation, an orientation period is permitted only if it does not exceed one month. For this purpose, one month is determined by adding one calendar month and subtracting one calendar day, measured from an employee's start date in a position that is otherwise eligible for coverage. For example, if an employee's start date in an otherwise eligible position is May 3, the last permitted day of the orientation period is June 2. Similarly, if an employee's start date in an otherwise eligible position is October 1, the last permitted day of the orientation period is October 31. If there is not a corresponding date in the next calendar month upon adding a calendar month, the last permitted day of the orientation period is the last day of the next calendar month. For example, if the employee's start date is January 30, the last permitted day of the orientation period is February 28 (or February 29 in a leap year). Similarly, if the employee's start date is August 31, the last permitted day of the orientation period is September 30.

(d) *Application to rehires.* A plan or issuer may treat an employee whose employment has terminated and who then is rehired as newly eligible upon rehire and, therefore, required to meet the plan's eligibility criteria and waiting period anew, if reasonable under the circumstances (for example, the termination and rehire cannot be a subterfuge to avoid compliance with the 90-day waiting period limitation).

(e) *Counting days.* Under this section, all calendar days are counted beginning on the enrollment date (as defined in §144.103), including weekends and holidays. A plan or issuer that imposes a 90-day waiting period may, for administrative convenience, choose to permit coverage to become effective

earlier than the 91st day if the 91st day is a weekend or holiday.

(f) *Examples.* The rules of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides that full-time employees are eligible for coverage under the plan. Employee *A* begins employment as a full-time employee on January 19.

(ii) *Conclusion.* In this *Example 1,* any waiting period for *A* would begin on January 19 and may not exceed 90 days. Coverage under the plan must become effective no later than April 19 (assuming February lasts 28 days).

Example 2. (i) *Facts.* A group health plan provides that only employees with job title *M* are eligible for coverage under the plan. Employee *B* begins employment with job title *L* on January 30.

(ii) *Conclusion.* In this *Example 2, B* is not eligible for coverage under the plan, and the period while *B* is working with job title *L* and therefore not in an eligible class of employees, is not part of a waiting period under this section.

Example 3. (i) *Facts.* Same facts as in *Example 2,* except that *B* transfers to a new position with job title *M* on April 11.

(ii) *Conclusion.* In this *Example 3, B* becomes eligible for coverage on April 11, but for the waiting period. Any waiting period for *B* begins on April 11 and may not exceed 90 days; therefore, coverage under the plan must become effective no later than July 10.

Example 4. (i) *Facts.* A group health plan provides that only employees who have completed specified training and achieved specified certifications are eligible for coverage under the plan. Employee *C* is hired on May 3 and meets the plan's eligibility criteria on September 22.

(ii) *Conclusion.* In this *Example 4, C* becomes eligible for coverage on September 22, but for the waiting period. Any waiting period for *C* would begin on September 22 and may not exceed 90 days; therefore, coverage under the plan must become effective no later than December 21.

Example 5. (i) *Facts.* A group health plan provides that employees are eligible for coverage after one year of service.

(ii) *Conclusion.* In this *Example 5,* the plan's eligibility condition is based solely on the lapse of time and, therefore, is impermissible under paragraph (c)(2) of this section because it exceeds 90 days.

Example 6. (i) *Facts.* Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period on or after the date an employee is hired and completes the applicable enrollment forms. Enrollment forms are distributed on an employee's start date and may be completed within 90 days. Employee *D* is hired and starts on October 31, which is the first day of a pay period. *D* completes the enrollment forms and submits them on the 90th day after *D*'s start date, which is January 28. Coverage is made effective 7 days later, February 4, which is the first day of the next pay period.

(ii) *Conclusion.* In this *Example 6,* under the terms of *V*'s plan, coverage may become effective as early as October 31, depending on when *D* completes the applicable enrollment forms. Under the terms of the plan, when coverage becomes effective depends solely on the length of time taken by *D* to complete the enrollment materials. Therefore, under the terms of the plan, *D* may elect coverage that would begin on a date that does not exceed the 90-day waiting period limitation, and the plan complies with this section.

Example 7. (i) *Facts.* Under Employer *W*'s group health plan, only employees who are full-time (defined under the plan as regularly averaging 30 hours of service per week) are eligible for coverage. Employee *E* begins employment for Employer *W* on November 26 of Year 1. *E*'s hours are reasonably expected to vary, with an opportunity to work between 20 and 45 hours per week, depending on shift availability and *E*'s availability. Therefore, it cannot be determined at *E*'s start date that *E* is reasonably expected to work full-time. Under the terms of the plan, variable-hour employees, such as *E,* are eligible to enroll in the plan if they are determined to be a full-time employee after a measurement period of 12 months that begins on the employee's start date. Coverage is made effective no later than the first day of the first calendar month after the applicable enrollment forms are received. *E*'s 12-month measurement period ends November 25 of Year 2. *E* is determined to be a full-time employee and is notified of *E*'s plan eligibility. If *E* then elects coverage, *E*'s first day of coverage will be January 1 of Year 3.

(ii) *Conclusion.* In this *Example 7,* the measurement period is permissible because it is not considered to be designed to avoid compliance with the 90-day waiting period limitation. The plan may use a reasonable period of time to determine whether a variable-hour employee is a full-time employee, provided that (a) the period of time is no longer than 12 months; (b) the period of time begins on a date between the employee's start date and the first day of the next calendar month (inclusive); (c) coverage is made effective no later than 13 months from *E*'s start date plus, if the employee's start date is not the first day of a calendar month, the time remaining until the first day of the next calendar month; and (d) in addition to the measurement period, no more than 90 days elapse prior to the employee's eligibility for coverage.

Example 8. (i) *Facts.* Employee *F* begins working 25 hours per week for Employer *X* on January 6 and is considered a part-time employee for purposes of *X*'s group health

plan. *X* sponsors a group health plan that provides coverage to part-time employees after they have completed a cumulative 1,200 hours of service. *F* satisfies the plan's cumulative hours of service condition on December 15.

(ii) *Conclusion.* In this *Example 8*, the cumulative hours of service condition with respect to part-time employees is not considered to be designed to avoid compliance with the 90-day waiting period limitation. Accordingly, coverage for *F* under the plan must begin no later than the 91st day after *F* completes 1,200 hours. (If the plan's cumulative hours-of-service requirement was more than 1,200 hours, the requirement would be considered to be designed to avoid compliance with the 90-day waiting period limitation.)

Example 9. (i) *Facts.* A multiemployer plan operating pursuant to an arms-length collective bargaining agreement has an eligibility provision that allows employees to become eligible for coverage by working a specified number of hours of covered employment for multiple contributing employers. The plan aggregates hours in a calendar quarter and then, if enough hours are earned, coverage begins the first day of the next calendar quarter. The plan also permits coverage to extend for the next full calendar quarter, regardless of whether an employee's employment has terminated.

(ii) *Conclusion.* In this *Example 9*, these eligibility provisions are designed to accommodate a unique operating structure, and, therefore, are not considered to be designed to avoid compliance with the 90-day waiting period limitation, and the plan complies with this section.

Example 10. (i) *Facts.* Employee *G* retires at age 55 after 30 years of employment with Employer *Y* with no expectation of providing further services to Employer *Y*. Three months later, *Y* recruits *G* to return to work as an employee providing advice and transition assistance for *G*'s replacement under a one-year employment contract. *Y*'s plan imposes a 90-day waiting period from an employee's start date before coverage becomes effective.

(ii) *Conclusion.* In this *Example 10*, *Y*'s plan may treat *G* as newly eligible for coverage under the plan upon rehire and therefore may impose the 90-day waiting period with respect to *G* for coverage offered in connection with *G*'s rehire.

Example 11. (i) *Facts.* Employee *H* begins working full time for Employer *Z* on October 16. *Z* sponsors a group health plan, under which full time employees are eligible for coverage after they have successfully completed a bona fide one-month orientation period. *H* completes the orientation period on November 15.

(ii) *Conclusion.* In this *Example 11*, the orientation period is not considered a subterfuge for the passage of time and is not considered to be designed to avoid compliance with the 90-day waiting period limitation. Accordingly, plan coverage for *H* must begin no later than February 14, which is the 91st day after *H* completes the orientation period. (If the orientation period was longer than one month, it would be considered to be a subterfuge for the passage of time and designed to avoid compliance with the 90-day waiting period limitation. Accordingly it would violate the rules of this section.)

(g) *Special rule for health insurance issuers.* To the extent coverage under a group health plan is insured by a health insurance issuer, the issuer is permitted to rely on the eligibility information reported to it by the employer (or other plan sponsor) and will not be considered to violate the requirements of this section with respect to its administration of any waiting period, if both of the following conditions are satisfied:

(1) The issuer requires the plan sponsor to make a representation regarding the terms of any eligibility conditions or waiting periods imposed by the plan sponsor before an individual is eligible to become covered under the terms of the plan (and requires the plan sponsor to update this representation with any changes), and

(2) The issuer has no specific knowledge of the imposition of a waiting period that would exceed the permitted 90-day period.

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of State or Federal law (including ERISA, the Code, or other provisions of the Patient Protection and Affordable Care Act). *See e.g.*, §146.121 of this subchapter and §147.110, which prohibits discrimination in eligibility for coverage based on a health factor and Code section 4980H, which generally requires applicable large employers to offer coverage to full-time employees and their dependents or make an assessable payment.

(i) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2015. *See* §147.140 providing that the prohibition on waiting periods exceeding 90 days applies to all group health plans and

group health insurance issuers, including grandfathered health plans.

[79 FR 10315, Feb. 24, 2014, as amended at 79 FR 35948, June 25, 2014]

§ 147.120 Eligibility of children until at least age 26.

(a) *In general.* (1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example*, the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent*—(1) *In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or primary subscriber, or any other person); residency with the participant (in the individual market, the primary subscriber) or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits dependent child coverage to children under age 26 who are described in section 152(f)(1) of the Code. For an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1*, the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3*, the plan violates the requirement of paragraph (d) of this section because the plan, by limiting

children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4,* the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72275, Nov. 18, 2015]

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term ''essential health benefits'' means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For the purpose of this section, a group health plan or a health insurance issuer that is not required to provide essential health benefits under section 1302(b) must define ''essential health benefits'' in a manner that is consistent with the following:

(1) For plan years beginning before January 1, 2020, one of the EHB-benchmark plans applicable in a State under §156.110 of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with §155.170(a)(2) of this subchapter, or one

of the three Federal Employees Health Benefits Program (FEHBP) plan options as defined by §156.100(a)(3) of this subchapter, supplemented as necessary, to satisfy the standards in §156.110 of this subchapter; or

(2) For plan years beginning on or after January 1, 2020, an EHB-benchmark plan selected by a State in accordance with the available options and requirements for EHB-benchmark plan selection at §156.111 of this subchapter, including an EHB-benchmark plan in a State that takes no action to change its EHB-benchmark plan and thus retains the EHB-benchmark plan applicable in that State for the prior year in accordance with §156.111(d)(1) of this subchapter, and including coverage of any additional required benefits that are considered essential health benefits consistent with §155.170(a)(2) of this subchapter.

(d) *Health reimbursement arrangements (HRAs) and other account-based group health plans*—(1) *In general.* If an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2711 and paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2711 and paragraph (a)(2) of this section. Similarly, if an HRA or other account-based group health plan is integrated with another group health plan or individual health insurance coverage and the other group health plan or individual health insurance coverage, as applicable, separately is subject to and satisfies the requirements in PHS Act section 2713 and §147.130(a)(1) of this subchapter, the fact that the benefits under the HRA or other account-based group health plan are limited does not cause the HRA or other account-based group health plan to fail to satisfy the requirements of PHS Act section 2713 and §147.130(a)(1) of this subchapter. For the purpose of this paragraph (d), all individual health insurance coverage, except for coverage that consists solely of excepted benefits, is treated as being subject to and complying with PHS Act sections 2711 and 2713.

(2) *Requirements for an HRA or other account-based group health plan to be integrated with another group health plan.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section if it satisfies the requirements under one of the integration methods set forth in paragraph (d)(2)(i) or (ii) of this section. For purposes of the integration methods under which an HRA or other account-based group health plan is integrated with another group health plan, integration does not require that the HRA or other account-based group health plan and the other group health plan with which it is integrated share the same plan sponsor, the same plan document or governing instruments, or file a single Form 5500, if applicable. An HRA or other account-based group health plan integrated with another group health plan for purposes of PHS Act section 2711 and paragraph (a)(2) of this section may not be used to purchase individual health insurance coverage unless that coverage consists solely of excepted benefits, as defined in §148.220 of this subchapter.

(i) *Method for integration with a group health plan: Minimum value not required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are enrolled in non-

HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based group health plan are limited to reimbursement of one or more of the following—co-payments, co-insurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care expenses that do not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(ii) *Method for integration with another group health plan: Minimum value required.* An HRA or other account-based group health plan is integrated with another group health plan for purposes of this paragraph (d) if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan) to the employee that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based group health plan is actually enrolled in a group health plan (other than the HRA or other account-based group health plan) that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based group health plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based group health plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based group health plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based group health plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based group health plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based group health plan (see paragraph (d)(3) of this section for additional rules regarding forfeiture and waiver).

(3) *Forfeiture.* For purposes of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For the purpose of this paragraph (d)(3), coverage under an HRA or other account-based group health plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based group health plan. This

means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based group health plan may not be used to reimburse or pay medical care expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *Requirements for an HRA or other account-based group health plan to be integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C.* An HRA or other account-based group health plan is integrated with individual health insurance coverage or Medicare Part A and B or Medicare Part C (and treated as complying with PHS Act sections 2711 and 2713) if the HRA or other account-based group health plan satisfies the requirements of §146.123(c) of this subchapter (as modified by §146.123(e), for HRAs or other account-based group health plans integrated with Medicare Part A and B or Medicare Part C).

(5) *Integration with Medicare Part B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based group health plan that may be used to reimburse premiums under Medicare Part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based group health plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based group health plan is actually enrolled in Medicare Part B or D;

(iii) The HRA or other account-based group health plan is available only to employees who are enrolled in Medicare Part B or D; and

(iv) The HRA or other account-based group health plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Definitions.* The following definitions apply for purposes of this section.

(i) *Account-based group health plan.* An account-based group health plan is an employer-provided group health plan that provides reimbursements of medical care expenses with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based group health plan. An account-based group health plan does not include a qualified small employer health reimbursement arrangement, as defined in section 9831(d)(2) of the Code.

(ii) *Medical care expenses.* Medical care expenses means expenses for medical care as defined under section 213(d) of the Code.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2020. Until the applicability date for this section, plans and issuers are required to continue to comply with the corresponding sections of this subchapter B, contained in the 45 CFR, subtitle A, parts 1–199, revised as of October 1, 2018.

[80 FR 72276, Nov. 18, 2015, as amended at 81 FR 75326, Oct. 31, 2016; 84 FR 29025, June 20, 2019]

§147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30

days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if —

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively, to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to §155.430 of this subchapter (other than under paragraph (b)(2)(iii) of this section).

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146 of this subchapter. The questionnaire includes the following question: ''Is there anything else relevant to your health that we should know?'' *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1*, the plan cannot rescind *A*'s coverage because *A*'s failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B*. After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B*'s coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2*, the plan cannot rescind *B*'s coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72277, Nov. 18, 2015]

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID–19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

(B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

(2) *Office visits.* (i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a

rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* (i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the

frequency, method, treatment, or setting for coverage of a recommended preventive health service.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing.* (1) A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) *Changes in recommendations or guidelines.* (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

(ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a ''D'' rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

(3) *Rapid coverage of preventive services for coronavirus.* In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* §147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

(e) *Sunset date.* The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as

a result of COVID–19, including any subsequent renewals of that determination.

[75 FR 41759, July 19, 2010, as amended at 76 FR 46626, Aug. 3, 2011; 78 FR 39896, July 2, 2013; 80 FR 41346, July 14, 2015; 82 FR 47833, 47861, Oct. 13, 2017; 85 FR 71202, Nov. 6, 2020]

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in §147.132(a)(1)(i) or (ii), or 45 CFR 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under §147.132(a) or §147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule.* If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and §147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule.* In plan years that begin after January 14, 2019, if contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in §147.132 or §147.133 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with §147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in §147.132 or §147.133 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to

which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of §147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in §147.132 or §147.133 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under §141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under §147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) ''Your [employer/institution of higher education] has

certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments . If you have any questions about this notice, contact [contact information for health insurance issuer].''

(f) *Reliance.* (1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(g) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of §147.130(a)(1)(iv).

(h) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47833, Oct. 13, 2017, as amended at 82 FR 47861, Oct. 13, 2017; 83 FR 57589, Nov. 15, 2018]

§147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan

sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in §147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of §147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47835, Oct. 13, 2017, as amended at 83 FR 57590, Nov. 15, 2018]

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in §147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[82 FR 47861, Oct. 13, 2017, as amended at 83 FR 57630, Nov. 15, 2018]

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*—(i) *In general.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(ii) *Application to grandfathered health plans and health insurance coverage.* The provisions of this section generally do not apply to coverage offered by health insurance issuers and group health plans that are grandfathered health plans, as defined under § 147.140. However, the external review process requirements under paragraphs (c) and (d) of this section, and related notice requirements under paragraph (e) of this section, apply to grandfathered health plans or coverage with respect to adverse benefit determinations involving items and services within the scope of the requirements for out-of-network emergency services, nonemergency services performed by nonparticipating providers at participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the

deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim;

such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants, beneficiaries and enrollees, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the

case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503–1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503–1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of

this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the issuer shall notify the claimant of the issuer's determination as soon as an issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) Avoiding conflicts of interest. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(3)(ii)(E).

(*1*) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the

name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(*2*) Notwithstanding paragraph (b)(3)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(*1*) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, as well as a consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections under PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived

the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise

providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant, beneficiary, or enrollee is entitled to a reasonable alternative standard for a reward under a wellness program; its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of PHS Act section 2726 and §§ 146.136 and 147.160, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant, beneficiary, or enrollee fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d));

(B) An adverse benefit determination that involves consideration of whether a plan or issuer is complying with the surprise billing and cost-sharing protections set forth in PHS Act sections 2799A–1 and 2799A–2 and §§ 149.110 through 149.130; and

(C) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

Example 1 —(i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2 —(i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network

provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

Example 3 —(i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *C* receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under §149.110 do not apply because the treatment did not involve ''emergency services'' within the meaning of §149.110(c)(2)(i). *C* receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

(ii) *Conclusion.* In this *Example 3,* the plan's determination that treatment received by *C* did not include emergency services involves medical judgment and consideration of whether the plan complied with §149.110. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 4 —(i) *Facts.* A group health plan generally provides benefits for anesthesiology services. Individual *D* undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under §149.120. As a result, *D* receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of §149.120.

(ii) *Conclusion.* In this *Example 4,* whether the plan was required to decide the claim in a manner consistent with the requirements of §149.120 involves considering whether the plan complied with §149.120, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 5 —(i) *Facts.* A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual *E* receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the post-stabilization services as not being for emergency services under §149.110(c)(2)(ii) based on representations made by the treating provider that *E* was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. *E* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with §149.110.

(ii) *Conclusion.* In this *Example 5,* whether *E* was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under §149.110(c)(2)(ii). Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

Example 6 —(i) *Facts.* Individual *F* gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a non-participating provider during the same visit as the birth. *F* was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under §149.120(a) and the fact that those protections may not be waived for neonatology services under §149.120(b).

(ii) *Conclusion.* In this *Example 6,* medical judgment is necessary to determine whether the correct code was used and compliance with §149.120(a) and (b) must also be considered. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. The Departments also note

that, to the extent the nonparticipating provider balance bills Individual *F* for the outstanding amounts not paid by the plan for the neonatology services, such provider would be in violation of PHS Act section 2799B–2 and its implementing regulations at 45 CFR 149.420(a).

Example 7 —(i) *Facts.* A group health plan generally provides benefits to cover knee replacement surgery. Individual *G* receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under §149.120(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under §149.120(b). *G* receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with §149.120(a) and (b).

(ii) *Conclusion.* In this *Example 7*, consideration of whether the plan complied with the requirements in §149.120(a) and (b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.*, worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer

must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's

decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or

health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section and a self-insured nonfederal governmental plan may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section generally are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. The external review scope provision at paragraph (d)(1)(i)(B) of this section is applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022. The external review provisions described in paragraphs (c) and (d) of this section are applicable to grandfathered health plans and grandfathered individual market policies, with respect to the types of claims specified under paragraph (a)(1)(ii) of this section, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

[80 FR 72278, Nov. 18, 2015, as amended at 86 FR 56122, Oct. 7, 2021]

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example —(i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in

the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1 —(i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2 —(i) *Facts.* Same facts as *Example 1,* except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with

respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1 —(i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

Example 2 —(i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C*, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3 —(i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4 —(i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or

your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A),(B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with

in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards.* (A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant, beneficiary, or enrollee from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant, beneficiary, or enrollee adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant, beneficiary, or enrollee.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1 —(i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2 —(i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3 —(i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4 —(i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5 —(i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6 —(i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an

average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize*, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning before January 1, 2022. *See also* subparts B and D of part 149 of this subchapter for rules applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

[80 FR 72286, Nov. 18, 2015, as amended at 86 FR 36970, July 13, 2021]

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status.* (i) To maintain status as a grandfathered

health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

> This [group health plan or health insurance issuer] believes this [plan or coverage] is a ''grandfathered health plan'' under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.
>
> Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/healthreform*. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthcare.gov*.]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*—(1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status.

(2) *Anti-abuse rules*—(i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of this paragraph (b)(2)(ii)(C), bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G*. During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G*.

(ii) *Conclusion.* In this *Example 1*, the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I*. On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option *H* and the employees that are moved are transferred to Option *I*. If instead of transferring employees from Option *H* to Option *I*, Option *H* was amended to match the terms of Option *I*, then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I*. Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule.* (1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the

Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage.* (1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraphs (g)(2) and (3) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that results in a change described in this paragraph (g)(1) becomes effective, regardless of when the amendment was adopted. Once grandfather status is lost, it cannot be regained.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For

this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. Whether or not a plan or coverage has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services provided for a particular condition under the plan on March 23, 2010, as compared to the benefits offered at the time the plan or coverage makes the benefit change effective.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, and determined for each copayment level if a plan has different copayment levels for different categories of services, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(4)(i) of this section (that is, $5 times medical inflation, plus $5); or

(B) The maximum percentage increase (as defined in paragraph (g)(4)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(4)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in §146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(4)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in §146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group or individual health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. (But see §147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* Grandfathered individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or

health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits). (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Special rule for certain grandfathered high deductible health plans.* With respect to a grandfathered group health plan or group health insurance coverage that is a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, increases to fixed-amount cost-sharing requirements made effective on or after June 15, 2021 that otherwise would cause a loss of grandfather status will not cause the plan or coverage to relinquish its grandfather status, but only to the extent such increases are necessary to maintain its status as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

(4) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor

using the 1982–1984 base of 100. For purposes of this paragraph (g)(4)(i), the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means:

(A) With respect to increases for a group health plan and group health insurance coverage made effective on or after March 23, 2010, and before June 15, 2021, medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points;

(B) With respect to increases for a group health plan and group health insurance coverage made effective on or after June 15, 2021, the greater of:

(*1*) Medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points; or

(*2*) The portion of the premium adjustment percentage, as defined in §156.130(e) of this subchapter, that reflects the relative change between 2013 and the calendar year prior to the effective date of the increase (that is, the premium adjustment percentage minus 1), expressed as a percentage, plus 15 percentage points; and

(C) With respect to increases for individual health insurance coverage, medical inflation (as defined in paragraph (g)(4)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(5) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1,* the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2,* the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40, effective before June 15, 2021. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed

37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3* of this paragraph (g)(5), except the grandfathered group health plan subsequently increases the $40 copayment requirement to $45 for a later plan year, effective before June 15, 2021. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 (5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* Same facts as *Example 4* of this paragraph (g)(5), except the grandfathered group health plan increases the copayment requirement to $45, effective *after* June 15, 2021. The greatest value of the overall medical care component of the CPI–U (unadjusted) in the preceding 12-month period is still 485. In the calendar year that includes the effective date of the increase, the applicable portion of the premium adjustment percentage is 36%.

(ii) *Conclusion.* In this *Example 5,* the grandfathered health plan may increase the copayment by the greater of: Medical inflation, expressed as a percentage, plus 15 percentage points; or the applicable portion of the premium adjustment percentage for the calendar year that includes the effective date of the increase, plus 15 percentage points. The latter amount is greater because it results in a 51% maximum percentage increase (36% + 15% = 51%) and, as demonstrated in *Example 4* of this paragraph (g)(5), determining the maximum percentage increase using medical inflation yields a result of 40.27%. The increase in the copayment, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Because the 50% increase in the copayment is less than the 51% maximum percentage increase, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 6. (i) *Facts.* On March 23, 2010, a grandfathered group health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15, effective before June 15, 2021. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 6,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a group plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20%), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) of this section, which would permit an increase in the copayment of up to $5.36.

Example 7. (i) *Facts.* Same facts as *Example 6* of this paragraph (g)(5), except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently, amended to increase the copayment requirement to $5, effective before June 15, 2021.

(ii) *Conclusion.* In this *Example 7,* medical inflation (as defined in paragraph (g)(4)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 7* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 8,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 9. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for

family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000 − 1,000)/5,000) for self-only coverage and 67% ((12,000 − 4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000 − 1,200)/6,000) for self-only coverage and 67% ((15,000 − 5,000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 9,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 10. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 10,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

Example 11. (i) *Facts.* A group health plan that is a grandfathered health plan and also a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code had a $2,400 deductible for family coverage on March 23, 2010. The plan is subsequently amended after June 15, 2021 to increase the deductible limit by the amount that is necessary to comply with the requirements for a plan to qualify as a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code, but that exceeds the maximum percentage increase.

(ii) *Conclusion.* In this *Example 11,* the increase in the deductible at that time does not cause the plan to cease to be a grandfathered health plan because the increase was necessary for the plan to continue to satisfy the definition of a high deductible health plan under section 223(c)(2)(A) of the Internal Revenue Code.

[80 FR 72289, Nov. 18, 2015, as amended at 85 FR 81120, Dec. 15, 2020]

§ 147.145 Student health insurance coverage.

(a) *Definition.* Student health insurance coverage is a type of individual health insurance coverage (as defined in § 144.103 of this subchapter) that is provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students enrolled in that institution of higher education and their dependents, that meets the following conditions:

(1) Does not make health insurance coverage available other than in connection with enrollment as a student (or as a dependent of a student) in the institution of higher education.

(2) Does not condition eligibility for the health insurance coverage on any health status-related factor (as defined in § 146.121(a) of this subchapter) relating to a student (or a dependent of a student).

(3) Meets any additional requirement that may be imposed under State law.

(b) *Exemptions from the Public Health Service Act and the Affordable Care Act—*(1) *Guaranteed availability and guaranteed renewability.* (i) For purposes of sections 2741(e)(1) and 2742(b)(5) of the Public Health Service Act, student health insurance coverage is deemed to be available only through a bona fide association.

(ii) For purposes of section 2702 of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to accept individuals who are not students or dependents of students in such coverage, and, notwithstanding the requirements of § 147.104(b), is not required to establish open enrollment periods or coverage effective dates that are based on a calendar policy year or to offer policies on a calendar year basis.

(iii) For purposes of section 2703(a) of the Public Health Service Act, a health insurance issuer that offers student health insurance coverage is not required to renew or continue in force coverage for individuals who are no longer students or dependents of students.

(2) *Levels of coverage.* The requirement to provide a specific level of coverage described in section 1302(d) of the Affordable Care Act does not apply to student health insurance coverage for policy years beginning on or after July 1, 2016. However, the benefits provided by such coverage must provide at least 60 percent actuarial value, as calculated in accordance with §156.135 of this subchapter. The issuer must specify in any plan materials summarizing the terms of the coverage the actuarial value and level of coverage (or next lowest level of coverage) the coverage would otherwise satisfy under §156.140 of this subchapter.

(3) *Single risk pool.* Student health insurance coverage is not subject to the requirements of section 1312(c) of the Affordable Care Act. A health insurance issuer that offers student health insurance coverage may establish one or more separate risk pools for an institution of higher education, if the distinction between or among groups of students (or dependents of students) who form the risk pool is based on a bona fide school-related classification and not based on a health factor (as described in §146.121 of this subchapter). However, student health insurance rates must reflect the claims experience of individuals who comprise the risk pool, and any adjustments to rates within a risk pool must be actuarially justified.

(c) *Student administrative health fees*—(1) *Definition.* A student administrative health fee is a fee charged by the institution of higher education on a periodic basis to students of the institution of higher education to offset the cost of providing health care through health clinics regardless of whether the students utilize the health clinics or enroll in student health insurance coverage.

(2) *Preventive services.* Notwithstanding the requirements under section 2713 of the Public Health Service Act and its implementing regulations, student administrative health fees as defined in paragraph (c)(1) of this section are not considered cost-sharing requirements with respect to specified recommended preventive services.

[77 FR 16468, Mar. 21, 2012, as amended at 78 FR 13439, Feb. 27, 2013; 79 FR 13834, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016]

§147.150 Coverage of essential health benefits.

(a) *Requirement to cover the essential health benefits package.* A health insurance issuer offering health insurance coverage in the individual or small group market must ensure that such coverage includes the essential health benefits package as defined in section 1302(a) of the Affordable Care Act effective for plan or policy years beginning on or after January 1, 2014.

(b) *Cost-sharing under group health plans.* [Reserved]

(c) *Child-only plans.* If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d)(1) of the Affordable Care Act, the issuer must offer coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

[78 FR 12865, Feb. 25, 2013]

§147.160 Parity in mental health and substance use disorder benefits.

(a) *In general.* The provisions of §146.136 of this subchapter apply to health insurance coverage offered by health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after the applicability dates set forth in §146.136(i) of this subchapter. This section applies to nongrandfathered and grandfathered health plans as defined in §147.140.

[78 FR 68296, Nov. 13, 2013]

EFFECTIVE DATE NOTE: At 89 FR 77751, Sept. 23, 2024, §147.160 was revised, effective Nov. 22, 2024. For the convenience of the user, the revised text is set forth as follows:

§ 147.160 Parity in mental health and substance use disorder benefits.

(a) *In general.* The provisions of §§146.136 and 146.137 of this subchapter apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after January 1, 2026. Until the applicability date in the preceding sentence, issuers are required to continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023. This section applies to non-grandfathered and grandfathered health plans as defined in §147.140.

§ 147.200 Summary of benefits and coverage and uniform glossary.

(a) *Summary of benefits and coverage*—(1) *In general.* A group health plan (and its administrator as defined in section 3(16)(A) of ERISA)), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) *SBC provided by a group health insurance issuer to a group health plan*—(A) *Upon application.* A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If an SBC was provided before application pursuant to paragraph (a)(1)(i)(D) of this section (relating to SBCs upon request), this paragraph (a)(1)(i)(A) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information required, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(i)(A).

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) *Upon renewal, reissuance, or reenrollment.* If the issuer renews or reissues a policy, certificate, or contract of insurance for a succeeding policy year, or automatically re-enrolls the policyholder or its participants and beneficiaries in coverage, the issuer must provide a new SBC as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) *SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries*—(A) *In general.* A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with the rules of paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) *Upon application.* The SBC must be provided as part of any written application materials that are distributed by the plan or issuer for enrollment. If the plan or issuer does not distribute written application materials for enrollment, the SBC must be provided no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries. If an SBC was provided before application pursuant to paragraph (a)(1)(ii)(F) of this section (relating to SBCs upon request), this paragraph (a)(1)(ii)(B) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information that is required to be in the SBC, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(ii)(B).

(C) *By first day of coverage (if there are changes).* (*1*) If there is any change to the information required to be in the SBC that was provided upon application and before the first day of coverage, the plan or issuer must update and provide a current SBC to a participant or beneficiary no later than the first day of coverage.

(*2*) If the plan sponsor is negotiating coverage terms after an application has been filed and the information required to be in the SBC changes, the plan or issuer is not required to provide an updated SBC (unless an updated SBC is requested) until the first day of coverage.

(D) *Special enrollees.* The plan or issuer must provide the SBC to special enrollees (as described in §146.117 of this subchapter) no later than the date by which a summary plan description is required to be provided under the timeframe set forth in ERISA section 104(b)(1)(A) and its implementing regulations, which is 90 days from enrollment.

(E) *Upon renewal, reissuance, or re-enrollment.* If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), or automatically re-enrolls participants and beneficiaries in coverage, the plan or issuer must provide a new SBC, as follows:

(*1*) If written application is required for renewal, reissuance, or reenrollment (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) *Upon request.* A plan or issuer must provide the SBC to participants or beneficiaries upon request for an SBC or summary information about the health coverage, as soon as practicable, but in no event later than seven business days following receipt of the request.

(iii) *Special rules to prevent unnecessary duplication with respect to group health coverage.* (A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual. An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual that contracts with another party to provide such SBC is considered to satisfy the requirement to provide such SBC if:

(*1*) The entity monitors performance under the contract;

(*2*) If the entity has knowledge that the SBC is not being provided in a manner that satisfies the requirements of this section and the entity has all information necessary to correct the

noncompliance, the entity corrects the noncompliance as soon as practicable; and

(*3*) If the entity has knowledge the SBC is not being provided in a manner that satisfies the requirements of this section and the entity does not have all information necessary to correct the noncompliance, the entity communicates with participants and beneficiaries who are affected by the noncompliance regarding the noncompliance, and begins taking significant steps as soon as practicable to avoid future violations.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address, then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. However, if a beneficiary's last known address is different than the participant's last known address, a separate SBC is required to be provided to the beneficiary at the beneficiary's last known address.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically to participants and beneficiaries upon renewal or reenrollment only with respect to the benefit package in which a participant or beneficiary is enrolled (or will be automatically re-enrolled under the plan); SBCs are not required to be provided automatically upon renewal or reenrollment with respect to benefit packages in which the participant or beneficiary is not enrolled (or will not automatically be enrolled). However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(D) Subject to paragraph (a)(2)(ii) of this section, a plan administrator of a group health plan that uses two or more insurance products provided by separate health insurance issuers with respect to a single group health plan may synthesize the information into a single SBC or provide multiple partial SBCs provided that all the SBC include the content in paragraph (a)(2)(iii) of this section.

(iv) *SBC provided by a health insurance issuer offering individual health insurance coverage*—(A) *Upon application.* A health insurance issuer offering individual health insurance coverage must provide an SBC to an individual covered under the policy (including every dependent) upon receiving an application for any health insurance policy, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application. If an SBC was provided before application pursuant to paragraph (a)(1)(iv)(D) of this section (relating to SBCs upon request), this paragraph (a)(1)(iv)(A) is deemed satisfied, provided there is no change to the information required to be in the SBC. However, if there has been a change in the information that is required to be in the SBC, a new SBC that includes the changed information must be provided upon application pursuant to this paragraph (a)(1)(iv)(A).

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the individual no later than the first day of coverage.

(C) *Upon renewal, reissuance, or reenrollment.* If the issuer renews or reissues a policy, certificate, or contract of insurance for a succeeding policy year, or automatically re-enrolls an individual (or dependent) covered under a policy, certificate, or contract of insurance into a policy, certificate, or contract of insurance under a different plan or product, the issuer must provide an SBC for the coverage in which the individual (including every dependent) will be enrolled, as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal, reissuance, or reenrollment, the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal, reissuance, or reenrollment is automatic, the SBC must be provided no later than 30 days prior to the first day of the new policy year; however, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30 day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* A health insurance issuer offering individual health insurance coverage must provide an SBC to any individual or dependent upon request for an SBC or summary information about a health insurance product as soon as practicable, but in no event later than seven business days following receipt of the request.

(v) *Special rule to prevent unnecessary duplication with respect to individual health insurance coverage*—(A) *In general.* If a single SBC is provided to an individual and any dependents at the individual's last known address, then the requirement to provide the SBC to the individual and any dependents is generally satisfied. However, if a dependent's last known address is different than the individual's last known address, a separate SBC is required to be provided to the dependent at the dependents' last known address.

(B) *Student health insurance coverage.* With respect to student health insurance coverage as defined at §147.145(a), the requirement to provide an SBC to an individual will be considered satisfied for an entity if another party provides a timely and complete SBC to the individual. An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual that contracts with another party to provide such SBC is considered to satisfy the requirement to provide such SBC if:

(*1*) The entity monitors performance under the contract;

(*2*) If the entity has knowledge that the SBC is not being provided in a manner that satisfies the requirements of this section and the entity has all information necessary to correct the noncompliance, the entity corrects the noncompliance as soon as practicable; and

(*3*) If the entity has knowledge the SBC is not being provided in a manner that satisfies the requirements of this section and the entity does not have all information necessary to correct the noncompliance, the entity communicates with covered individuals and dependents who are affected by the noncompliance regarding the noncompliance, and begins taking significant steps as soon as practicable to avoid future violations.

(2) *Content*—(i) *In general.* Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(A) Uniform definitions of standard insurance terms and medical terms so that consumers may compare health coverage and understand the terms of (or exceptions to) their coverage, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with the rules of paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) and whether the plan's or coverage's share of the total allowed costs of benefits provided under the plan or coverage meets applicable requirements;

(H) A statement that the SBC is only a summary and that the plan document, policy, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions;

(J) For issuers, an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained;

(K) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(L) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage;

(M) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available; and

(N) For qualified health plans sold through an individual market Exchange that exclude or provide for coverage of the services described in §156.280(d)(1) or (2) of this subchapter, a notice of coverage or exclusion of such services.

(ii) *Coverage examples.* The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) *Number of examples.* The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) *Benefits scenarios.* For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions, including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) *Illustration of benefit provided.* For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the plan, policy, or benefit package. The illustration of benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) *Coverage provided outside the United States.* In lieu of summarizing coverage for items and services provided outside the United States, a plan or issuer may provide an Internet address (or similar contact information) for obtaining information about benefits and coverage provided outside the United States. In any case, the plan or issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) *Appearance.* (i) A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee (or, in the case of individual market coverage, the average individual covered under a health insurance policy), not exceed four double-sided pages in length, and not include print smaller than 12-point font. A health insurance issuer offering individual health insurance coverage must provide the SBC as a stand-alone document.

(ii) A group health plan that utilizes two or more benefit packages (such as major medical coverage and a health flexible spending arrangement) may synthesize the information into a single SBC, or provide multiple SBCs.

(4) *Form.* (i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied—

(A) The format is readily accessible by the plan (or its sponsor);

(B) The SBC is provided in paper form free of charge upon request; and

(C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the requirements of this paragraph (a)(4)(ii) are met.

(A) With respect to participants and beneficiaries covered under the plan or coverage, the SBC may be provided electronically as described in this paragraph (a)(4)(ii)(A). However, in all cases, the plan or issuer must provide the SBC in paper form if paper form is requested.

(*1*) In accordance with the Department of Labor's disclosure regulations at 29 CFR 2520.104b–1;

(*2*) In connection with online enrollment or online renewal of coverage under the plan; or

(*3*) In response to an online request made by a participant or beneficiary for the SBC.

(B) With respect to participants and beneficiaries who are eligible but not enrolled for coverage, the SBC may be provided electronically if:

(*1*) The format is readily accessible;

(*2*) The SBC is provided in paper form free of charge upon request; and

(*3*) In a case in which the electronic form is an Internet posting, the plan or issuer timely notifies the individual in paper form (such as a postcard) or email that the documents are available on the Internet, provides the Internet address, and notifies the individual that the documents are available in paper form upon request.

(iii) An issuer offering individual health insurance coverage must provide an SBC in a manner that can reasonably be expected to provide actual notice in paper or electronic form.

(A) An issuer satisfies the requirements of this paragraph (a)(4)(iii) if the issuer:

(*1*) Hand-delivers a printed copy of the SBC to the individual or dependent;

(*2*) Mails a printed copy of the SBC to the mailing address provided to the issuer by the individual or dependent;

(*3*) Provides the SBC by email after obtaining the individual's or dependent's agreement to receive the SBC or other electronic disclosures by email;

(*4*) Posts the SBC on the Internet and advises the individual or dependent in paper or electronic form, in a manner compliant with paragraphs (a)(4)(iii)(A)(*1*) through (*3*) of this section, that the SBC is available on the Internet and includes the applicable Internet address; or

(*5*) Provides the SBC by any other method that can reasonably be expected to provide actual notice.

(B) An SBC may not be provided electronically unless:

(*1*) The format is readily accessible;

(*2*) The SBC is placed in a location that is prominent and readily accessible;

(*3*) The SBC is provided in an electronic form which can be electronically retained and printed;

(*4*) The SBC is consistent with the appearance, content, and language requirements of this section;

(*5*) The issuer notifies the individual or dependent that the SBC is available in paper form without charge upon request and provides it upon request.

(C) *Deemed compliance.* A health insurance issuer offering individual health insurance coverage that provides the content required under paragraph (a)(2) of this section, as specified in guidance published by the Secretary, to the federal health reform Web portal described in §159.120 of this subchapter will be deemed to satisfy the requirements of paragraph (a)(1)(iv)(D) of this section with respect to a request for summary information about a health insurance product made prior to an application for coverage. However, nothing in this paragraph should be construed as otherwise limiting such issuer's obligations under this section.

(iv) An SBC provided by a self-insured non-Federal governmental plan may be provided in paper form. Alternatively, the SBC may be provided electronically if the plan conforms to either the substance of the provisions

in paragraph (a)(4)(ii) or (iii) of this section.

(5) *Language.* A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of §147.136(e) are met as applied to the SBC.

(b) *Notice of modification.* If a group health plan, or health insurance issuer offering group or individual health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees (or, in the case of individual market coverage, an individual covered under a health insurance policy) not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section.

(c) *Uniform glossary*—(1) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries, and a health insurance issuer offering individual health insurance coverage must make available to applicants, policyholders, and covered dependents, the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) *Health-coverage-related terms and medical terms.* The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network coinsurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) *Appearance.* A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee (or, in the case of individual market coverage, an average individual covered under a health insurance policy).

(4) *Form and manner.* A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) *Preemption.* For purposes of this section, the provisions of section 2724 of the PHS Act continue to apply with respect to preemption of State law. State laws that conflict with this section (including a state law that requires a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section) are preempted.

(e) *Failure to provide.* A health insurance issuer or a non-federal governmental health plan that willfully fails to provide information to a covered individual required under this section is

subject to a fine of not more than $1,000 as adjusted annually under 45 CFR part 102 for each such failure. A failure with respect to each covered individual constitutes a separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with §§ 150.101 through 150.465 of this subchapter.

(f) *Applicability to Medicare Advantage benefits.* The requirements of this section do not apply to a group health plan benefit package that provides Medicare Advantage benefits pursuant to or 42 U.S.C. Chapter 7, Subchapter XVIII, Part C.

(g) *Applicability date.* (1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (g). (See § 147.140(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this section applies beginning on the first day of the first open enrollment period that begins on or after September 1, 2015; and

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 1, 2015.

(2) For disclosures with respect to plans, this section is applicable to health insurance issuers beginning September 1, 2015.

(3) For disclosures with respect individuals and covered dependents in the individual market, this section is applicable to health insurance issuers beginning with respect to SBCs issued for coverage that begins on or after January 1, 2016.

[80 FR 34310, June 16, 2015, as amended at 81 FR 61581, Sept. 6, 2016]

§ 147.210 Transparency in coverage—definitions.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth definitions for the price transparency requirements for group health plans and health insurance issuers in the individual and group markets established in this section and §§ 147.211 and 147.212.

(2) *Definitions.* For purposes of this section and §§ 147.211 and 147.212, the following definitions apply:

(i) *Accumulated amounts* means:

(A) The amount of financial responsibility a participant, beneficiary, or enrollee has incurred at the time a request for cost-sharing information is made, with respect to a deductible or out-of-pocket limit. If an individual is enrolled in other than self-only coverage, these accumulated amounts shall include the financial responsibility a participant, beneficiary, or enrollee has incurred toward meeting his or her individual deductible or out-of-pocket limit, as well as the amount of financial responsibility that all the individuals enrolled under the plan or coverage have incurred, in aggregate, toward meeting the other than self-only deductible or out-of-pocket limit, as applicable. Accumulated amounts include any expense that counts toward a deductible or out-of-pocket limit (such as a copayment or coinsurance), but exclude any expense that does not count toward a deductible or out-of-pocket limit (such as any premium payment, out-of-pocket expense for out-of-network services, or amount for items or services not covered under the group health plan or health insurance coverage); and

(B) To the extent a group health plan or health insurance issuer imposes a cumulative treatment limitation on a particular covered item or service (such as a limit on the number of items, days, units, visits, or hours covered in a defined time period) independent of individual medical necessity determinations, the amount that has accrued toward the limit on the item or service (such as the number of items, days, units, visits, or hours the participant, beneficiary, or enrollee has used within that time period).

(ii) *Billed charge* means the total charges for an item or service billed to a group health plan or health insurance issuer by a provider.

(iii) *Billing code* means the code used by a group health plan or health insurance issuer or provider to identify

health care items or services for purposes of billing, adjudicating, and paying claims for a covered item or service, including the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS) code, Diagnosis-Related Group (DRG) code, National Drug Code (NDC), or other common payer identifier.

(iv) *Bundled payment arrangement* means a payment model under which a provider is paid a single payment for all covered items and services provided to a participant, beneficiary, or enrollee for a specific treatment or procedure.

(v) *Copayment assistance* means the financial assistance a participant, beneficiary, or enrollee receives from a prescription drug or medical supply manufacturer towards the purchase of a covered item or service.

(vi) *Cost-sharing liability* means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost-sharing liability generally includes deductibles, coinsurance, and copayments, but does not include premiums, balance billing amounts by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

(vii) *Cost-sharing information* means information related to any expenditure required by or on behalf of a participant, beneficiary, or enrollee with respect to health care benefits that are relevant to a determination of the participant's, beneficiary's, or enrollee's cost-sharing liability for a particular covered item or service.

(viii) *Covered items or services* means those items or services, including prescription drugs, the costs for which are payable, in whole or in part, under the terms of a group health plan or health insurance coverage.

(ix) *Derived amount* means the price that a group health plan or health insurance issuer assigns to an item or service for the purpose of internal accounting, reconciliation with providers or submitting data in accordance with the requirements of §153.710(c) of this subchapter.

(x) *Enrollee* means an individual who is covered under an individual health insurance policy as defined under section 2791(b)(5) of the Public Health Service (PHS) Act.

(xi) *Historical net price* means the retrospective average amount a group health plan or health insurance issuer paid for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug. The allocation shall be determined by dollar value for non-product specific and product-specific rebates, discounts, chargebacks, fees, and other price concessions to the extent that the total amount of any such price concession is known to the group health plan or health insurance issuer at the time of publication of the historical net price in a machine-readable file in accordance with §147.212. However, to the extent that the total amount of any non-product specific and product-specific rebates, discounts, chargebacks, fees, or other price concessions is not known to the group health plan or health insurance issuer at the time of file publication, then the plan or issuer shall allocate such rebates, discounts, chargebacks, fees, and other price concessions by using a good faith, reasonable estimate of the average price concessions based on the rebates, discounts, chargebacks, fees, and other price concessions received over a time period prior to the current reporting period and of equal duration to the current reporting period, as determined under §147.212(b)(1)(iii)(D)(*3*).

(xii) *In-network provider* means any provider of any item or service with which a group health plan or health insurance issuer, or a third party for the plan or issuer, has a contract setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee.

(xiii) *Items or services* means all encounters, procedures, medical tests, supplies, prescription drugs, durable medical equipment, and fees (including facility fees), provided or assessed in

connection with the provision of health care.

(xiv) *Machine-readable file* means a digital representation of data or information in a file that can be imported or read by a computer system for further processing without human intervention, while ensuring no semantic meaning is lost.

(xv) *National Drug Code* means the unique 10- or 11-digit 3-segment number assigned by the Food and Drug Administration, which provides a universal product identifier for drugs in the United States.

(xvi) *Negotiated rate* means the amount a group health plan or health insurance issuer has contractually agreed to pay an in-network provider, including an in-network pharmacy or other prescription drug dispenser, for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager.

(xvii) *Out-of-network allowed amount* means the maximum amount a group health plan or health insurance issuer will pay for a covered item or service furnished by an out-of-network provider.

(xviii) *Out-of-network provider* means a provider of any item or service that does not have a contract under a participant's, beneficiary's, or enrollee's group health plan or health insurance coverage to provide items or services.

(xix) *Out-of-pocket limit* means the maximum amount that a participant, beneficiary, or enrollee is required to pay during a coverage period for his or her share of the costs of covered items and services under his or her group health plan or health insurance coverage, including for self-only and other than self-only coverage, as applicable.

(xx) *Plain language* means written and presented in a manner calculated to be understood by the average participant, beneficiary, or enrollee.

(xxi) *Prerequisite* means concurrent review, prior authorization, and step-therapy or fail-first protocols related to covered items and services that must be satisfied before a group health plan or health insurance issuer will cover the item or service. The term prerequisite does not include medical necessity determinations generally or other forms of medical management techniques.

(xxii) *Underlying fee schedule rate* means the rate for a covered item or service from a particular in-network provider, or providers that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the negotiated rate or derived amount.

(b) [Reserved]

[85 FR 72305, Nov. 12, 2020]

§ 147.211 Transparency in coverage—required disclosures to participants, beneficiaries, or enrollees.

(a) *Scope and definitions*—(1) *Scope.* This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions.* For purposes of this section, the definitions in §147.210 apply.

(b) *Required disclosures to participants, beneficiaries, or enrollees.* At the request of a participant, beneficiary, or enrollee who is enrolled in a group health plan or health insurance issuer offering group or individual health insurance coverage, the plan or issuer must provide to the participant, beneficiary, or enrollee the information required under paragraph (b)(1) of this section, in accordance with the method and format requirements set forth in paragraph (b)(2) of this section.

(1) *Required cost-sharing information.* The information required under this paragraph (b)(1) is the following cost-sharing information, which is accurate at the time the request is made, with respect to a participant's, beneficiary's, or enrollee's cost-sharing liability for covered items and services:

(i) An estimate of the participant's, beneficiary's, or enrollee's cost-sharing liability for a requested covered item or service furnished by a provider or providers, which must reflect any cost-sharing reductions the enrollee would receive, that is calculated based on the

information described in paragraphs (b)(1)(ii) through (iv) of this section.

(A) If the request for cost-sharing information relates to items and services that are provided within a bundled payment arrangement, and the bundled payment arrangement includes items or services that have a separate cost-sharing liability, the group health plan or health insurance issuer must provide estimates of the cost-sharing liability for the requested covered item or service, as well as an estimate of the cost-sharing liability for each of the items and services in the bundled payment arrangement that have separate cost-sharing liabilities. While group health plans and health insurance issuers are not required to provide estimates of cost-sharing liability for a bundled payment arrangement where the cost-sharing is imposed separately for each item and service included in the bundled payment arrangement, nothing prohibits plans or issuers from providing estimates for multiple items and services in situations where such estimates could be relevant to participants or beneficiaries, as long as the plan or issuer also discloses information about the relevant items or services individually, as required in paragraph (b)(1)(v) of this section.

(B) For requested items and services that are recommended preventive services under section 2713 of the Public Health Service Act (PHS Act), if the group health plan or health insurance issuer cannot determine whether the request is for preventive or non-preventive purposes, the plan or issuer must display the cost-sharing liability that applies for non-preventive purposes. As an alternative, a group health plan or health insurance issuer may allow a participant, beneficiary, or enrollee to request cost-sharing information for the specific preventive or non-preventive item or service by including terms such as ''preventive'', ''non-preventive'' or ''diagnostic'' as a means to request the most accurate cost-sharing information.

(ii) Accumulated amounts.

(iii) In-network rate, comprised of the following elements, as applicable to the group health plan's or health insurance issuer's payment model:

(A) Negotiated rate, reflected as a dollar amount, for an in-network provider or providers for the requested covered item or service; this rate must be disclosed even if it is not the rate the plan or issuer uses to calculate cost-sharing liability; and

(B) Underlying fee schedule rate, reflected as a dollar amount, for the requested covered item or service, to the extent that it is different from the negotiated rate.

(iv) Out-of-network allowed amount or any other rate that provides a more accurate estimate of an amount a group health plan or health insurance issuer will pay for the requested covered item or service, reflected as a dollar amount, if the request for cost-sharing information is for a covered item or service furnished by an out-of-network provider; provided, however, that in circumstances in which a plan or issuer reimburses an out-of-network provider a percentage of the billed charge for a covered item or service, the out-of-network allowed amount will be that percentage.

(v) If a participant, beneficiary, or enrollee requests information for an item or service subject to a bundled payment arrangement, a list of the items and services included in the bundled payment arrangement for which cost-sharing information is being disclosed.

(vi) If applicable, notification that coverage of a specific item or service is subject to a prerequisite.

(vii) A notice that includes the following information in plain language:

(A) A statement that out-of-network providers may bill participants, beneficiaries, or enrollees for the difference between a provider's billed charges and the sum of the amount collected from the group health plan or health insurance issuer and from the participant, beneficiary, or enrollee in the form of a copayment or coinsurance amount (the difference referred to as balance billing), and that the cost-sharing information provided pursuant to this paragraph (b)(1) does not account for these potential additional amounts. This statement is only required if balance billing is permitted under state law;

(B) A statement that the actual charges for a participant's, beneficiary's, or enrollee's covered item or service may be different from an estimate of cost-sharing liability provided pursuant to paragraph (b)(1)(i) of this section, depending on the actual items or services the participant, beneficiary, or enrollee receives at the point of care;

(C) A statement that the estimate of cost-sharing liability for a covered item or service is not a guarantee that benefits will be provided for that item or service;

(D) A statement disclosing whether the plan counts copayment assistance and other third-party payments in the calculation of the participant's, beneficiary's, or enrollee's deductible and out-of-pocket maximum;

(E) For items and services that are recommended preventive services under section 2713 of the PHS Act, a statement that an in-network item or service may not be subject to cost-sharing if it is billed as a preventive service if the group health plan or health insurance issuer cannot determine whether the request is for a preventive or non-preventive item or service; and

(F) Any additional information, including other disclaimers, that the group health plan or health insurance issuer determines is appropriate, provided the additional information does not conflict with the information required to be provided by this paragraph (b)(1).

(2) *Required methods and formats for disclosing information to participants, beneficiaries, or enrollees.* The methods and formats for the disclosure required under this paragraph (b) are as follows:

(i) *Internet-based self-service tool.* Information provided under this paragraph (b) must be made available in plain language, without subscription or other fee, through a self-service tool on an internet website that provides real-time responses based on cost-sharing information that is accurate at the time of the request. Group health plans and health insurance issuers must ensure that the self-service tool allows users to:

(A) Search for cost-sharing information for a covered item or service provided by a specific in-network provider or by all in-network providers by inputting:

(*1*) A billing code (such as CPT code 87804) or a descriptive term (such as ''rapid flu test''), at the option of the user;

(*2*) The name of the in-network provider, if the user seeks cost-sharing information with respect to a specific in-network provider; and

(*3*) Other factors utilized by the plan or issuer that are relevant for determining the applicable cost-sharing information (such as location of service, facility name, or dosage).

(B) Search for an out-of-network allowed amount, percentage of billed charges, or other rate that provides a reasonably accurate estimate of the amount a group health plan or health insurance issuer will pay for a covered item or service provided by out-of-network providers by inputting:

(*1*) A billing code or descriptive term, at the option of the user; and

(*2*) Other factors utilized by the plan or issuer that are relevant for determining the applicable out-of-network allowed amount or other rate (such as the location in which the covered item or service will be sought or provided).

(C) Refine and reorder search results based on geographic proximity of in-network providers, and the amount of the participant's, beneficiary's, or enrollee's estimated cost-sharing liability for the covered item or service, to the extent the search for cost-sharing information for covered items or services returns multiple results.

(ii) *Paper method.* Information provided under this paragraph (b) must be made available in plain language, without a fee, in paper form at the request of the participant, beneficiary, or enrollee. In responding to such a request, the group health plan or health insurance issuer may limit the number of providers with respect to which cost-sharing information for covered items and services is provided to no fewer than 20 providers per request. The group health plan or health insurance issuer is required to:

(A) Disclose the applicable provider-per-request limit to the participant, beneficiary, or enrollee;

(B) Provide the cost-sharing information in paper form pursuant to the individual's request, in accordance with the requirements in paragraphs (b)(2)(i)(A) through (C) of this section; and

(C) Mail the cost-sharing information in paper form no later than 2 business days after an individual's request is received.

(D) To the extent participants, beneficiaries, and enrollees request disclosure other than by paper (for example, by phone or email), plans and issuers may provide the disclosure through another means, provided the participant, beneficiary, or enrollee agrees that disclosure through such means is sufficient to satisfy the request and the request is fulfilled at least as rapidly as required for the paper method.

(3) *Special rule to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information required by this paragraph (b) in compliance with this section pursuant to a written agreement. Accordingly, if a health insurance issuer and a plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a pharmacy benefit manager or other third-party) provides the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2023 with respect to the 500 items and services to be posted on a publicly available website, and with respect to all covered items and services, for plan years (in the individual market, for policy years) beginning on or after January 1, 2024.

(2) As provided under §147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in §147.126(d)(6) or short term limited duration insurance as defined in 45 CFR 144.103.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, beneficiary, or enrollee information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to

comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability*. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[85 FR 72305, Nov. 12, 2020]

§ 147.212 Transparency in coverage—requirements for public disclosure.

(a) *Scope and definitions*—(1) *Scope*. This section establishes price transparency requirements for group health plans and health insurance issuers in the individual and group markets for the timely disclosure of information about costs related to covered items and services under a plan or health insurance coverage.

(2) *Definitions*. For purposes of this section, the definitions in § 147.210 apply.

(b) *Requirements for public disclosure of in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs*. A group health plan or health insurance issuer must make available on an internet website the information required under paragraph (b)(1) of this section in three machine-readable files, in accordance with the method and format requirements described in paragraph (b)(2) of this section, and that are updated as required under paragraph (b)(3) of this section.

(1) *Required information*. Machine-readable files required under this paragraph (b) that are made available to the public by a group health plan or health insurance issuer must include:

(i) An in-network rate machine-readable file that includes the required information under this paragraph (b)(1)(i) for all covered items and services, except for prescription drugs that are subject to a fee-for-service reimbursement arrangement, which must be reported in the prescription drug machine-readable file pursuant to paragraph (b)(1)(iii) of this section. The in-network rate machine-readable file must include:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit Health Insurance Oversight System (HIOS) identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or if no HIOS identifier is available, the Employer Identification Number (EIN);

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) All applicable rates, which may include one or more of the following: Negotiated rates, underlying fee schedule rates, or derived amounts. If a group health plan or health insurance issuer does not use negotiated rates for provider reimbursement, then the plan or issuer should disclose derived amounts to the extent these amounts are already calculated in the normal course of business. If the group health plan or health insurance issuer uses underlying fee schedule rates for calculating cost sharing, then the plan or issuer should include the underlying fee schedule rates in addition to the negotiated rate or derived amount. Applicable rates, including for both individual items and services and items and services in a bundled payment arrangement, must be:

(*1*) Reflected as dollar amounts, with respect to each covered item or service that is furnished by an in-network provider. If the negotiated rate is subject to change based upon participant, beneficiary, or enrollee-specific characteristics, these dollar amounts should be reflected as the base negotiated rate applicable to the item or service prior to adjustments for participant, beneficiary, or enrollee-specific characteristics;

(*2*) Associated with the National Provider Identifier (NPI), Tax Identification Number (TIN), and Place of Service Code for each in-network provider;

(*3*) Associated with the last date of the contract term or expiration date for each provider-specific applicable rate that applies to each covered item or service; and

(*4*) Indicated with a notation where a reimbursement arrangement other than a standard fee-for-service model (such as capitation or a bundled payment arrangement) applies.

(ii) An out-of-network allowed amount machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) A billing code, which in the case of prescription drugs must be an NDC, and a plain language description for each billing code for each covered item or service under each coverage option offered by a plan or issuer; and

(C) Unique out-of-network allowed amounts and billed charges with respect to covered items or services furnished by out-of-network providers during the 90-day time period that begins 180 days prior to the publication date of the machine-readable file (except that a group health plan or health insurance issuer must omit such data in relation to a particular item or service and provider when compliance with this paragraph (b)(1)(ii)(C) would require the plan or issuer to report payment of out-of-network allowed amounts in connection with fewer than 20 different claims for payments under a single plan or coverage). Consistent with paragraph (c)(3) of this section, nothing in this paragraph (b)(1)(ii)(C) requires the disclosure of information that would violate any applicable health information privacy law. Each unique out-of-network allowed amount must be:

(*1*) Reflected as a dollar amount, with respect to each covered item or service that is furnished by an out-of-network provider; and

(*2*) Associated with the NPI, TIN, and Place of Service Code for each out-of-network provider.

(iii) A prescription drug machine-readable file, including:

(A) For each coverage option offered by a group health plan or health insurance issuer, the name and the 14-digit HIOS identifier, or, if the 14-digit HIOS identifier is not available, the 5-digit HIOS identifier, or, if no HIOS identifier is available, the EIN;

(B) The NDC, and the proprietary and nonproprietary name assigned to the NDC by the Food and Drug Administration (FDA), for each covered item or service that is a prescription drug under each coverage option offered by a plan or issuer;

(C) The negotiated rates which must be:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the last date of the contract term for each provider-specific negotiated rate that applies to each NDC; and

(D) Historical net prices that are:

(*1*) Reflected as a dollar amount, with respect to each NDC that is furnished by an in-network provider, including an in-network pharmacy or other prescription drug dispenser;

(*2*) Associated with the NPI, TIN, and Place of Service Code for each in-network provider, including each in-network pharmacy or other prescription drug dispenser; and

(*3*) Associated with the 90-day time period that begins 180 days prior to the publication date of the machine-readable file for each provider-specific historical net price that applies to each NDC (except that a group health plan or health insurance issuer must omit such data in relation to a particular NDC and provider when compliance with this paragraph (b)(1)(iii)(D) would require the plan or issuer to report payment of historical net prices calculated using fewer than 20 different claims for payment). Consistent with paragraph (b)(3) of this section, nothing in this paragraph (b)(1)(iii)(D) requires the disclosure of information

that would violate any applicable health information privacy law.

(2) *Required method and format for disclosing information to the public.* The machine-readable files described in this paragraph (b) must be available in a form and manner as specified in guidance issued by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services. The machine-readable files must be publicly available and accessible to any person free of charge and without conditions, such as establishment of a user account, password, or other credentials, or submission of personally identifiable information to access the file.

(3) *Timing.* A group health plan or health insurance issuer must update the machine-readable files and information required by this paragraph (b) monthly. The group health plan or health insurance issuer must clearly indicate the date that the files were most recently updated.

(4) *Special rules to prevent unnecessary duplication*—(i) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan satisfies the requirements of this paragraph (b) if the plan requires the health insurance issuer offering the coverage to provide the information pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under this paragraph (b) in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the transparency disclosure requirements of this paragraph (b).

(ii) *Other contractual arrangements.* A group health plan or health insurance issuer may satisfy the requirements under this paragraph (b) by entering into a written agreement under which another party (such as a third-party administrator or health care claims clearinghouse) will provide the information required by this paragraph (b) in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the information in compliance with this paragraph (b), the plan or issuer violates the transparency disclosure requirements of this paragraph (b).

(iii) *Aggregation permitted for out-of-network allowed amounts.* Nothing in this section prohibits a group health plan or health insurance issuer from satisfying the disclosure requirement described in paragraph (b)(1)(ii) of this section by disclosing out-of-network allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information, provided the minimum claim threshold described in paragraph (b)(1)(ii)(C) of this section is independently met for each item or service and for each plan or coverage included in an aggregated Allowed Amount File. Under such circumstances, health insurance issuers, service providers, or other parties with which the group health plan or issuer has contracted may aggregate out-of-network allowed amounts for more than one plan or insurance policy or contract. Additionally, nothing in this section prevents the Allowed Amount File from being hosted on a third-party website or prevents a plan administrator or issuer from contracting with a third party to post the file. However, if a plan or issuer chooses not to also host the file separately on its own website, it must provide a link on its own public website to the location where the file is made publicly available.

(c) *Applicability.* (1) The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after January 1, 2022.

(2) As provided under §147.140, this section does not apply to grandfathered health plans. This section also does not apply to health reimbursement arrangements or other account-based group health plans as defined in §147.126(d)(6) or short term limited duration insurance as defined in §144.103 of this subchapter.

(3) Nothing in this section alters or otherwise affects a group health plan's or health insurance issuer's duty to

comply with requirements under other applicable state or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access participant, or beneficiary information held by plans and issuers.

(4) A group health plan or health insurance issuer will not fail to comply with this section solely because it, acting in good faith and with reasonable diligence, makes an error or omission in a disclosure required under paragraph (b) of this section, provided that the plan or issuer corrects the information as soon as practicable.

(5) A group health plan or health insurance issuer will not fail to comply with this section solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable.

(6) To the extent compliance with this section requires a group health plan or health insurance issuer to obtain information from any other entity, the plan or issuer will not fail to comply with this section because it relied in good faith on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[85 FR 72305, Nov. 12, 2020]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

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AUTHORITY: 42 U.S.C. 300gg through 300gg–63, 300gg–11 300gg–91, and 300–gg92, as amended.

SOURCE: 62 FR 16995, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage

from discrimination based on genetic information.

[79 FR 30340, May 27, 2014]

§ 148.102 Scope and applicability date.

(a) *Scope and applicability.* (1) Individual health insurance coverage includes all health insurance coverage (as defined in §144.103 of this subchapter) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited-duration coverage as defined in §144.103 of this subchapter.

(2) The requirements that pertain to guaranteed renewability for all individuals, to protections for mothers and newborns with respect to hospital stays in connection with childbirth, and to protections against discrimination based on genetic information apply to all issuers of individual health insurance coverage in the State.

(b) *Applicability dates.* Except as provided in §§148.124, 148.170, and 148.180, the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997. Notwithstanding the previous sentence, for short-term, limited-duration insurance sold or issued on or after September 1, 2024, the definition of *short-term, limited-duration insurance* in §144.103 of this subchapter applies for coverage periods beginning on or after September 1, 2024. For short-term, limited-duration insurance sold or issued before September 1, 2024 (including any subsequent renewal or extension consistent with applicable law), the definition of *short-term, limited-duration insurance* in 45 CFR 144.103, revised as of October 1, 2023, continues to apply, except that paragraph (1)(ii) of the definition of *short-term, limited-duration insurance* in §144.103 applies for coverage periods beginning on or after September 1, 2024.

[79 FR 30340, May 27, 2014, as amended at 81 FR 75327, Oct. 31, 2016; 83 FR 38243, Aug. 3, 2018; 89 FR 23419, Apr. 3, 2024]

Subpart B—Requirements Relating to Access and Renewability of Coverage

§ 148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

[79 FR 30340, May 27, 2014]

§ 148.122 Guaranteed renewability of individual health insurance coverage.

(a) *Applicability.* This section applies to non-grandfathered and grandfathered health plans (within the meaning of §147.140 of this subchapter) that are individual health insurance coverage. *See* also §147.106 of this subchapter for requirements relating to guaranteed renewability of coverage with respect to non-grandfathered health plans.

(b) *General rules.* (1) Except as provided in paragraphs (c) through (g) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

(2) Medicare entitlement or enrollment is not a basis to nonrenew an individual's health insurance coverage in the individual market under the same policy or contract of insurance.

(c) *Exceptions to renewing coverage.* An issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) *Nonpayment of premiums.* The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) *Termination of product.* The issuer is ceasing to offer coverage in the market in accordance with paragraph (d) or (e) of this section and applicable State law.

(4) *Movement outside the service area.* For network plans, the individual no longer resides, lives, or works in the service area of the issuer, or area for which the issuer is authorized to do business, but only if coverage is terminated uniformly without regard to any health status-related factor of covered individuals; provided the issuer provides notice in accordance with the requirements of paragraph (d)(1) of this section.

(5) *Association membership ceases.* For coverage made available in the individual market only through one or more bona fide associations, the individual's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(d) *Discontinuing a particular type of coverage.* An issuer may discontinue offering a particular type of health insurance coverage offered in the individual market only if it meets the following requirements:

(1) Provides notice in writing, in a form and manner specified by the Secretary, to each individual provided coverage of that type of health insurance at least 90 calendar days before the date the coverage will be discontinued.

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(e) *Discontinuing all coverage.* An issuer may discontinue offering all health insurance coverage in the individual market in a State only if it meets the following requirements.

(1) Provides notice in writing to the applicable State authority and to each individual of the discontinuation at least 180 days before the date the coverage will expire.

(2) Discontinues and does not renew all health insurance policies it issues or delivers for issuance in the State in the individual market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(4) For purposes of this paragraph (e), subject to applicable State law, an issuer will not be considered to have discontinued offering all health insurance coverage in a market in a State if—

(i) The issuer (in this paragraph referred to as the initial issuer) or, if the issuer is a member of a controlled group, any other issuer that is a member of such controlled group, offers and makes available in the applicable market in the State at least one product that is considered in accordance with §144.103 of this subchapter to be the same product as a product the initial issuer had been offering in such market in such State; or

(ii) The issuer—

(A) Offers and makes available at least one product (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the new product) in the applicable market in the State, even if such product is not considered in accordance with §144.103 of this subchapter to be the same product as a product the issuer had been offering in the applicable market in the State (in paragraphs (e)(4)(ii)(A) through (C) of this section referred to as the discontinued product);

(B) Subjects such new product or products to the applicable process and requirements established under part 154 of this title as if such process and requirements applied with respect to that product or products, to the extent such process and requirements are otherwise applicable to coverage of the same type and in the same market; and

(C) Reasonably identifies the discontinued product or products that correspond to the new product or products for purposes of the process and requirements applied pursuant to paragraph (e)(4)(ii)(B) of this section.

(5) For purposes of this section, the term controlled group means a group of two or more persons that is treated as

a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended, or a narrower group as may be provided by applicable State law.

(f) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage under paragraph (e) of this section may not issue coverage in the market and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(g) *Exception for uniform modification of coverage.* (1) An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a product offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that product.

(2) For purposes of paragraph (g) of this section, modifications made uniformly and solely pursuant to applicable Federal or State requirements are considered a uniform modification of coverage if:

(i) The modification is made within a reasonable time period after the imposition or modification of the Federal or State requirement; and

(ii) The modification is directly related to the imposition or modification of the Federal or State requirement.

(3) For purposes of paragraph (g) of this section, other types of modifications made uniformly are considered a uniform modification of coverage if the health insurance coverage for the product meets all of the following criteria:

(i) The product is offered by the same health insurance issuer (within the meaning of section 2791(b)(2) of the PHS Act), or if the issuer that is a member of a controlled group (as described in paragraph (e)(5) of this section), any other health insurance issuer that is a member of such controlled group;

(ii) The product is offered as the same product network type (for example, health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity);

(iii) The product continues to cover at least a majority of the same service area;

(iv) Within the product, each plan has the same cost-sharing structure as before the modification, except for any variation in cost sharing solely related to changes in cost and utilization of medical care, or to maintain the same metal tier level described in sections 1302(d) and (e) of the Affordable Care Act; and

(v) The product provides the same covered benefits, except for any changes in benefits that cumulatively impact the rate for any plan within the product within an allowable variation of ±2 percentage points (not including changes pursuant to applicable Federal or State requirements).

(4) A State may only broaden the standards in paragraphs (g)(3)(iii) and (iv) of this section.

(h) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the individual market only through one or more associations, any reference in this section to an ''individual'' is deemed to include a reference to the association of which the individual is a member.

(i) *Notice of renewal of coverage.* If an issuer is renewing grandfathered coverage as described in paragraph (b) of this section, or uniformly modifying grandfathered coverage as described in paragraph (g) of this section, the issuer must provide to each individual written notice of the renewal at least 60 calendar days before the date the coverage will be renewed in a form and manner specified by the Secretary.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 79 FR 30340, May 27, 2014; 79 FR 42986, July 24, 2014; 79 FR 53004, Sept. 5, 2014; 81 FR 94174, Dec. 22, 2016; 84 FR 17561, Apr. 25, 2019]

§ 148.124 Certification and disclosure of coverage.

(a) *General rule.* The rules for providing certificates of creditable coverage and demonstrating creditable coverage have been superseded by the prohibition on preexisting condition

exclusions. *See* §147.108 of this subchapter for rules prohibiting the imposition of a preexisting condition exclusion.

(b) *Applicability*. The provisions of this section apply beginning December 31, 2014.

[79 FR 30341, May 27, 2014]

§ 148.126 Determination of an eligible individual.

The rules for guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

[79 FR 30341, May 27, 2014]

§ 148.128 State flexibility in individual market reforms—alternative mechanisms.

The rules for a State to implement an acceptable alternative mechanism for purposes of guaranteeing the availability of individual health insurance coverage to certain eligible individuals with prior group coverage have been superseded by the requirements of §147.104 of this subchapter, which set forth Federal requirements for guaranteed availability of coverage in the group and individual markets.

[79 FR 30341, May 27, 2014]

Subpart C—Requirements Related to Benefits

§ 148.170 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule*. Except as provided in paragraph (a)(5) of this section, an issuer offering health insurance coverage in the individual market that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital*. If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital*. If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples*. The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the issuer provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts*. A pregnant woman covered under a policy issued in the individual market goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion*. In this *Example 1*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts*. A woman covered under a policy issued in the individual market gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion*. In this *Example 2*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts*. A woman covered under a policy issued in the individual market gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion*. In this *Example 3*, the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general*. An issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this

section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, an issuer subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the issuer requires an attending provider to complete a certificate of medical necessity. The issuer then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example*, the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, an issuer, plan, hospital, or managed care organization is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a policy offered by an issuer subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The issuer pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example*, the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* An issuer subject to the requirements of this section may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll in or renew coverage solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under a policy issued in the individual market are discharged within 24 hours after the delivery, the issuer will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the issuer violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the issuer provides for a follow-up visit by a nurse

within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, an issuer may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* An issuer subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the issuer automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the covered individual must call the issuer to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the issuer will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit an issuer from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the issuer based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* An issuer may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a covered individual in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a covered individual in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any issuer that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent an issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The issuer covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the issuer also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* An issuer generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth.

However, the issuer will cover 80 percent of the cost of the stay if the covered individual notifies the issuer of the pregnancy in advance of admission and uses whatever hospital the issuer may designate.

(ii) *Conclusion.* In this *Example 2*, the issuer does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the issuer does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent an issuer from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(5) *Applicability.* This section applies to all health insurance coverage issued in the individual market, and is not limited in its application to coverage that is provided to eligible individuals as defined in section 2741(b) of the PHS Act.

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, an issuer offering health insurance in the individual market must meet the following requirements with respect to benefits for hospital lengths of stay in connection with childbirth:

(1) Required statement. The insurance contract must disclose information that notifies covered individuals of their rights under this section.

(2) Disclosure notice. To meet the disclosure requirements set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, health insurance issuers generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the issuer may pay for a shorter stay if the attending provider (*e.g.* , your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, an issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your issuer.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to the covered individuals in the form of a copy of the contract, or a rider (or equivalent amendment to the contract) no later than December 19, 2008. To the extent an issuer has already provided the disclosure notice in paragraph (d)(2) of this section to covered individuals, it need not provide another such notice by December 19, 2008.

(4) *Exception.* The requirements of this paragraph (d) do not apply with respect to coverage regulated under a state law described in paragraph (e) of this section.

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2751 of the PHS Act and this section do not apply with respect to health insurance coverage in the individual market if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending

provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Relation to section 2762(a) of the PHS Act*. The preemption provisions contained in section 2762(a) of the PHS Act and §148.210(b) do not supersede a state law described in paragraph (e)(1) of this section.

(f) *Applicability date*. Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

[73 FR 62427, Oct. 20, 2008]

§ 148.180 Prohibition of discrimination based on genetic information.

(a) *Definitions*. For purposes of this section, the following definitions as set forth in §146.122 of this subchapter pertain to health insurance issuers in the individual market to the extent that those definitions are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect or operated in the individual market:

Collect has the meaning set forth at §146.122(a).

Family member has the meaning set forth at §146.122(a).

Genetic information has the meaning set forth at §146.122(a).

Genetic services has the meaning set forth at §146.122(a).

Genetic test has the meaning set forth at §146.122(a).

Manifestation or manifested has the meaning set forth at §146.122(a).

Preexisting condition exclusion has the meaning set forth at §144.103.

Underwriting purposes has the meaning set forth at §148.180(f)(1).

(b) *Prohibition on genetic information as a condition of eligibility*—(1) *In general*. An issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) *Rule of construction*. Nothing in paragraph (b)(1) of this section precludes an issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of that individual when the family member is covered under the policy that covers the individual.

(3) *Examples*. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts*. A State implements the HIPAA guaranteed availability requirement in the individual health insurance market in accordance with §148.120. Individual *A* and his spouse *S* are not ''eligible individuals'' as that term is defined at §148.103 and, therefore, they are not entitled to obtain individual health insurance coverage on a guaranteed available basis. They apply for individual coverage with Issuer *M*. As part of the application for coverage, *M* receives health information about *A* and *S*. Although *A* has no known medical conditions, *S* has high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion*. In this *Example 1*, *M* permissibly may decline to offer coverage to *S* because *S* has a manifested disorder (high blood pressure) that makes her ineligible for coverage under the policy's rules for eligibility.

Example 2. (i) *Facts*. Same facts as *Example 1*, except that *S* does not have high blood pressure or any other known medical condition. The only health information relevant to *S* that *M* receives in the application indicates that both of *S*'s parents are overweight and have high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion*. In this *Example 2*, *M* cannot decline to offer coverage to *S* because *S* does not have a manifested disease or disorder. The only health information *M* has that relates to her pertains to a manifested disease or disorder of family members, which as family medical history constitutes genetic information with respect to *S*. If *M* denies eligibility to *S* based on genetic information, the denial will violate this paragraph (b).

(c) *Prohibition on genetic information in setting premium rates*—(1) *In general*. An issuer offering health insurance coverage in the individual market must not adjust premium amounts for an individual on the basis of genetic information regarding the individual or a family member of the individual.

(2) *Rule of construction.* (i) Nothing in paragraph (c)(1) of this section precludes an issuer from adjusting premium amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or on the basis of a manifestation of a disease or disorder in a family member of that individual when the family member is covered under the policy that covers the individual.

(ii) The manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to that individual and to further increase premium amounts.

(3) *Examples.* The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *B* is covered under an individual health insurance policy through Issuer *N*. Every other policy year, before renewal, *N* requires policyholders to submit updated health information before the policy renewal date for purposes of determining an appropriate premium, in excess of any increases due to inflation, based on the policyholders' health status. *B* complies with that requirement. During the past year, *B*'s blood glucose levels have increased significantly. *N* increases its premium for renewing *B*'s policy to account for *N*'s increased risk associated with *B*'s elevated blood glucose levels.

(ii) *Conclusion.* In this *Example 1*, *N* is permitted to increase the premium for *B*'s policy on the basis of a manifested disorder (elevated blood glucose) in *B*.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *B*'s blood glucose levels have not increased and are well within the normal range. In providing updated health information to *N*, *B* indicates that both his mother and sister are being treated for adult onset diabetes mellitus (Type 2 diabetes). *B* provides this information voluntarily and not in response to a specific request for family medical history or other genetic information. *N* increases *B*'s premium to account for *B*'s genetic predisposition to develop Type 2 diabetes in the future.

(ii) *Conclusion.* In this *Example 2*, *N* cannot increase *B*'s premium on the basis of *B*'s family medical history of Type 2 diabetes, which is genetic information with respect to *B*. Since there is no manifestation of the disease in *B* at this point in time, *N* cannot increase *B*'s premium.

(d) *Prohibition on genetic information as preexisting condition*—(1) *In general.* An issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion with respect to that coverage.

(2) *Rule of construction.* Nothing in paragraph (d)(1) of this section precludes an issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(3) *Examples:* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *C* has encountered delays in receiving payment from the issuer of his individual health insurance policy for covered services. He decides to switch carriers and applies for an individual health insurance policy through Issuer *O*. *C* is generally in good health, but has arthritis for which he has received medical treatment. *O* offers *C* an individual policy that excludes coverage for a 12-month period for any services related to *C*'s arthritis.

(ii) *Conclusion.* In this *Example 1*, *O* is permitted to impose a preexisting condition exclusion with respect to *C* because *C* has a manifested disease (arthritis).

Example 2. (i) *Facts.* Individual *D* applies for individual health insurance coverage through Issuer *P*. *D* has no known medical conditions. However, in response to *P*'s request for medical information about *D*, *P* receives information from *D*'s physician that indicates that both of *D*'s parents have adult onset diabetes mellitus (Type 2 diabetes). *P* offers *D* an individual policy with a rider that permanently excludes coverage for any treatment related to diabetes that *D* may receive while covered by the policy, based on the fact that both of *D*'s parents have the disease.

(ii) *Conclusion.* In this *Example 2*, the rider violates this paragraph (d) because the preexisting condition exclusion is based on genetic information with respect to *D* (family medical history of Type 2 diabetes).

(e) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (e), an issuer offering health insurance coverage in the individual market must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (e)(1) of this section limits the authority of a health care professional who is providing health care services to

an individual to request that the individual undergo a genetic test.

(3) *Examples.* The rules of paragraphs (e)(1) and (e)(2) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *E* goes to a physician for a routine physical examination. The physician reviews *E*'s family medical history, and *E* informs the physician that *E*'s mother has been diagnosed with Huntington's Disease. The physician advises *E* that Huntington's Disease is hereditary, and recommends that E undergo a genetic test.

(ii) *Conclusion.* In this *Example 1,* the physician is a health care professional who is providing health care services to *E.* Therefore, the physician's recommendation that *E* undergo the genetic test does not violate this paragraph (e).

Example 2. (i) *Facts.* Individual *F* is covered by a health maintenance organization (HMO). *F* is a child being treated for leukemia. *F*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *F*'s physician recommends that *F* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion.* In this *Example 2,* even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *F.* Therefore, the physician's recommendation that *F* undergo the genetic test does not violate this paragraph (e).

(4) *Determination regarding payment*—(i) *In general.* As provided in this paragraph (e)(4), nothing in paragraph (e)(1) of this section precludes an issuer offering health insurance in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in §164.501 of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if an issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on a covered individual's genetic makeup, the issuer is permitted to condition payment on the outcome of a genetic test, and may refuse payment if the covered individual does not undergo the genetic test.

(ii) *Limitation.* An issuer in the individual market is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in §164.502(b) of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (g) of this section for examples illustrating the rules of this paragraph (e)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (e)(1) of this section, an issuer may request, but not require, that an individual or family member covered under the same policy undergo a genetic test if all of the conditions of this paragraph (e)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The issuer makes the request pursuant to research, as defined in §46.102(d) of this subtitle, that complies with part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The issuer makes the request in writing, and the request clearly indicates to each individual (or, in the case of a minor child, to the child's legal guardian) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in paragraph (b) of this section) or premium amounts (as described in paragraph (c) of this section).

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (e)(5) can be used for underwriting purposes (as described in paragraph (f)(1) of this section).

(iv) *Notice to Federal agencies.* The issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and

provides the notice to the address specified in the instructions thereto.

(f) *Prohibitions on collection of genetic information*—(1) *For underwriting purposes*—(i) *General rule.* An issuer offering health insurance coverage in the individual market must not collect (as defined in paragraph (a) of this section) genetic information for underwriting purposes. *See* paragraph (g) of this section for examples illustrating the rules of this paragraph (f)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (f)(1)(iii) of this section, *underwriting purposes* means, with respect to any issuer offering health insurance coverage in the individual market—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the coverage;

(B) The computation of premium amounts under the coverage;

(C) The application of any preexisting condition exclusion under the coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance.

(iii) *Medical appropriateness.* An issuer in the individual market may limit or exclude a benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an issuer conditions a benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on a covered individual's genetic information, the issuer is permitted to condition the benefit on the genetic information. An issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness, and may deny the benefit if the covered individual does not provide the genetic information required to determine medical appropriateness. *See* paragraph (g) of this section for examples illustrating the applicability of this paragraph (f)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment*—(i) *In general.* An issuer offering health insurance coverage in the individual market must not collect genetic information with respect to any individual prior to that individual's enrollment under the coverage or in connection with that individual's enrollment. Whether or not an individual's information is collected prior to that individual's enrollment is determined at the time of collection.

(ii) *Incidental collection exception*—(A) *In general.* If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (f)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly provides that genetic information should not be provided.

(iii) *Examples.* The rules of this paragraph (f)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *G* applies for a health insurance policy through Issuer *Q*. *Q*'s application materials ask for the applicant's medical history, but not for family medical history. The application's instructions state that no genetic information, including family medical history, should be provided. *G* answers the questions in the application completely and truthfully, but volunteers certain health information about diseases his parents had, believing that *Q* also needs this information.

(ii) *Conclusion.* In this *Example 1, G*'s family medical history is genetic information with respect to *G*. However, since *Q* did not request this genetic information, and *Q*'s instructions stated that no genetic information should be provided, *Q*'s collection is an incidental collection under paragraph (f)(2)(ii). However, *Q* may not use the genetic information it obtained incidentally for underwriting purposes.

Example 2. (i) *Facts.* Individual *H* applies for a health insurance policy through Issuer *R*. *R*'s application materials request that an applicant provide information on his or her individual medical history, including the names and contact information of physicians from whom the applicant sought treatment.

The application includes a release which authorizes the physicians to furnish information to *R*. *R* forwards a request for health information about *H*, including the signed release, to his primary care physician. Although the request for information does not ask for genetic information, including family medical history, it does not state that no genetic information should be provided. The physician's office administrator includes part of *H*'s family medical history in the package to *R*.

(ii) *Conclusion*. In this *Example 2*, *R*'s request was for health information solely about its applicant, *H*, which is not genetic information with respect to *H*. However, *R*'s materials did not state that genetic information should not be provided. Therefore, *R*'s collection of *H*'s family medical history (which is genetic information with respect to *H*), violates the rule against collection of genetic information and does not qualify for the incidental collection exception under paragraph (f)(2)(ii).

Example 3. (i) *Facts*. Issuer *S* acquires Issuer *T*. *S* requests *T*'s records, stating that *S* should not provide genetic information and should review the records to excise any genetic information. *T* assembles the data requested by *S* and, although *T* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *S* receives genetic information about some of *T*'s covered individuals.

(ii) *Conclusion*. In this *Example 3*, *S*'s request for health information explicitly stated that genetic information should not be provided. Therefore, its collection of genetic information was within the incidental collection exception. However, *S* may not use the genetic information it obtained incidentally for underwriting purposes.

(g) *Examples regarding determinations of medical appropriateness*. The application of the rules of paragraphs (e) and (f) of this section to issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts*. Individual *I* has an individual health insurance policy through Issuer *U* that covers genetic testing for celiac disease for individuals who have family members with this condition. *I*'s policy includes dependent coverage. After *I*'s son is diagnosed with celiac disease, *I* undergoes a genetic test and promptly submits a claim for the test to *U* for reimbursement. *U* asks *I* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion*. In this *Example 1*, under the rules of paragraph (e)(4) of this section, *U* is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for *U* to make a decision regarding the payment of *I*'s claim, *U*'s request for the results of the genetic test violates paragraph (e) of this section.

Example 2. (i) *Facts*. Individual *J* has an individual health insurance policy through Issuer *V* that covers a yearly mammogram for participants starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *J* is 33 years old and has the BRCA2 mutation. *J* undergoes a mammogram and promptly submits a claim to *V* for reimbursement. *V* asks *J* for evidence of increased risk of breast cancer, such as the results of a genetic test, before the claim for the mammogram is paid.

(ii) *Conclusion*. In this *Example 2*, *V* does not violate paragraphs (e) or (f) of this section. Under paragraph (e), an issuer is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the issuer requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the covered individual's genetic makeup, the minimum amount of information necessary includes the results of the genetic test. Similarly, *V* does not violate paragraph (f) of this section because an issuer is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts*. Individual *K* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *K*'s physician, *K* has been taking a regular dose of tamoxifen to help prevent a recurrence. *K* has an individual health insurance policy through Issuer *W* which adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

(ii) *Conclusion*. In this *Example 3*, *W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K*'s undergoing a genetic test to determine the genetic markers *K* has for making the CYP_2D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that

tamoxifen is not medically appropriate for *K*.

(h) *Applicability date.* The provisions of this section are effective with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

[74 FR 51693, Oct. 7, 2009]

Subpart D—Preemption; Excepted Benefits

§ 148.210 Preemption.

(a) *Scope.* (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers.* The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

§ 148.220 Excepted benefits.

The requirements of this part and part 147 of this subchapter do not apply to any individual coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(9) Travel insurance, within the meaning of §144.103 of this subchapter.

(b) *Other excepted benefits.* The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following:

(1) Limited scope dental or vision benefits. These benefits are dental or vision benefits that are limited in scope to a narrow range or type of benefits that are generally excluded from benefit packages that combine hospital, medical, and surgical benefits.

(2) Long-term care benefits. These benefits are benefits that are either—

(i) Subject to State long-term care insurance laws;

(ii) For qualified long-term care insurance services, as defined in section 7702B(c)(1) of the Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Code; or

(iii) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(3) Coverage only for a specified disease or illness (for example, cancer policies) if the policies meet the requirements of §146.145(b)(4)(ii)(B) and (C) of this subchapter regarding noncoordination of benefits.

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage;

(ii) The benefits are paid in a fixed dollar amount per period of hospitalization or illness and/or per service (for example, $100/day or $50/visit) regardless of the amount of expenses incurred and without regard to the amount of benefits provided with respect to the event or service under any other health coverage; and

(iii)(A) For coverage periods beginning on or after January 1, 2025, the

issuer displays prominently on the first page (in either paper or electronic form, including on a website) of any marketing, application, and enrollment or reenrollment materials that are provided at or before the time an individual has the opportunity to apply, enroll or reenroll in coverage, and on the first page of the policy, certificate, or contract of insurance, in at least 14-point font, the language in the following notice:

IMPORTANT: This is a fixed indemnity policy, NOT health insurance

This fixed indemnity policy may pay you a limited dollar amount if you're sick or hospitalized. You're still responsible for paying the cost of your care.

- The payment you get isn't based on the size of your medical bill.
- There might be a limit on how much this policy will pay each year.
- This policy isn't a substitute for comprehensive health insurance.
- Since this policy isn't health insurance, it doesn't have to include most Federal consumer protections that apply to health insurance.

Looking for comprehensive health insurance?

- **Visit HealthCare.gov** or call **1-800-318-2596** (TTY: 1-855-889-4325) to find health coverage options.
- To find out if you can get health insurance through your job, or a family member's job, contact the employer.

Questions about this policy?

- For questions or complaints about this policy, contact your State Department of Insurance. Find their number on the National Association of Insurance Commissioners' website (naic.org) under "Insurance Departments."
- If you have this policy through your job, or a family member's job, contact the employer.

(B) For coverage periods beginning on or after January 1, 2015, and prior to January 1, 2025, the issuer continues to follow the notice provision in 45 CFR 148.220(b)(4)(iv), revised as of October 1, 2023.

(iv) If any provision of this paragraph (b)(4) is held to be invalid or unenforceable by its terms, or as applied to any entity or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, along with other provisions not found invalid or unenforceable, including as applied

to entities not similarly situated or to dissimilar circumstances, unless such holding is that the provision is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (b)(4) and shall not affect the remainder thereof.

(5) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act. 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance). The requirements of this part 148 (including genetic nondiscrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic nondiscrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at *http://www.naic.org*.).

(6) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(7) Similar supplemental coverage provided to coverage under a group health plan (as described in §146.145(b)(5)(i)(C) of this subchapter).

[62 FR 16995, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 74 FR 51696, Oct. 7, 2009; 79 FR 30341, May 27, 2014; 81 FR 75327, Oct. 31, 2016; 89 FR 23420, Apr. 3, 2024]

Subpart E—Grants to States for Operation of Qualified High Risk Pools

SOURCE: 68 FR 23414, May 2, 2003, unless otherwise noted.

§ 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (PHS Act). It extends grants to States that have qualified high risk pools that meet the specific requirements described in §148.310. It also provides specific instructions on how to apply for the grants and outlines the grant review and grant award processes.

[73 FR 22285, Apr. 25, 2008]

§ 148.308 Definitions.

For the purposes of this subpart, the following definitions apply:

Bonus grants means funds that the Secretary provides from the appropriated grant funds to be used to provide supplemental consumer benefits to enrollees or potential enrollees in qualified high risk pools.

CMS stands for Centers for Medicare & Medicaid Services.

Loss means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and the premiums collected by the pool.

Qualified high risk pool as defined in sections 2744(c)(2) and 2745(g) of the PHS Act means a risk pool that—

(1) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, except that it may provide for enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 2744 of the PHS Act) that includes a high risk pool as a component; and

(2) Provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act that was in effect at the time of the enactment of the Health Insurance Portability and Accountability Act of 1996 (August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

Standard risk rate means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard rate may be adjusted based upon age, sex, and geographical location.

State means any of the 50 States and the District of Columbia and includes

the U.S. Territories of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State fiscal year, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.310 Eligibility requirements for a grant.

A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in §148.308.

(b) The pool restricts premiums charged under the pool to no more than 200 percent of the premium for applicable standard risk rates for the State.

(c) The pool offers a choice of two or more coverage options through the pool.

(d) The pool has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State after the end of each fiscal year for which the State applies for Federal Funding in fiscal year (FY) 2005 through FY 2010 in connection with the operation of the pool.

(e) The pool has incurred a loss in a period described in §148.314.

(f) In the case of a qualified high risk pool in a State that charges premiums that exceed 150 percent of the premium for applicable standard risks, the State will use at least 50 percent of the amount of the grant provided to the State to reduce premiums for enrollees.

(g) In no case will the aggregate amount allotted and made available to the U.S. Territories for a fiscal year exceed $1,000,000 in total.

(h) Bonus grant funding must be used for one or more of the following benefits:

(1) Low income premium subsidies;

(2) Reduction in premium trends, actual premium or other cost-sharing requirements;

(3) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules;

(4) Less stringent rules or additional waiver authority with respect to coverage of pre-existing conditions;

(5) Increased benefits; and

(6) The establishment of disease management programs.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.312 Amount of grant payment.

(a) An eligible State may receive a grant to fund up to 100 percent of the losses incurred in the operation of its qualified high risk pool during the period for which it is applying or a lesser amount based on the limits of the allotment under the formula.

(b) Funds will be allocated in accordance with this paragraph to each State that meets the eligibility requirements of §148.310 and files an application in accordance with §148.316. The amount will be divided among the States that apply and are awarded grants according to the allotment rules that generally provide that: 40 percent will be equally divided among those States; 30 percent will be divided among States and territories based on their number of uninsured residents in the State during the specified year as compared to all States that apply; and 30 percent will be divided among States and territories based on the number of people in State high risk pools during the specified year as compared to all States that apply.

For purposes of this paragraph:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau during the period for which it is applying. The 3-year average will be calculated using numbers available as of March 1 of each year.

(2) The number of individuals enrolled in health care coverage through the qualified high risk pool of the State will be determined by attestation by the State in its grant application and verified for reasonability by the

Secretary through acceptable industry data sources.

(c) The amount awarded to each eligible State will be the lesser of the 50 percent of losses incurred by its qualified risk pool for the fiscal year in question or its allotment under the formula.

(d) One-third of the total appropriation will be available for the bonus grants. In no case will a State for a fiscal year receive bonus grants that exceed 10 percent of the total allotted funds for bonus grants.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.314 Periods during which eligible States may apply for a grant.

(a) *General rule.* A State that meets the eligibility requirements in § 148.310 may apply for a grant to fund losses that were incurred during the State's FYs 2005, 2006, 2007, 2008 and 2009 in connection with the operation of its qualified high risk pool. Funding for FY 2007 through FY 2010 under the Extension Act requires subsequent enactment of appropriations authority. States will be unable to apply for grants unless and until such funding becomes available. Grants funding is on a retrospective basis and applies to the States previous fiscal year. If a State becomes eligible for a grant in the middle of its fiscal year, a State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Only losses that are incurred after eligibility is established will qualify for a grant.

(b) *Maximum number of grants.* An eligible State may only be awarded a maximum of five grants, with one grant per fiscal year. A grant for a partial fiscal year counts as a full grant.

(c) *Deadline for submitting grant applications.* The deadlines for submitting grant applications are stated in § 148.316(d).

(d) *Distribution of grant funds.* States that meet all of the eligibility requirements in § 148.310 and submit timely requests in accordance with paragraph (c) of this section will receive an initial distribution of grant funds using the following methodology: Grant applications for losses will be on a retrospective basis. For example, grant applications for 2006 funds are based on the State's FY 2005 incurred losses. Grant funding was appropriated for Federal FY 2006 and is authorized to be appropriated for Federal FYs 2008 through 2010.

(e) *Grant allocations.* Grant allocations for each fiscal year will be determined by taking all grant applications during the period for which States are applying and allocating the funds in accordance with § 148.312.

(1) In no case will a State receive funds greater than 100 percent of their losses.

(2) If any excess funds remain after the initial calculation, these excess funds will be proportionately redistributed to the States whose allocations have not exceeded 100 percent of their losses.

[73 FR 22285, Apr. 25, 2008]

§ 148.316 Grant application instructions.

Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority. Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(a) *Application for operational losses.* Each State must compile an application package that documents that it has met the requirements for a grant. If a risk pool entity applies on behalf of a State, it must provide documentation that it has been delegated appropriate authority by the State. At a minimum, the application package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool.* Provide a detailed description of the qualified high risk pool that includes the following:

(i) Brief history, including date of inception.

(ii) Enrollment criteria (including provisions for the admission of eligible individuals as defined in § 148.103) and number of enrollees.

(iii) Description of how coverage is provided administratively in the qualified high risk pool (that is, self-insured, through a private carrier, etc.).

(iv) Benefits options and packages offered in the qualified high risk pool to both eligible individual (as defined in §148.103) and other applicants.

(v) Outline of plan benefits and coverage offered in the pool. Provide evidence that the level of plan benefits is consistent with either Alternative One or Alternative Two in Section 8 of the NAIC Model Health Plan for Uninsurable Individuals Act. See appendix for the text of Section 8 of the NAIC Model.

(vi) Premiums charged (in terms of dollars and in percentage of standard risk rate) and other cost-sharing mechanisms, such as co-pays and deductibles, imposed on enrollees (both eligible individuals (as defined in §148.103) and non-eligible individuals if a distinction is made).

(vii) How the standard risk rate for the State is calculated and when it was last calculated.

(viii) Revenue sources for the qualified high risk pool, including current funding mechanisms and, if different, future funding mechanisms. Provide current projections of future income.

(ix) Copies of all governing authorities of the pool, including statutes, regulations and plan of operation.

(2) *Accounting of risk pool losses.* Provide a detailed accounting of claims paid, administrative expenses, and premiums collected for the fiscal year for which the grant is being requested. Indicate the timing of the fiscal year upon which the accounting is based. Provide the methodology of projecting losses and expenses, and include current projections of future operating losses (this information is needed to judge compliance with the requirements in §148.310(d)).

(3) *Bonus grants for supplemental consumer benefits.* Provide detailed information about the following supplemental consumer benefits for which the entity is applying:

(i) A narrative description of one or more of the following of the supplemental consumer benefits to be provided to enrollees and/or potential enrollees in the high risk pool:

(A) Low income premium subsidies;

(B) Reduction in premium trends, actual premium or other cost-sharing requirements;

(C) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment;

(D) Less stringent rules, or additional waiver authority with respect to coverage of pre-existing conditions;

(E) Increased benefits; and

(F) The establishment of disease management programs.

(ii) A description of the population or subset population that will be eligible for the supplemental consumer benefits.

(iii) A projected budget for the use of bonus grant funds using the SF 424 A.

(4) *Contact person.* Identify the name, position title, address, e-mail address, and telephone number of the person to contact for further information and questions.

(b) Standard form application kit—(1) Forms. (i) The following standard forms must be completed with an original signature and enclosed as part of the application package:

SF–424 Application for Federal Assistance.
SF–424A Budget Information.
SF–424B Assurances Non-Construction Programs.
SF–LLL Disclosure of Lobbying Activities Biographical Sketch.

(ii) These forms can be accessed from the following Web site: *http://www.grants.gov.*

(2) *Other narrative.* All other narrative in the application must be submitted on 8½ × 11 inches white paper.

(c) *Application submission.* Submission of application package is through *http://www.grants.gov.* Submissions by facsimile (fax) transmissions will not be accepted.

(d) *Application deadlines.* (1) The deadline for States to submit an application for losses incurred in a State fiscal year is June 30 of the next Federal fiscal year that begins after the end of the State fiscal year. Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority.

Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(2) *Deadline for States to submit an application for losses incurred in their fiscal year 2005.* States had to submit an application to CMS no later than June 30, 2006.

(3) *Deadline for States to submit an application for losses incurred in their fiscal year 2006.* States must submit an application to CMS by no later than June 30, 2007.

(4) *Deadline for States to submit an application for losses incurred in their fiscal year 2007.* States must submit an application to CMS by no later than June 30, 2008.

(5) *Deadline for States to submit an application for losses incurred in their fiscal year 2008.* States must submit an application to CMS by no later than June 30, 2009.

(6) *Deadline for States to submit an application for losses incurred in their fiscal year 2009.* States must submit an application to CMS by no later than June 30, 2010.

(e) *Where to submit an application.* Applications must be submitted to *http://www.grants.gov.* Submissions by facsimile (fax) transmissions will not be accepted.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15701, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§ 148.318 Grant application review.

(a) *Executive Order 12372.* This grant program is not listed by the Secretary under § 100.3 of this title, and therefore the grant program is not subject to review by States under part 100 of this title, which implements Executive Order 12372, ''Intergovernmental Review of Federal Programs'' (see part 100 of this title).

(b) *Review team.* A team consisting of staff from CMS and the Department of Health and Human Services will review all applications. The team will meet as necessary on an ongoing basis as applications are received.

(c) *Eligibility criteria.* To be eligible for a grant, a State must submit sufficient documentation that its high risk pool meets the eligibility requirements described in § 148.310. A State must include sufficient documentation of the losses incurred in the operation of the qualified high risk pool in the period for when it is applying.

(d) *Review criteria.* If the review team determines that a State meets the eligibility requirements described in § 148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State's pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after each fiscal year for which it is applying for grant funds.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§ 148.320 Grant awards.

(a) *Notification and award letter.* (1) Each State applicant will be notified in writing of CMS's decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

(iii) The grantee will be required to submit quarterly progress and financial reports under part 92 of this title and in accordance with section 2745(f) of the Public Health Service Act, requiring the Secretary to make an annual report to Congress that includes information on the use of these grant funds by States.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS' Acquisition and

Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

Subpart A—General Provisions

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Subpart C [Reserved]

Subpart D—Additional Patient Protections

149.310 Choice of health care professional.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

149.410 Balance billing in cases of emergency services.
149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.
149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.
149.440 Balance billing in cases of air ambulance services.
149.450 Complaints process for balance billing regarding providers and facilities.

Subpart F—Independent Dispute Resolution Process

149.510 Independent dispute resolution process.
149.520 Independent dispute resolution process for air ambulance services.

Subpart G—Protection of Uninsured or Self-Pay Individuals

149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.
149.620 Requirements for the patient-provider dispute resolution process.

Subpart H—Prescription Drug and Health Care Spending

149.710 Definitions.
149.720 Reporting requirements related to prescription drug and health care spending.
149.730 Aggregate reporting.
149.740 Required information.

AUTHORITY: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

SOURCE: 86 FR 36970, July 13, 2021, unless otherwise noted.

Subpart A—General Provisions

§ 149.10 Basis and scope.

(a) *Basis.* This part implements parts D and E of title XXVII of the PHS Act.

(b) *Scope.* This part establishes standards for group health plans, health insurance issuers offering group or individual health insurance coverage, health care providers and facilities, and providers of air ambulance services with respect to surprise medical bills, transparency in health care coverage, and additional patient protections. This part also establishes an independent dispute resolution process, and standards for certifying independent dispute resolution entities. This part also establishes a Patient-Provider Dispute Resolution Process and standards for certifying Selected Dispute Resolution entities.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021]

§ 149.20 Applicability.

(a) *In general.* (1) The requirements in subparts B, D, and H of this part apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in §147.140 of this subchapter), except as specified in paragraph (b) of this section.

(2) The requirements in subpart E of this part apply to health care providers, health care facilities, and providers of air ambulance services.

(3) The requirements in subpart F of this part apply to certified IDR entities, health care providers, health care facilities, and providers of air ambulance services and group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans as defined in §147.140 of this subchapter) except as specified in paragraph (b) of this section.

(4) The requirements in subpart G of this part apply to Selected Dispute Resolution Entities, health care providers, providers of air ambulance services, health care facilities and uninsured (or self-pay) individuals, as defined in subpart G.

(b) *Exceptions.* The requirements in subparts B, D, E, F, and H of this part do not apply to the following:

(1) Excepted benefits as described in §§146.145 and 148.220 of this subchapter.

(2) Short-term, limited-duration insurance as defined in §144.103 of this subchapter.

(3) Health reimbursement arrangements or other account-based group health plans as described in §147.126(d) of this subchapter.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021; 86 FR 66702, Nov. 23, 2021]

§149.30 Definitions.

The definitions in part 144 of this subchapter apply to this part, unless otherwise specified. In addition, for purposes of this part, the following definitions apply:

Air ambulance service means medical transport by a rotary wing air ambulance, as defined in 42 CFR 414.605, or fixed wing air ambulance, as defined in 42 CFR 414.605, for patients.

Cost sharing means the amount a participant, beneficiary, or enrollee is responsible for paying for a covered item or service under the terms of the group health plan or health insurance coverage. Cost sharing generally includes copayments, coinsurance, and amounts paid towards deductibles, but does not include amounts paid towards premiums, balance billing by out-of-network providers, or the cost of items or services that are not covered under a group health plan or health insurance coverage.

Emergency department of a hospital includes a hospital outpatient department that provides emergency services.

Emergency medical condition has the meaning given the term in §149.110(c)(1).

Emergency services has the meaning given the term in §149.110(c)(2).

Health care facility, with respect to a group health plan or group or individual health insurance coverage, in the context of non-emergency services, is each of the following:

(1) A hospital (as defined in section 1861(e) of the Social Security Act);

(2) A hospital outpatient department;

(3) A critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act); and

(4) An ambulatory surgical center described in section 1833(i)(1)(A) of the Social Security Act.

Independent freestanding emergency department means a health care facility (not limited to those described in the definition of health care facility with respect to non-emergency services) that—

(1) Is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(2) Provides any emergency services as described in §149.110(c)(2)(i).

Nonparticipating emergency facility means an emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to §149.110(c)(2)(ii) are included as emergency services), that does not have a contractual relationship directly or indirectly with a group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Nonparticipating provider means any physician or other health care provider who does not have a contractual relationship directly or indirectly with a

group health plan or group or individual health insurance coverage offered by a health insurance issuer, with respect to the furnishing of an item or service under the plan or coverage, respectively.

Notice of denial of payment means, with respect to an item or service for which benefits subject to the protections of §§149.110 through 149.130 are provided or covered, a written notice from the plan or issuer to the health care provider, facility, or provider of air ambulance services, as applicable, that payment for such item or service will not be made by the plan or coverage and which explains the reason for denial. The term notice of denial of payment does not include a notice of benefit denial due to an adverse benefit determination as defined in 29 CFR 2560.503–1.

Out-of-network rate means, with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law;

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law—

(i) Subject to paragraph (2)(ii) of this definition, if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment (including if the amount agreed upon is the initial payment sent by the plan or issuer under 26 CFR 54.9816–4T(b)(3)(iv)(A), 54.9816–5T(c)(3), or 54.9817–1T(b)(4)(i); 29 CFR 2590.716–4(b)(3)(iv)(A), 2590.716–5(c)(3), or 2590.717–1(b)(4)(i); or §149.110(b)(3)(iv)(A), §149.120(c)(3), or §149.130(b)(4)(i), as applicable, or is agreed on through negotiations with respect to such item or service), such agreed on amount; or

(ii) If the nonparticipating provider or nonparticipating emergency facility and the plan or issuer enter into the independent dispute resolution (IDR) process under section 9816(c) or 9817(b) of the Internal Revenue Code, section 716(c) or 717(b) of ERISA, or section 2799A–1(c) or 2799A–2(b) of the PHS Act, as applicable, and do not agree before the date on which a certified IDR entity makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Participating emergency facility means any emergency department of a hospital, or an independent freestanding emergency department (or a hospital, with respect to services that pursuant to §149.110(c)(2)(ii) are included as emergency services), that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between an emergency facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship for purposes of this definition, and is limited to the parties to the agreement.

Participating health care facility means any health care facility described in this section that has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively. A single case agreement between a health care facility and a plan or issuer that is used to address unique situations in which a participant, beneficiary, or enrollee requires services that typically occur out-of-network constitutes a contractual relationship

for purposes of this definition, and is limited to the parties to the agreement.

Participating provider means any physician or other health care provider who has a contractual relationship directly or indirectly with a group health plan or health insurance issuer offering group or individual health insurance coverage setting forth the terms and conditions on which a relevant item or service is provided to a participant, beneficiary, or enrollee under the plan or coverage, respectively.

Physician or health care provider means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, but does not include a provider of air ambulance services.

Provider of air ambulance services means an entity that is licensed under applicable State and Federal law to provide air ambulance services.

Same or similar item or service has the meaning given the term in §149.140(a)(13).

Service code has the meaning given the term in §149.140(a)(14).

Qualifying payment amount has the meaning given the term in §149.140(a)(16).

Recognized amount means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility—

(1) Subject to paragraph (3) of this definition, in a State that has in effect a specified State law, the amount determined in accordance with such law.

(2) Subject to paragraph (3) of this definition, in a State that does not have in effect a specified State law, the lesser of—

(i) The amount that is the qualifying payment amount (as determined in accordance with §149.140); or

(ii) The amount billed by the provider or facility.

(3) In a State that has an All-Payer Model Agreement under section 1115A of the Social Security Act that applies with respect to the plan or issuer; the nonparticipating provider or nonparticipating emergency facility; and the item or service, the amount that the State approves under the All-Payer Model Agreement for the item or service.

Specified State law means a State law that provides for a method for determining the total amount payable under a group health plan or group or individual health insurance coverage offered by a health insurance issuer to the extent such State law applies for an item or service furnished by a nonparticipating provider or nonparticipating emergency facility (including where it applies because the State has allowed a plan that is not otherwise subject to applicable State law an opportunity to opt in, subject to section 514 of the Employee Retirement Income Security Act of 1974). A group health plan that opts in to such a specified State law must do so for all items and services to which the specified State law applies and in a manner determined by the applicable State authority, and must prominently display in its plan materials describing the coverage of out-of-network services a statement that the plan has opted into the specified State law, identify the relevant State (or States), and include a general description of the items and services provided by nonparticipating facilities and providers that are covered by the specified State law.

State means each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Treating provider is a physician or health care provider who has evaluated the individual.

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.

Subpart B—Protections Against Balance Billing for the Group and Individual Health Insurance Markets

§ 149.110 Preventing surprise medical bills for emergency services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department, the plan or issuer must cover emergency services, as defined in paragraph (c)(2) of this section, and this coverage must be provided in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage for emergency services in the following manner—

(1) Without the need for any prior authorization determination, even if the services are provided on an out-of-network basis.

(2) Without regard to whether the health care provider furnishing the emergency services is a participating provider or a participating emergency facility, as applicable, with respect to the services.

(3) If the emergency services are provided by a nonparticipating provider or a nonparticipating emergency facility—

(i) Without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities.

(ii) Without imposing cost-sharing requirements that are greater than the requirements that would apply if the services were provided by a participating provider or a participating emergency facility.

(iii) By calculating the cost-sharing requirement as if the total amount that would have been charged for the services by such participating provider or participating emergency facility were equal to the recognized amount for such services.

(iv) The plan or issuer—

(A) Not later than 30 calendar days after the bill for the services is transmitted by the provider or facility (or, in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement), determines whether the services are covered under the plan or coverage and, if the services are covered, sends to the provider or facility, as applicable, an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(3)(iv)(A), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(B) Pays a total plan or coverage payment directly to the nonparticipating provider or nonparticipating facility that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(3)(ii) and (iii) of this section), less any initial payment amount made under paragraph (b)(3)(iv)(A) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(v) By counting any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to the emergency services toward any in-network deductible or in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and in-network out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to emergency services furnished by a participating

provider or a participating emergency facility.

(4) Without limiting what constitutes an emergency medical condition (as defined in paragraph (c)(1) of this section) solely on the basis of diagnosis codes.

(5) Without regard to any other term or condition of the coverage, other than—

(i) The exclusion or coordination of benefits (to the extent not inconsistent with benefits for an emergency medical condition, as defined in paragraph (c)(1) of this section).

(ii) An affiliation or waiting period (each as defined in §144.103 of this subchapter).

(iii) Applicable cost sharing.

(c) *Definitions.* In this section—

(1) *Emergency medical condition* means a medical condition, including a mental health condition or substance use disorder, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(2) *Emergency services* means, with respect to an emergency medical condition—

(i) *In general.* (A) An appropriate medical screening examination (as required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(B) Within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd), or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) *Inclusion of additional services.* (A) Subject to paragraph (c)(2)(ii)(B) of this section, items and services—

(*1*) For which benefits are provided or covered under the plan or coverage; and

(*2*) That are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in paragraph (c)(2)(i) of this section are furnished.

(B) Items and services described in paragraph (c)(2)(ii)(A) of this section are not included as emergency services if all of the conditions in §149.410(b) are met.

(3) *To stabilize,* with respect to an emergency medical condition, has the meaning given such term in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§149.120 Preventing surprise medical bills for non-emergency services performed by nonparticipating providers at certain participating facilities.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance

coverage, provides or covers any benefits with respect to items and services described in paragraph (b) of this section, the plan or issuer must cover the items and services when furnished by a nonparticipating provider in accordance with paragraph (c) of this section.

(b) *Items and services described.* The items and services described in this paragraph (b) are items and services (other than emergency services) furnished to a participant, beneficiary, or enrollee by a nonparticipating provider with respect to a visit at a participating health care facility, unless the provider has satisfied the notice and consent criteria of §149.420(c) through (i) with respect to such items and services.

(c) *Coverage requirements.* In the case of items and services described in paragraph (b) of this section, the plan or issuer—

(1) Must not impose a cost-sharing requirement for the items and services that is greater than the cost-sharing requirement that would apply if the items or services had been furnished by a participating provider.

(2) Must calculate the cost-sharing requirements as if the total amount that would have been charged for the items and services by such participating provider were equal to the recognized amount for the items and services.

(3) Not later than 30 calendar days after the bill for the items or services is transmitted by the provider (or in cases where the recognized amount is determined by a specified State law or All-Payer Model Agreement, such other timeframe as specified under the State law or All-Payer Model Agreement), must determine whether the items and services are covered under the plan or coverage and, if the items and services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (c)(3), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the items or services.

(4) Must pay a total plan or coverage payment directly to the nonparticipating provider that is equal to the amount by which the out-of-network rate for the items and services involved exceeds the cost-sharing amount for the items and services (as determined in accordance with paragraphs (c)(1) and (2) of this section), less any initial payment amount made under paragraph (c)(3) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–1(c)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(5) Must count any cost-sharing payments made by the participant, beneficiary, or enrollee toward any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if such cost-sharing payments were made with respect to items and services furnished by a participating provider.

(d) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§149.130 Preventing surprise medical bills for air ambulance services.

(a) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits for air ambulance services, the plan or issuer must cover such services from a nonparticipating provider of air ambulance services in accordance with paragraph (b) of this section.

(b) *Coverage requirements.* A plan or issuer described in paragraph (a) of this section must provide coverage of air ambulance services in the following manner—

(1) The cost-sharing requirements with respect to the services must be the same requirements that would apply if the services were provided by a participating provider of air ambulance services.

(2) The cost-sharing requirement must be calculated as if the total amount that would have been charged for the services by a participating provider of air ambulance services were equal to the lesser of the qualifying payment amount (as determined in accordance with §149.140) or the billed amount for the services.

(3) The cost-sharing amounts must be counted towards any in-network deductible and in-network out-of-pocket maximums (including the annual limitation on cost sharing under section 2707(b) of the PHS Act) (as applicable) applied under the plan or coverage (and the in-network deductible and out-of-pocket maximums must be applied) in the same manner as if the cost-sharing payments were made with respect to services furnished by a participating provider of air ambulance services.

(4) The plan or issuer must—

(i) Not later than 30 calendar days after the bill for the services is transmitted by the provider of air ambulance services, determine whether the services are covered under the plan or coverage and, if the services are covered, send to the provider an initial payment or a notice of denial of payment. For purposes of this paragraph (b)(4)(i), the 30-calendar-day period begins on the date the plan or issuer receives the information necessary to decide a claim for payment for the services.

(ii) Pay a total plan or coverage payment directly to the nonparticipating provider furnishing such air ambulance services that is equal to the amount by which the out-of-network rate for the services exceeds the cost-sharing amount for the services (as determined in accordance with paragraphs (b)(1) and (2) of this section), less any initial payment amount made under paragraph (b)(4)(i) of this section. The total plan or coverage payment must be made in accordance with the timing requirement described in section 2799A–2(b)(6) of the PHS Act, or in cases where the out-of-network rate is determined under a specified State law or All-Payer Model Agreement, such other timeframe as specified by the State law or All-Payer Model Agreement.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

§ 149.140 Methodology for calculating qualifying payment amount.

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

(1) *Contracted rate* means the total amount (including cost sharing) that a group health plan or health insurance issuer has contractually agreed to pay a participating provider, facility, or provider of air ambulance services for covered items and services, whether directly or indirectly, including through a third-party administrator or pharmacy benefit manager. Solely for purposes of this definition, a single case agreement, letter of agreement, or other similar arrangement between a provider, facility, or air ambulance provider and a plan or issuer, used to supplement the network of the plan or coverage for a specific participant, beneficiary, or enrollee in unique circumstances, does not constitute a contract.

(2) *Derived amount* has the meaning given the term in §147.210 of this subchapter.

(3) *Eligible database* means—

(i) A State all-payer claims database; or

(ii) Any third-party database which—

(A) Is not affiliated with, or owned or controlled by, any health insurance issuer, or a health care provider, facility, or provider of air ambulance services (or any member of the same controlled group as, or under common control with, such an entity). For purposes of this paragraph (a)(3)(ii)(A), the term controlled group means a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended;

(B) Has sufficient information reflecting in-network amounts paid by group health plans or health insurance issuers offering group or individual health insurance coverage to providers, facilities, or providers of air ambulance services for relevant items and services

furnished in the applicable geographic region; and

(C) Has the ability to distinguish amounts paid to participating providers and facilities by commercial payers, such as group health plans and health insurance issuers offering group or individual health insurance coverage, from all other claims data, such as amounts billed by nonparticipating providers or facilities and amounts paid by public payers, including the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act (or a demonstration project under title XI of the Social Security Act), or the Children's Health Insurance Program under title XXI of the Social Security Act.

(4) *Facility of the same or similar facility type* means, with respect to emergency services, either—

(i) An emergency department of a hospital; or

(ii) An independent freestanding emergency department.

(5) *First coverage year* means, with respect to an item or service for which coverage is not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, the first year after 2019 for which coverage for such item or service is offered under that plan or coverage.

(6) *First sufficient information year* means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(i) In the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019, the first year after 2022 for which the plan or issuer has sufficient information to calculate the median of such contracted rates in the year immediately preceding that first year after 2022; and

(ii) In the case of a newly covered item or service, the first year after the first coverage year for such item or service with respect to such plan or coverage for which the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in the year immediately preceding that first year.

(7) *Geographic region* means—

(i) For items and services other than air ambulance services—

(A) Subject to paragraphs (a)(7)(i)(B) and (C) of this section, one region for each metropolitan statistical area, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in a State, and one region consisting of all other portions of the State.

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State.

(C) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an item or service provided in a geographic region described in paragraph (a)(7)(i)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau.

(ii) For air ambulance services—

(A) Subject to paragraph (a)(7)(ii)(B) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in the State, and one region consisting of all other portions of the State, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(B) If a plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section for an air ambulance service provided in a geographic region described in

paragraph (a)(7)(ii)(A) of this section, one region consisting of all metropolitan statistical areas, as described by the U.S. Office of Management and Budget and published by the U.S. Census Bureau, in each Census division and one region consisting of all other portions of the Census division, as described by the U.S. Census Bureau, determined based on the point of pick-up (as defined in 42 CFR 414.605).

(8) *Insurance market* is, irrespective of the State, one of the following:

(i) The individual market (other than short-term, limited-duration insurance or individual health insurance coverage that consists solely of excepted benefits).

(ii) The large group market (other than coverage that consists solely of excepted benefits).

(iii) The small group market (other than coverage that consists solely of excepted benefits).

(iv) In the case of a self-insured group health plan, all self-insured group health plans (other than account-based plans, as defined in §147.126(d)(6)(i) of this subchapter, and plans that consist solely of excepted benefits) of the same plan sponsor, or at the option of the plan sponsor, all self-insured group health plans administered by the same entity (including a third-party administrator contracted by the plan), to the extent otherwise permitted by law, that is responsible for calculating the qualifying payment amount on behalf of the plan.

(9) *Modifiers* mean codes applied to the service code that provide a more specific description of the furnished item or service and that may adjust the payment rate or affect the processing or payment of the code billed.

(10) *Newly covered item or service* means an item or service for which coverage was not offered in 2019 under a group health plan or group or individual health insurance coverage offered by a health insurance issuer, but that is offered under the plan or coverage in a year after 2019.

(11) *New service code* means a service code that was created or substantially revised in a year after 2019.

(12) *Provider in the same or similar specialty* means the practice specialty of a provider, as identified by the plan or issuer consistent with the plan's or issuer's usual business practice, except that, with respect to air ambulance services, all providers of air ambulance services are considered to be a single provider specialty.

(13) *Same or similar item or service* means a health care item or service billed under the same service code, or a comparable code under a different procedural code system.

(14) *Service code* means the code that describes an item or service using the Current Procedural Terminology (CPT) code, Healthcare Common Procedure Coding System (HCPCS), or Diagnosis-Related Group (DRG) codes.

(15) *Sufficient information* means, for purposes of determining whether a group health plan or health insurance issuer offering group or individual health insurance coverage has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section—

(i) The plan or issuer has at least three contracted rates on January 31, 2019, to calculate the median of the contracted rates in accordance with paragraph (b) of this section; or

(ii) For an item or service furnished during a year after 2022 that is used to determine the first sufficient information year—

(A) The plan or issuer has at least three contracted rates on January 31 of the year immediately preceding that year to calculate the median of the contracted rates in accordance with paragraph (b) of this section; and

(B) The contracted rates under paragraph (a)(15)(ii)(A) of this section account (or are reasonably expected to account) for at least 25 percent of the total number of claims paid for that item or service for that year with respect to all plans of the sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by the issuer that are offered in the same insurance market.

(16) *Qualifying payment amount* means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage, the amount calculated using the methodology described in paragraph (c) of this section.

(17) *Underlying fee schedule rate* means the rate for a covered item or service from a particular participating provider, providers, or facility that a group health plan or health insurance issuer uses to determine a participant's, beneficiary's, or enrollee's cost-sharing liability for the item or service, when that rate is different from the contracted rate.

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

(b) *Methodology for calculation of median contracted rate*—(1) *In general.* The median contracted rate for an item or service is calculated by arranging in order from least to greatest the contracted rates of all group health plans of the plan sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all group or individual health insurance coverage offered by the issuer in the same insurance market for the same or similar item or service that is provided by a provider in the same or similar specialty or facility of the same or similar facility type and provided in the geographic region in which the item or service is furnished and selecting the middle number. If there are an even number of contracted rates, the median contracted rate is the average of the middle two contracted rates. In determining the median contracted rate, the amount negotiated under each contract is treated as a separate amount. If a plan or issuer has a contract with a provider group or facility, the rate negotiated with that provider group or facility under the contract is treated as a single contracted rate if the same amount applies with respect to all providers of such provider group or facility under the single contract. However, if a plan or issuer has a contract with multiple providers, with separate negotiated rates with each particular provider, each unique contracted rate with an individual provider constitutes a single contracted rate. Further, if a plan or issuer has separate contracts with individual providers, the contracted rate under each such contract constitutes a single contracted rate (even if the same amount is paid to multiple providers under separate contracts).

(2) *Calculation rules.* In calculating the median contracted rate, a plan or issuer must:

(i) Calculate the median contracted rate with respect to all plans of such sponsor (or the administering entity as provided in paragraph (a)(8)(iv) of this section, if applicable) or all coverage offered by such issuer that are offered in the same insurance market;

(ii) Calculate the median contracted rate using the full contracted rate applicable to the service code, except that the plan or issuer must—

(A) Calculate separate median contracted rates for CPT code modifiers ''26'' (professional component) and ''TC'' (technical component);

(B) For anesthesia services, calculate a median contracted rate for the anesthesia conversion factor for each service code;

(C) For air ambulance services, calculate a median contracted rate for the air mileage service codes (A0435 and A0436); and

(D) Where contracted rates otherwise vary based on applying a modifier code, calculate a separate median contracted rate for each such service code-modifier combination;

(iii) In the case of payments made by a plan or issuer that are not on a fee-for-service basis (such as bundled or capitation payments), calculate a median contracted rate for each item or service using the underlying fee schedule rates for the relevant items or services. If the plan or issuer does not have an underlying fee schedule rate for the item or service, it must use the derived amount to calculate the median contracted rate; and

(iv) Exclude risk sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments.

(3) *Provider specialties; facility types.* (i) If a plan or issuer has contracted rates that vary based on provider specialty for a service code, the median

contracted rate is calculated separately for each provider specialty, as applicable.

(ii) If a plan or issuer has contracted rates for emergency services that vary based on facility type for a service code, the median contracted rate is calculated separately for each facility of the same or similar facility type.

(c) *Methodology for calculation of the qualifying payment amount*—(1) *In general.* (i) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2022, the plan or issuer must calculate the qualifying payment amount by increasing the median contracted rate (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, by the combined percentage increase as published by the Department of the Treasury and the Internal Revenue Service to reflect the percentage increase in the CPI–U over 2019, such percentage increase over 2020, and such percentage increase over 2021.

(A) The combined percentage increase for 2019, 2020, and 2021 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and the Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(i), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for 2019, 2020, and 2021 will be calculated as:

(CPI–U 2019/CPI–U 2018) × (CPI–U 2020/CPI–U 2019) × (CPI–U 2021/CPI–U 2020)

(ii) For an item or service (other than items or services described in paragraphs (c)(1)(iii) through (vii) of this section) furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(1)(i) of this section, for such an item or service furnished in the immediately preceding year, by the percentage increase as published by the Department of the Treasury and the Internal Revenue Service.

(A) The percentage increase for any year after 2022 will be published in guidance by the Internal Revenue Service. The Department of the Treasury and Internal Revenue Service will calculate the percentage increase using the CPI–U published by the Bureau of Labor Statistics of the Department of Labor.

(B) For purposes of this paragraph (c)(1)(ii), the CPI–U for each calendar year is the average of the CPI–U as of the close of the 12-month period ending on August 31 of the calendar year, rounded to 10 decimal places.

(C) The combined percentage increase for any year will be calculated as CPI–U present year/CPI–U prior year.

(iii) For anesthesia services furnished during 2022, the plan or issuer must calculate the qualifying payment amount by first increasing the median contracted rate for the anesthesia conversion factor (as determined in accordance with paragraph (b) of this section) for the same or similar item or service under such plans or coverage, respectively, on January 31, 2019, in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median contracted rate for the anesthesia conversion factor). The plan or issuer must then multiply the indexed median contracted rate for the anesthesia conversion factor by the sum of the base unit, time unit, and physical status modifier units of the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(A) The base units for an anesthesia service code are the base units for that service code specified in the most recent edition (as of the date of service) of the American Society of Anesthesiologists Relative Value Guide.

(B) The time unit is measured in 15-minute increments or a fraction thereof.

(C) The physical status modifier on a claim is a standard modifier describing the physical status of the patient and

is used to distinguish between various levels of complexity of the anesthesia services provided, and is expressed as a unit with a value between zero (0) and three (3).

(D) The anesthesia conversion factor is expressed in dollars per unit and is a contracted rate negotiated with the plan or issuer.

(iv) For anesthesia services furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median contracted rate for the anesthesia conversion factor, determined under paragraph (c)(1)(iii) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply that amount by the sum of the base unit, time unit, and physical status modifier units for the participant, beneficiary, or enrollee to whom anesthesia services are furnished to determine the qualifying payment amount.

(v) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2022, the plan or issuer must calculate the qualifying payment amount for services billed using the air mileage service codes by first increasing the median contracted rate (as determined in accordance with paragraph (b) of this section), in accordance with paragraph (c)(1)(i) of this section (referred to in this section as the indexed median air mileage rate). The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(A) The air mileage rate is expressed in dollars per loaded mile flown, is expressed in statute miles (not nautical miles), and is a contracted rate negotiated with the plan or issuer.

(B) The number of loaded miles is the number of miles a patient is transported in the air ambulance vehicle.

(C) The qualifying payment amount for other service codes associated with air ambulance services is calculated in accordance with paragraphs (c)(1)(i) and (ii) of this section.

(vi) For air ambulance services billed using the air mileage service codes (A0435 and A0436) that are furnished during 2023 or a subsequent year, the plan or issuer must calculate the qualifying payment amount by first increasing the indexed median air mileage rate, determined under paragraph (c)(1)(v) of this section for such services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii) of this section. The plan or issuer must then multiply the indexed median air mileage rate by the number of loaded miles provided to the participant, beneficiary, or enrollee to determine the qualifying payment amount.

(vii) For any other items or services for which a plan or issuer generally determines payment for the same or similar items or services by multiplying a contracted rate by another unit value, the plan or issuer must calculate the qualifying payment amount using a methodology that is similar to the methodology required under paragraphs (c)(1)(iii) through (vi) of this section and reasonably reflects the payment methodology for same or similar items or services.

(2) *New plans and coverage.* With respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which the sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(i) For the first year in which the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region—

(A) If the plan or issuer has sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1) of this section for items and services that are covered by the plan or coverage and furnished during the first year; and

(B) If the plan or issuer does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section

for an item or service provided in a geographic region, the plan or issuer must determine the qualifying payment amount for the item or service in accordance with paragraph (c)(3)(i) of this section.

(ii) For each subsequent year the group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in the region, the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under this paragraph (c)(2) for the items and services furnished in the immediately preceding year, in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable.

(3) *Insufficient information; newly covered items and services.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section in 2019 (or, in the case of a newly covered item or service, in the first coverage year for such item or service with respect to such plan or coverage if the plan or issuer does not have sufficient information) for an item or service provided in a geographic region—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must calculate the qualifying payment amount by first identifying the rate that is equal to the median of the in-network allowed amounts for the same or similar item or service provided in the geographic region in the year immediately preceding the year in which the item or service is furnished (or, in the case of a newly covered item or service, the year immediately preceding such first coverage year) determined by the plan or issuer, respectively, through use of any eligible database, and then increasing that rate by the percentage increase in the CPI–U over such preceding year. For purposes of this section, in cases in which an eligible database is used to determine the qualifying payment amount with respect to an item or service furnished during a calendar year, the plan or issuer must use the same database for determining the qualifying payment amount for that item or service furnished through the last day of the calendar year, and if a different database is selected for some items or services, the basis for that selection must be one or more factors not directly related to the rate of those items or services (such as sufficiency of data for those items or services).

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(3)(i) of this section or this paragraph (c)(3)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI–U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(i), (iii), or (v) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2022' is treated as a reference to furnished during such first sufficient information year, the reference to 'in 2019' is treated as a reference to such sufficient information year, and the increase described in such paragraph is not applied; and

(iv) For an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(1)(ii), (iv), or (vi) of this section, as applicable, except that in applying such paragraph to such item or service, the reference to 'furnished during 2023 or a subsequent year' is treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(4) *New service codes.* In the case of a plan or issuer that does not have sufficient information to calculate the median of the contracted rates described in paragraph (b) of this section and determine the qualifying payment amount under paragraphs (c)(1) through (3) of this section because the item or service furnished is billed under a new service code—

(i) For an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for the item or service with respect to the plan or coverage), the plan or issuer must identify a reasonably related service code that existed in the immediately preceding year and—

(A) If the Centers for Medicare & Medicaid Services has established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that Medicare pays for the item or service billed under the new service code compared to the rate that Medicare pays for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code for the year in which the item or service is furnished.

(B) If the Centers for Medicare & Medicaid Services has not established a Medicare payment rate for the item or service billed under the new service code, the plan or issuer must calculate the qualifying payment amount by first calculating the ratio of the rate that the plan or issuer reimburses for the item or service billed under the new service code compared to the rate that the plan or issuer reimburses for the item or service billed under the related service code, and then multiplying the ratio by the qualifying payment amount for an item or service billed under the related service code.

(ii) For an item or service furnished in a subsequent year (before the first sufficient information year for such item or service with respect to such plan or coverage or before the first year for which an eligible database has sufficient information to a calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year), the plan or issuer must calculate the qualifying payment amount by increasing the qualifying payment amount determined under paragraph (c)(4)(i) of this section or this paragraph (c)(4)(ii), as applicable, for such item or service for the year immediately preceding such subsequent year, by the percentage increase in CPI–U over such preceding year;

(iii) For an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage or the first year for which an eligible database has sufficient information to calculate a rate under paragraph (c)(3)(i) of this section in the immediately preceding year, the plan or issuer must calculate the qualifying payment amount in accordance with paragraph (c)(3) of this section.

(d) *Information to be shared about qualifying payment amount.* In cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services is the qualifying payment amount, the plan or issuer must provide in writing, in paper or electronic form, to the provider or facility, as applicable—

(1) With each initial payment or notice of denial of payment under §149.110, §149.120, or §149.130:

(i) The qualifying payment amount for each item or service involved;

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded;

(iii) A statement to certify that, based on the determination of the plan or issuer—

(A) The qualifying payment amount applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing); and

(B) Each qualifying payment amount shared with the provider or facility was determined in compliance with this section;

(iv) A statement that if the provider or facility, as applicable, wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider or facility may contact the appropriate person or office to initiate open negotiation, and that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the independent dispute resolution process within 4 days after the end of the open negotiation period; and

(v) Contact information, including a telephone number and email address, for the appropriate person or office to initiate open negotiations for purposes of determining an amount of payment (including cost sharing) for such item or service.

(2) In a timely manner upon request of the provider or facility:

(i) Information about whether the qualifying payment amount for items and services involved included contracted rates that were not on a fee-for-service basis for those specific items and services and whether the qualifying payment amount for those items and services was determined using underlying fee schedule rates or a derived amount;

(ii) If a plan or issuer uses an eligible database under paragraph (c)(3) of this section to determine the qualifying payment amount, information to identify which database was used; and

(iii) If a related service code was used to determine the qualifying payment amount for an item or service billed under a new service code under paragraph (c)(4)(i) or (ii) of this section, information to identify the related service code; and

(iv) If applicable, a statement that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments for the items and services involved (as applicable) that were excluded for purposes of calculating the qualifying payment amount.

(e) *Certain access fees to databases.* In the case of a plan or issuer that, pursuant to this section, uses an eligible database to determine the qualifying payment amount for an item or service, the plan or issuer is responsible for any costs associated with accessing such database.

(f) *Audits.* The procedures described in part 150 of this subchapter apply with respect to ensuring that a plan or coverage is in compliance with the requirement of applying a qualifying payment amount under this subpart and ensuring that such amount so applied satisfies the requirements under this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable for plan years or in the individual market, policy years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term ''downcode'' and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market, policy years beginning on or after January 1, 2022.

[86 FR 36970, July 13, 2021, as amended at 87 FR 52652, Aug. 26, 2022]

§ 149.150 Complaints process for surprise medical bills regarding group health plans and group and individual health insurance coverage.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process to receive and resolve complaints regarding information that a specific group health plan or health insurance issuer offering group or individual health insurance coverage may be failing to

meet the requirements under this subpart, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) *Complaint* means a communication, written or oral, that indicates there has been a potential violation of the requirements under subpart B of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral or written statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. As part of the response, HHS may request additional information needed to process the complaint. Such additional information may include:

(i) Explanations of benefits;

(ii) Processed claims;

(iii) Information about the health care provider, facility, or provider of air ambulance services involved;

(iv) Information about the group health plan or health insurance issuer covering the individual;

(v) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(vi) The summary plan description, policy, certificate, contract of insurance, membership booklet, outline of coverage, or other evidence of coverage the plan or issuer provides to participants, beneficiaries, or enrollees;

(vii) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(viii) Any other information HHS may need to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint and the plan or issuer involved, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the plan or issuer;

(iii) Refer the plan or issuer for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of the resolution of the complaint and any corrective action taken.

Subpart C [Reserved]

Subpart D—Additional Patient Protections

§ 149.310 Choice of health care professional.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the

plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

(A) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until the individual has made a designation. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(B) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(*2*) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(2)(iii)(A) of this section), except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(*2*) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section, may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by

a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

(A) *Example 1—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(*2*) *Conclusion.* In this *Example 1,* the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaning gynecological services.

(B) *Example 2—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that *A* seeks gynecological services from *C*, an out-of-network provider.

(*2*) *Conclusion.* In this *Example 2,* the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

(C) *Example 3—(1) Facts.* Same facts as *Example 1* (paragraph (a)(3)(iv)(A) of this section) except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(*2*) *Conclusion.* In this *Example 3,* the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires the designated primary care physician to be notified of treatment decisions does not violate this paragraph (a)(3).

(D) *Example 4—(1) Facts.* A group health plan requires each participant to designate a physician to serve as the

primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(*2*) *Conclusion*. In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general*. If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing*. In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language*. The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Applicability date*. The provisions of this section are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Subpart E—Health Care Provider, Health Care Facility, and Air Ambulance Service Provider Requirements

§ 149.410 Balance billing in cases of emergency services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition with respect to a visit at an emergency department of a hospital or an independent freestanding emergency department—

(1) A nonparticipating emergency facility must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for such emergency services (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and §149.110(c)(2), as applicable) that exceeds the cost-sharing requirement for such services (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and §149.110(b)(3)(ii) and (iii), as applicable).

(2) A nonparticipating provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for an emergency service (as defined in 26 CFR 54.9816–4T(c)(2), 29 CFR 2590.716–4(c)(2), and §149.110(c)(2), as applicable) furnished to such individual by such provider with respect to such emergency medical condition and visit for which the individual receives emergency services at the hospital or independent freestanding emergency department that exceeds the cost-sharing requirement for such service (as determined in accordance with 26 CFR 54.9816–4T(b)(3)(ii) and (iii), 29 CFR 2590.716–4(b)(3)(ii) and (iii), and §149.110(b)(3)(ii) and (iii), as applicable).

(b) *Notice and consent to be treated by a nonparticipating provider or nonparticipating emergency facility.* The requirements in paragraph (a) of this section do not apply with respect to items and services described in 26 CFR, 54.9816–4T(c)(2)(ii)(A), 29 CFR 2590.716–4(c)(2)(ii)(A), §149.110(c)(2)(ii)(A), as applicable, and are not included as emergency services if all of the following conditions are met:

(1) The attending emergency physician or treating provider determines that the participant, beneficiary, or enrollee is able to travel using nonmedical transportation or nonemergency medical transportation to an available participating provider or facility located within a reasonable travel distance, taking into account the individual's medical condition. The attending emergency physician's or treating provider's determination is binding on the facility for purposes of this requirement.

(2) The provider or facility furnishing such additional items and services satisfies the notice and consent criteria of §149.420(c) through (g) with respect to such items and services, provided that the written notice additionally satisfies paragraphs (b)(2)(i) and (ii) of this section, as applicable. In applying this paragraph (b)(2), a reference in §149.420 to a nonparticipating provider is deemed to include a nonparticipating emergency facility.

(i) In the case of a participating emergency facility and a nonparticipating provider, the written notice must also include a list of any participating providers at the facility who are able to furnish such items and services involved and notification that the participant, beneficiary, or enrollee may be referred, at their option, to such a participating provider.

(ii) In the case of a nonparticipating emergency facility, the written notice must include the good faith estimated amount that the participant, beneficiary, or enrollee may be charged for items or services furnished by the nonparticipating emergency facility or by nonparticipating providers with respect to the visit at such facility (including any item or service that is reasonably expected to be furnished by the nonparticipating emergency facility or nonparticipating providers in conjunction with such items or services).

(3) The participant, beneficiary, or enrollee (or an authorized representative of such individual) is in a condition to receive the information described in §149.420, as determined by

the attending emergency physician or treating provider using appropriate medical judgment, and to provide informed consent under such section, in accordance with applicable State law. For purposes of this section and § 149.420, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee.

(4) The provider or facility satisfies any additional requirements or prohibitions as may be imposed under State law.

(c) *Inapplicability of notice and consent exception to certain items and services.* A nonparticipating provider or nonparticipating facility specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider or nonparticipating emergency facility satisfied the notice and consent criteria in § 149.420(c) through (g).

(d) *Retention of certain documents.* A nonparticipating emergency facility (with respect to such facility or any nonparticipating provider at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage (or an authorized representative of such an individual) a written consent in accordance with § 149.420(e), with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, or such individual's authorized representative, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(e) *Notification to plan or issuer.* In the case of a participant, beneficiary, or enrollee who is stabilized and furnished additional items and services described in § 149.110(c)(2)(ii), a nonparticipating provider or nonparticipating emergency facility must notify the plan or issuer, respectively, when transmitting the bill for such items and services, either on the bill or in a separate document, as to whether all of the conditions described in paragraph (b) of this section are met with respect to each of the items and services for which the bill is submitted, and if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraph (b)(2) of this section.

(f) *Applicability date.* The provisions of this section are applicable with respect to emergency services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.420 Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating health care facilities.

(a) *In general.* A nonparticipating provider of a group health plan or group or individual health insurance coverage who provides items or services (other than emergency services) for which benefits are provided under the plan or coverage at a participating health care facility must not bill, and must not hold liable, a participant, beneficiary, or enrollee of such plan or coverage for a payment amount for such an item or service furnished by such provider with respect to a visit at the facility that exceeds the cost-sharing requirement for such item or service (as determined in accordance with 26 CFR 54.9816–5T(c)(1) and (2), 29 CFR 2590.717–1(c)(1) and (2), and § 149.120(c)(1) and (2), as applicable), unless the provider (or the participating health care facility on behalf of the provider) satisfies the notice and consent criteria of paragraph (c) of this section.

(b) *Inapplicability of notice and consent exception to certain items and services.* The notice and consent criteria in

paragraphs (c) through (i) of this section do not apply, and a nonparticipating provider specified in paragraph (a) of this section will always be subject to the prohibitions in paragraph (a) of this section, with respect to the following services:

(1) Ancillary services, meaning—

(i) Items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether provided by a physician or non-physician practitioner;

(ii) Items and services provided by assistant surgeons, hospitalists, and intensivists;

(iii) Diagnostic services, including radiology and laboratory services; and

(iv) Items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(2) Items or services furnished as a result of unforeseen, urgent medical needs that arise at the time an item or service is furnished, regardless of whether the nonparticipating provider satisfied the notice and consent criteria in paragraph (c) of this section.

(c) *Notice and consent to be treated by a nonparticipating provider.* Subject to paragraph (f) of this section, and unless prohibited by State law, a nonparticipating provider satisfies the notice and consent criteria of this paragraph (c) with respect to items or services furnished by the provider to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage, if the provider (or a participating health care facility on behalf on a nonparticipating provider)—

(1) Provides to the participant, beneficiary, or enrollee a written notice in paper or, as practicable, electronic form, as selected by the individual, that contains the information required under paragraph (d) of this section, provided such written notice is provided:

(i) In accordance with guidance issued by HHS, and in the form and manner specified in such guidance;

(ii) With the consent document, and is provided physically separate from other documents and not attached to or incorporated into any other document; and

(iii) To such participant, beneficiary, or enrollee—

(A) Not later than 72 hours prior to the date on which the individual is furnished such items or services, in the case where the appointment to be furnished such items or services is scheduled at least 72 hours prior to the date on which the individual is to be furnished such items and services; or

(B) On the date the appointment to be furnished such items or services is scheduled, in the case where the appointment is scheduled within 72 hours prior to the date on which such items or services are to be furnished. Where an individual is provided the notice on the same date that the items or services are to be furnished, providers and facilities are required to provide the notice no later than 3 hours prior to furnishing items or services to which the notice and consent requirements apply.

(2) Obtains from the participant, beneficiary, or enrollee the consent described in paragraph (e) of this section to be treated by the nonparticipating provider. An authorized representative may receive the notice on behalf of a participant, beneficiary, or enrollee, and may provide consent on behalf of the participant, beneficiary, or enrollee. For purposes of this section and §149.410, an authorized representative is an individual authorized under State law to provide consent on behalf of the participant, beneficiary, or enrollee, provided that the individual is not a provider affiliated with the facility or an employee of the facility, unless such provider or employee is a family member of the participant, beneficiary, or enrollee. The consent must—

(i) Be provided voluntarily, meaning the individual is able to consent freely, without undue influence, fraud, or duress;

(ii) Be obtained in accordance with, and in the form and manner specified in, guidance issued by HHS; and

(iii) Not be revoked, in writing, by the participant, beneficiary, or enrollee prior to the receipt of items and services to which the consent applies.

(3) Provides a copy of the signed written notice and consent to the participant, beneficiary, or enrollee in-person or through mail or email, as selected

by the participant, beneficiary, or enrollee.

(d) *Information required under written notice.* The written notice described in paragraph (c)(1) of this section must be provided in the form and manner specified by HHS in guidance, and must—

(1) State that the health care provider is a nonparticipating provider, with respect to the health plan or coverage.

(2) Include the good faith estimated amount that such nonparticipating provider may charge the participant, beneficiary, or enrollee for the items and services involved (including any item or service that is reasonably expected to be furnished by the nonparticipating provider in conjunction with such items or services), including notification that the provision of the estimate or consent to be treated under paragraph (e) of this section does not constitute a contract with respect to the charges estimated for such items and services or a contract that binds the participant, beneficiary, or enrollee to be treated by that provider or facility.

(3) Provide a statement that prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility.

(4) Clearly state that consent to receive such items and services from such nonparticipating provider is optional and that the participant, beneficiary, or enrollee may instead seek care from an available participating provider, with respect to the plan or coverage, as applicable, and that in such cases the cost-sharing responsibility of the participant, beneficiary, or enrollee would not exceed the responsibility that would apply with respect to such an item or service that is furnished by a participating provider, as applicable, with respect to such plan.

(e) *Consent described to be treated by a nonparticipating provider.* The consent described in this paragraph (e), with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage who is to be furnished items or services by a nonparticipating provider, must be documented on a form specified by the Secretary, in consultation with the Secretary of Labor, through guidance and provided in accordance with such guidance, that must be signed by the participant, beneficiary, or enrollee before such items and services are furnished and that—

(1) Acknowledges in clear and understandable language that the participant, beneficiary, or enrollee has been—

(i) Provided with the written notice under paragraph (c) of this section, in the form selected by the participant, beneficiary, or enrollee.

(ii) Informed that the payment of such charge by the participant, beneficiary, or enrollee might not accrue toward meeting any limitation that the plan or coverage places on cost sharing, including an explanation that such payment might not apply to an in-network deductible or out-of-pocket maximum applied under the plan or coverage.

(2) States that by signing the consent, the individual agrees to be treated by the nonparticipating provider and understands the individual may be balance billed and subject to cost-sharing requirements that apply to services furnished by the nonparticipating provider.

(3) Documents the time and date on which the participant, beneficiary, or enrollee received the written notice described in paragraph (c) of this section and the time and date on which the individual signed the consent to be furnished such items or services by such nonparticipating provider.

(f) *Language access.* (1) A nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) must provide the individual with the choice to receive the written notice and consent document in any of the 15 most common languages in the State in which the applicable facility is located, except that the notice and consent document may instead be available in any of the 15 most common languages in a geographic region that reasonably reflects the geographic region served by the applicable facility; and

(2) If the individual's preferred language is not among the 15 most common languages in which the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) makes the notice and consent document available and the individual cannot understand the language in which the notice and consent document are provided, the notice and consent criteria in paragraph (c) of this section are not met unless the nonparticipating provider (or the participating health care facility on behalf of the nonparticipating provider) has obtained the services of a qualified interpreter to assist the individual with understanding the information contained in the notice and consent document.

(g) *Scope of consent.* The consent described in paragraph (e) of this section will constitute consent only to the receipt of the information provided pursuant to this section and will not constitute a contractual agreement of the participant, beneficiary, or enrollee to any estimated charge or amount included in such information, or to be treated by that provider or facility.

(h) *Retention of certain documents.* A participating health care facility (with respect to nonparticipating providers at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage a written consent in accordance with paragraph (e) of this section, with respect to furnishing an item or service to such an individual, must retain the written notice and consent for at least a 7-year period after the date on which the item or service is so furnished. If a nonparticipating provider obtains a signed consent from a participant, beneficiary, or enrollee, where the facility does not otherwise obtain the consent on behalf of the provider, the provider may either coordinate with the facility to retain the written notice and consent for a 7-year period, or the provider must retain the written notice and consent for a 7-year period.

(i) *Notification to plan or issuer.* For each item or service furnished by a nonparticipating provider described in paragraph (a) of this section, the provider (or the participating facility on behalf of the nonparticipating provider) must timely notify the plan or issuer that the item or service was furnished during a visit at a participating health care facility, and, if applicable, provide to the plan or issuer a copy of the signed written notice and consent document described in paragraphs (c) and (e) of this section. In instances where, to the extent permitted by this section, the nonparticipating provider bills the participant, beneficiary, or enrollee directly, the provider may satisfy the requirement to notify the plan or issuer by including the notice with the bill to the participant, beneficiary, or enrollee.

(j) *Applicability date.* The provisions of this section are applicable with respect to items and services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.430 Provider and facility disclosure requirements regarding patient protections against balance billing.

(a) *In general.* Each health care provider and health care facility (including an emergency department of a hospital and an independent freestanding emergency department) must make publicly available, post on a public website of such provider or facility (if applicable), and provide to any individual who is a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer and to whom the provider or facility furnishes items or services, the information described in paragraph (b) of this section regarding patient protections against balance billing, except as provided in paragraphs (e) and (f) of this section. A provider or facility must make the disclosures in accordance with the method and timing requirements set forth in paragraphs (c) and (d) of this section.

(b) *Content.* The disclosures required under this section must include, in clear and understandable language, all the information described in this paragraph (b) (and may include any additional information that does not conflict with that information).

(1) A statement that explains the requirements of and prohibitions applicable to the health care provider or health care facility under sections 2799B–1 and 2799B–2 of the PHS Act and their implementing regulations in §§ 149.410 and 149.420;

(2) If applicable, a statement that explains any State law requirements regarding the amounts such provider or facility may, with respect to an item or service, charge a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer with respect to which such provider or facility does not have a contractual relationship, after receiving payment, if any, from the plan or coverage, respectively, for such item or service and any applicable cost-sharing payment from such participant, beneficiary, or enrollee; and

(3) A statement providing contact information for the appropriate State and Federal agencies that an individual may contact if the individual believes the provider or facility has violated a requirement described in the notice.

(c) *Required methods for disclosing information.* Health care providers and health care facilities must provide the disclosure required under this section as follows:

(1) With respect to the required disclosure to be posted on a public website, the information described in paragraph (b) of this section, or a link to such information, must appear on a searchable homepage of the provider's or facility's website. A provider or facility that does not have its own website is not required to make a disclosure under this paragraph (c)(1).

(2) With respect to the required disclosure to the public, a provider or facility must make public the information described in paragraph (b) of this section on a sign posted prominently at the location of the provider or facility. A provider that does not have a publicly accessible location is not required to make a disclosure under this paragraph (c)(2).

(3) With respect to the required disclosure to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a provider or facility must provide the information described in paragraph (b) of this section in a one-page (double-sided) notice, using print no smaller than 12-point font. The notice must be provided in-person or through mail or email, as selected by the participant, beneficiary, or enrollee.

(d) *Timing of disclosure to individuals.* A health care provider or health care facility is required to provide the notice to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer no later than the date and time on which the provider or facility requests payment from the individual, or with respect to an individual from whom the provider or facility does not request payment, no later than the date on which the provider or facility submits a claim to the group health plan or health insurance issuer.

(e) *Exceptions.* A health care provider is not required to make the disclosures required under this section—

(1) If the provider does not furnish items or services at a health care facility, or in connection with visits at health care facilities; or

(2) To individuals to whom the provider furnishes items or services, if such items or services are not furnished at a health care facility, or in connection with a visit at a health care facility.

(f) *Special rule to prevent unnecessary duplication with respect to health care providers.* To the extent a provider furnishes an item or service covered under the plan or coverage at a health care facility (including an emergency department of a hospital or independent freestanding emergency department), the provider satisfies the requirements of paragraphs (c)(2) and (3) of this section if the facility makes the information available, in the required form and manner, pursuant to a written agreement. Accordingly, if a provider and facility enter into a written agreement under which the facility agrees to make the information required under this section available on a sign posted prominently at the facility and to provide the one-page notice to individuals

in compliance with this section, and the facility fails to do so, then the facility, but not the provider, violates the disclosure requirements of this section.

(g) *Applicability date.* The provisions of this section are applicable beginning on January 1, 2022.

§ 149.440 Balance billing in cases of air ambulance services.

(a) *In general.* In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is furnished air ambulance services (for which benefits are available under such plan or coverage) from a nonparticipating provider of air ambulance services, with respect to such plan or coverage, the provider must not bill, and must not hold liable, the participant, beneficiary, or enrollee for a payment amount for the air ambulance services furnished by the provider that is more than the cost-sharing amount for such service (as determined in accordance with 26 CFR 54.9817–1T(b)(1) and (2), 29 CFR 2590.717–1(b)(1) and (2), and § 149.130(b)(1) and (2), as applicable).

(b) *Applicability date.* The provisions of this section are applicable with respect to air ambulance services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

§ 149.450 Complaint process for balance billing regarding providers and facilities.

(a) *Scope and definitions*—(1) *Scope.* This section establishes a process for HHS to receive and resolve complaints regarding information that a health care provider, provider of air ambulance services, or health care facility may be failing to meet the requirements under subpart E or subpart G of this part, which may warrant an investigation.

(2) *Definitions.* In this section—

(i) Complaint means a communication, written, or oral, that indicates there has been a potential violation of the requirements under this subpart or subpart G of this part, whether or not a violation actually occurred.

(ii) *Complainant* means any individual, or their authorized representative, who files a complaint as defined in paragraph (a)(2)(i) of this section.

(b) *Complaints process.* (1) HHS will consider the date a complaint is filed to be the date upon which HHS receives an oral, written, or electronic statement that identifies information about the complaint sufficient to identify the parties involved and the action or inaction complained of.

(2) HHS will notify complainants, by oral or written means, of receipt of the complaint no later than 60 business days after the complaint is received. HHS will include a response acknowledging receipt of the complaint, notifying the complainant of their rights and obligations under the complaints process, and describing the next steps of the complaints resolution process. HHS may request additional information that may be needed to process the complaint as part of the response. Such additional information may include:

(i) Health care provider, air ambulance provider, or health care facility bills;

(ii) Health care provider, air ambulance provider, or health care facility network status;

(iii) Information regarding the participant's, beneficiary's, or enrollee's health care plan or health insurance coverage;

(iv) Information to support a determination regarding whether the service was an emergency service or non-emergency service;

(v) Documents regarding the facts in the complaint in the possession of, or otherwise attainable by, the complainant; or

(vi) Any other information HHS needs to make a determination of facts for an investigation.

(3) HHS will make reasonable efforts consistent with agency practices to notify the complainant of the outcome of the complaint after the submission is processed through appropriate methods as determined by HHS. A complaint is considered processed after HHS has reviewed the complaint and accompanying information and made an outcome determination. Based on the nature of the complaint, HHS may—

(i) Refer the complainant to another appropriate Federal or State resolution process;

(ii) Notify the complainant and make reasonable efforts to refer the complainant to the appropriate State or Federal regulatory authority if HHS receives a complaint where another entity has enforcement jurisdiction over the health care provider, air ambulance provider or health care facility;

(iii) Refer the health care provider, air ambulance provider or health care facility for an investigation for enforcement action under 45 CFR part 150; or

(iv) Provide the complainant with an explanation of resolution and any corrective action taken.

[86 FR 36970, July 13, 2021, as amended at 86 FR 56124, Oct. 7, 2021]

Subpart F—Independent Dispute Resolution Process

SOURCE: 86 FR 56124, Oct. 7, 2021, unless otherwise noted.

§ 149.510 Independent dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to the independent dispute resolution (IDR) process (referred to in this section as the Federal IDR process) under which a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services (as applicable), and a group health plan or health insurance issuer offering group or individual health insurance coverage completes a requisite open negotiation period and at least one party submits a notification under paragraph (b) of this section to initiate the Federal IDR process under paragraph (c) of this section, and under which an IDR entity (as certified under paragraph (e) of this section) determines the amount of payment under the plan or coverage for an item or service furnished by the provider or facility.

(2) *Definitions.* Unless otherwise stated, the definitions in §149.30 of this part apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Batched items and services* means multiple qualified IDR items or services that are considered jointly as part of one payment determination by a certified IDR entity for purposes of the Federal IDR process. In order for a qualified IDR item or service to be included in a batched item or service, the qualified IDR item or service must meet the criteria set forth in paragraph (c)(3) of this section.

(ii) *Breach* means the acquisition, access, use, or disclosure of individually identifiable health information (IIHI) in a manner not permitted under paragraph (e)(2)(v) of this section that compromises the security or privacy of the IIHI.

(A) Breach excludes:

(*1*) Any unintentional acquisition, access, or use of IIHI by personnel, a contractor, or a subcontractor of a certified IDR entity that is acting under the authority of that certified IDR entity, if the acquisition, access, or use was made in good faith and within the scope of that authority and that does not result in further use or disclosure in a manner not permitted under paragraph (e)(2)(v) of this section.

(*2*) Any inadvertent disclosure by a person who is authorized to access IIHI at a certified IDR entity to another person authorized to access IIHI at the same certified IDR entity, and the information received as a result of the disclosure is not further used or disclosed in a manner not permitted under paragraph (e)(2)(v) of this section.

(*3*) A disclosure of IIHI in which a certified IDR entity has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(B) Except as provided in paragraph (a)(2)(ii)(A) of this definition, access, use, or disclosure of IIHI in a manner not permitted under paragraph (e)(2)(v) of this section is presumed to be a breach unless the certified IDR entity demonstrates that there is a low probability that the security or privacy of the IIHI has been compromised based on a risk assessment encompassing at least the following factors:

(*1*) The nature and extent of the IIHI involved, including the types of identifiers and the likelihood of re-identification;

(*2*) The unauthorized person who used the IIHI or to whom the disclosure was made;

(*3*) Whether the IIHI was actually acquired or viewed; and

(*4*) The extent to which the risk to the IIHI has been mitigated.

(iii) *Certified IDR entity* means an entity responsible for conducting determinations under paragraph (c) of this section that meets the certification criteria specified in paragraph (e) of this section and that has been certified by the Secretary, jointly with the Secretaries of Labor and the Treasury.

(iv) *Conflict of interest* means, with respect to a party to a payment determination, or certified IDR entity, a material relationship, status, or condition of the party, or certified IDR entity that impacts the ability of the certified IDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when a certified IDR entity is:

(A) A group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term, limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(B) An affiliate or a subsidiary of a group health plan; a health insurance issuer offering group health insurance coverage, individual health insurance coverage, or short-term limited-duration insurance; a carrier offering a health benefits plan under 5 U.S.C. 8902; or a provider, a facility, or a provider of air ambulance services;

(C) An affiliate or subsidiary of a professional or trade association representing group health plans; health insurance issuers offering group health insurance coverage, individual health insurance coverage, or short-term limited duration insurance; carriers offering a health benefits plan under 5 U.S.C. 8902; or providers, facilities, or providers of air ambulance services.

(D) A certified IDR entity, that has, or that has any personnel, contractors, or subcontractors assigned to a determination who have, a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the plan, issuer, or carrier offering a health benefits plan under 5 U.S.C. 8902; the plan or coverage administrator, plan or coverage fiduciaries, or plan, issuer or carrier employees; the health care provider, the health care provider's group or practice association; the provider of air ambulance services, the provider of air ambulance services' group or practice association, or the facility that is a party to the dispute.

(v) *Credible information* means information that upon critical analysis is worthy of belief and is trustworthy.

(vi) *IDR entity* means an entity that may apply or has applied for certification to conduct determinations under paragraph (c) of this section, and that currently is not certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, pursuant to paragraph (e) of this section.

(vii) *Individually identifiable health information (IIHI)* means any information, including demographic data, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(A) That identifies the individual; or

(B) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(viii) *Material familial relationship* means any relationship as a spouse, domestic partner, child, parent, sibling, spouse's or domestic partner's parent, spouse's or domestic partner's sibling, spouse's or domestic partner's child, child's parent, child's spouse or domestic partner, or sibling's spouse or domestic partner.

(ix) *Material financial relationship* means any financial interest of more than five percent of total annual revenue or total annual income of a certified IDR entity or an officer, director, or manager thereof, or of a reviewer or

reviewing physician employed or engaged by a certified IDR entity to conduct or participate in any review in the Federal IDR process. The terms annual revenue and annual income do not include mediation fees received by mediators who are also arbitrators, provided that the mediator acts in the capacity of a mediator and does not represent a party in the mediation.

(x) *Material professional relationship* means any physician-patient relationship, any partnership or employment relationship, any shareholder or similar ownership interest in a professional corporation, partnership, or other similar entity; or any independent contractor arrangement that constitutes a material financial relationship with any expert used by the certified IDR entity or any officer or director of the certified IDR entity.

(xi) *Qualified IDR item or service* means an item or service:

(A) That is an emergency service furnished by a nonparticipating provider or nonparticipating facility subject to the protections of 26 CFR 54.9816–4T, 29 CFR 2590.716–4, or §149.110, as applicable, for which the conditions of §149.410(b) are not met, or an item or service furnished by a nonparticipating provider at a participating health care facility, subject to the requirements of 26 CFR 54.9816–5T, 29 CFR 2590.717–5, or §149.120, as applicable, for which the conditions of §149.420(c)–(i) are not met, or air ambulance services furnished by a nonparticipating provider of air ambulance services subject to the protections of 26 CFR 54.9817–1T, 29 CFR 2590.717–1, or §149.130, as applicable, and for which the out-of-network rate is not determined by reference to an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law as defined in §149.30;

(B) With respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (b)(2) of this section;

(C) That is not an item or service that is the subject of an open negotiation under paragraph (b)(1) of this section; and

(D) That is not an item or service for which a notification under paragraph (b)(2) of this section is submitted during the 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, but that may include such an item or service if the notification is submitted during the subsequent 30-business-day period under paragraph (c)(4)(vi)(C) of this section.

(xii) *Unsecured IIHI* means IIHI that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(b) *Determination of payment amount through open negotiation and initiation of the Federal IDR process*—(1) *Determination of payment amount through open negotiation*—(i) *In general.* With respect to an item or service that meets the requirements of paragraph (a)(2)(xii)(A) of this section, the provider, facility, or provider of air ambulance services or the group health plan or health insurance issuer offering group or individual health insurance coverage may, during the 30-business-day period beginning on the day the provider, facility, or provider of air ambulance services receives an initial payment or notice of denial of payment regarding the item or service, initiate an open negotiation period for purposes of determining the out-of-network rate for such item or service. To initiate the open negotiation period, a party must send a notice to the other party (open negotiation notice) in accordance with paragraph (b)(1)(ii) of this section.

(ii) *Open negotiation notice*—(A) *Content.* The open negotiation notice must include information sufficient to identify the item(s) and service(s) (including the date(s) the item(s) or service(s) were furnished, the service code, and initial payment amount, if applicable), an offer of an out-of-network rate, and contact information for the party sending the open negotiation notice.

(B) *Manner.* The open negotiation notice must be provided, using the standard form developed by the Secretary, in writing within 30 business days beginning on the day the provider, facility, or provider of air ambulance services

receives an initial payment or a notice of denial of payment from the plan or issuer regarding the item or service. The day on which the open negotiation notice is first sent by a party is the date the 30-business-day open negotiation period begins. This notice may be provided to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The party sending the open negotiation notice has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(2) *Initiating the Federal IDR process*—(i) *In general.* With respect to an item or service for which the parties do not agree upon an out-of-network rate by the last day of the open negotiation period under paragraph (b)(1) of this section, either party may initiate the Federal IDR process. To initiate the Federal IDR process, a party must submit a written notice of IDR initiation to the other party and to the Secretary, using the standard form developed by the Secretary, during the 4-business-day period beginning on the 31st business day after the start of the open negotiation period.

(ii) *Exception for items and services provided by certain nonparticipating providers and facilities.* A party may not initiate the Federal IDR process with respect to an item or service if, with respect to that item or service, the party knows (or reasonably should have known) that the provider or facility provided notice and received consent under 45 CFR 149.410(b) or 149.420(c) through (i).

(iii) *Notice of IDR initiation*—(A) *Content.* The notice of IDR initiation must include:

(*1*) Information sufficient to identify the qualified IDR items or services under dispute (and whether the qualified IDR items or services are designated as batched items and services as described in paragraph (c)(3) of this section), including the date(s) and location the item or service was furnished, the type of item or service (such as whether the qualified IDR item or service is an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(i), 29 CFR 2590.716–4(c)(2)(i), or §149.110(c)(2)(i), as applicable, an emergency service as defined in 26 CFR 54.9816–4T(c)(2)(ii), 29 CFR 2590.716–4(c)(2)(ii), or §149.110(c)(2)(ii), as applicable, or a nonemergency service; and whether any service is a professional service or facility-based service), corresponding service codes, place of service code, the amount of cost sharing allowed, and the amount of the initial payment made for the qualified IDR item or service, if applicable;

(*2*) Names of the parties involved and contact information, including name, email address, phone number, and mailing address;

(*3*) State where the qualified IDR item or service was furnished;

(*4*) Commencement date of the open negotiation period under paragraph (b)(1) of this section;

(*5*) Preferred certified IDR entity;

(*6*) An attestation that the items and services under dispute are qualified IDR items or services;

(*7*) Qualifying payment amount;

(*8*) Information about the qualifying payment amount as described in §149.140(d); and

(*9*) General information describing the Federal IDR process as specified by the Secretary.

(B) *Manner.* The initiating party must provide written notice of IDR initiation to the other party. The initiating party may satisfy this requirement by furnishing the notice of IDR initiation to the other party electronically (such as by email) if the following two conditions are satisfied—

(*1*) The initiating party has a good faith belief that the electronic method is readily accessible by the other party; and

(*2*) The notice is provided in paper form free of charge upon request.

(C) *Notice to the Secretary.* The initiating party must also furnish the notice of IDR initiation to the Secretary by submitting the notice through the Federal IDR portal. The initiation date of the Federal IDR process will be the date of receipt by the Secretary.

(c) *Federal IDR process following initiation*—(1) *Selection of certified IDR entity*—(i) *In general.* The plan or issuer or the provider, facility, or provider of air ambulance services receiving the notice of IDR initiation under paragraph

(b)(2) of this section may agree or object to the preferred certified IDR entity identified in the notice of IDR initiation. If the party in receipt of the notice of IDR initiation fails to object within 3 business days, the preferred certified IDR entity identified in the notice of IDR initiation will be selected and will be treated as jointly agreed to by the parties, provided that the certified IDR entity does not have a conflict of interest. If the party in receipt of the notice of IDR initiation objects, that party must notify the initiating party of the objection and propose an alternative certified IDR entity. The initiating party must then agree or object to the alternative certified IDR entity; if the initiating party fails to agree or object to the alternative certified IDR entity, the alternative certified IDR entity will be selected and will be treated as jointly agreed to by the parties. In order to select a preferred certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services must jointly agree on a certified IDR entity not later than 3 business days after the initiation date of the Federal IDR process. If the plan or issuer and the provider, facility, or provider of air ambulance services fail to agree upon a certified IDR entity within that time, the Secretary shall select a certified IDR entity in accordance with paragraph (c)(1)(iv) of this section.

(ii) *Requirements for selected certified IDR entity.* The certified IDR entity selected must be an IDR entity certified under paragraph (e) of this section, that:

(A) Does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(B) Ensures that assignment of personnel to a payment determination and decisions regarding hiring, compensation, termination, promotion, or other similar matters related to personnel assigned to the dispute are not made based upon the likelihood that the assigned personnel will support a particular party to the determination being disputed other than as outlined under paragraph (c)(4)(iii) of this section; and

(C) Ensures that any personnel assigned to a payment determination do not have any conflicts of interests as defined in paragraph (a)(2) of this section regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18 U.S.C. 207(b).

(iii) *Notice of certified IDR entity selection.* Upon the selection of a certified IDR entity, in accordance with paragraph (c)(1)(i) of this section, the plan or issuer or the provider or emergency facility that submitted the notice of IDR initiation under paragraph (b)(2) of this section must notify the Secretary of the selection as soon as reasonably practicable, but no later than 1 business day after such selection, through the Federal IDR portal. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding the Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of certified IDR entity selection must be submitted.

(A) *Content.* If the parties have agreed on the selection of a certified IDR entity or the party in receipt of the notice of IDR initiation has not objected to the other party's selection, the notice of the certified IDR entity selection must include the following information:

(*1*) Name of the certified IDR entity;

(*2*) The certified IDR entity number; and

(*3*) Attestation by both parties, or by the initiating party if the non-initiating party fails to object to the selection of the certified IDR entity, that the selected certified IDR entity meets the requirements of paragraph (c)(1)(ii) of this section.

(B) [Reserved]

(iv) *Failure to select a certified IDR entity.* If the plan or issuer and the provider, facility, or provider of air ambulance services fail to select a certified IDR entity in accordance with paragraph (c)(1)(i) of this section, the initiating party must notify the Secretary of the failure no later than 1 business day after the date of such failure (or in

other words, 4 business days after initiation of the Federal IDR process) by electronically submitting the notice as described in paragraph (c)(1)(iii) of this section but indicating that the parties have failed to select a certified IDR entity. In addition, if the non-initiating party believes that the Federal IDR process is not applicable, the non-initiating party must also provide information regarding Federal IDR process's inapplicability through the Federal IDR portal by the same date that the notice of failure to select must be submitted. Upon notification of the failure of the parties to select a certified IDR entity, the Secretary will select a certified IDR entity that charges a fee within the allowed range of certified IDR entity fees through a random selection method not later than 6 business days after the date of initiation of the Federal IDR process and will notify the plan or issuer and the provider or facility of the selection. If there are insufficient certified IDR entities that charge a fee within the allowed range of certified IDR entity fees available to arbitrate the dispute, the Secretary, jointly with the Secretary of the Treasury and Secretary of Labor, will select a certified IDR entity that has received approval, as described in paragraph (e)(2)(vi)(B) of this section, to charge a fee outside of the allowed range of certified IDR entity fees.

(v) *Review by certified IDR entity.* After selection by the parties (including when the initiating party selects a certified IDR entity and the other party does not object), or by the Secretary under paragraph (c)(1)(iv) of this section, the certified IDR entity must review the selection and attest that it meets the requirements of paragraph (c)(1)(ii) of this section. If the certified IDR entity is unable to attest that it meets the requirements of paragraph (c)(1)(ii) of this section within 3 business days of selection, the parties, upon notification, must select another certified IDR entity under paragraph (c)(1) of this section, treating the date of notification of the failure to attest to the requirements of (c)(1)(ii) as the date of initiation of the Federal IDR process for purposes of the time periods in paragraphs (c)(1)(i) and (iv) of this section. Additionally, the certified IDR entity selected must review the information submitted in the notice of IDR initiation to determine whether the Federal IDR process applies. If the Federal IDR process does not apply, the certified IDR entity must notify the Secretary and the parties within 3 business days of making that determination.

(2) *Authority to continue negotiations*—(i) *In general.* If the parties to the Federal IDR process agree on an out-of-network rate for a qualified IDR item or service after providing the notice of IDR initiation to the Secretary consistent with paragraph (b)(2) of this section, but before the certified IDR entity has made its payment determination, the amount agreed to by the parties for the qualified IDR item or service will be treated as the out-of-network rate for the qualified IDR item or service. To the extent the amount exceeds the initial payment amount (or initial denial of payment) and any cost sharing paid or required to be paid by the participant or beneficiary, payment must be made directly by the plan or issuer to the nonparticipating provider, facility, or nonparticipating provider of air ambulance services not later than 30 business days after the agreement is reached. In no instance may either party seek additional payment from the participant or beneficiary, including in instances in which the out-of-network rate exceeds the qualifying payment amount. The initiating party must send a notification to the Secretary and to the certified IDR entity (if selected) electronically, through the Federal IDR portal, as soon as possible, but no later than 3 business days after the date of the agreement. The notification must include the out-of-network rate for the qualified IDR item or service and signatures from authorized signatories for both parties.

(ii) *Method of allocation of the certified IDR entity fee.* In the case of an agreement described in paragraph (c)(2)(i) of this section, the certified IDR entity is required to return half of each parties' certified IDR entity fee, unless directed otherwise by both parties. The administrative fee under paragraph (d)(2) of this section will not be returned to the parties.

(3) *Treatment of batched items and services*—(i) *In general.* Batched items and services may be submitted and considered jointly as part of one payment determination by a certified IDR entity only if the batched items and services meet the requirements of this paragraph (c)(3)(i). Batched items and services submitted and considered jointly as part of one payment determination under this paragraph (c)(3)(i) are treated as a batched determination and subject to the fee for batched determinations under this section.

(A) The qualified IDR items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services. Items and services are billed by the same provider or group of providers, the same facility, or the same provider of air ambulance services if the items or services are billed with the same National Provider Identifier or Tax Identification Number;

(B) Payment for the qualified IDR items and services would be made by the same plan or issuer;

(C) The qualified IDR items and services are the same or similar items and services. The qualified IDR items and services are considered to be the same or similar items or services if each is billed under the same service code, or a comparable code under a different procedural code system, such as Current Procedural Terminology (CPT) codes with modifiers, if applicable, Healthcare Common Procedure Coding System (HCPCS) with modifiers, if applicable, or Diagnosis-Related Group (DRG) codes with modifiers, if applicable; and

(D) All the qualified IDR items and services were furnished within the same 30-business-day period, or the same 90-calendar-day period under paragraph (c)(4)(vi)(B) of this section, as applicable.

(ii) *Treatment of bundled payment arrangements.* In the case of qualified IDR items and services billed by a provider, facility, or provider of air ambulance services as part of a bundled payment arrangement, or where a plan or issuer makes or denies an initial payment as a bundled payment, the qualified IDR items and services may be submitted as part of one payment determination. Bundled payment arrangements submitted under this paragraph (c)(3)(ii) are subject to the rules for batched determinations and the certified IDR entity fee for single determinations.

(4) *Payment determination for a qualified IDR item or service*—(i) *Submission of offers.* Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(*1*) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(*2*) Information requested by the certified IDR entity relating to the offer.

(*3*) The following additional information, as applicable—

(*i*) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(*ii*) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(*iii*) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(*iv*) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) *Payment determination and notification.* Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, weighing only the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(B) Notify the plan or issuer and the provider or facility, as applicable, of the selection of the offer under paragraph (c)(4)(ii)(A) of this section, and provide the written decision required under (c)(4)(vi) of this section.

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*1*) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(*2*) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(*3*) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(*4*) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(*5*) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does

not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1—(1) Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B)

through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4—(1) Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix

and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5—*(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under §149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under §149.140(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) *Prohibition on consideration of certain factors.* In determining which offer to select, the certified IDR entity must not consider:

(A) Usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges);

(B) The amount that would have been billed by the provider or facility with

respect to the qualified IDR item or service had the provisions of 45 CFR 149.410 and 149.420 (as applicable) not applied; or

(C) The payment or reimbursement rate for items and services furnished by the provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act; the Medicaid program under title XIX of the Social Security Act; the Children's Health Insurance Program under title XXI of the Social Security Act; the TRICARE program under chapter 55 of title 10, United States Code; chapter 17 of title 38, United States Code; or demonstration projects under section 1115 of the Social Security Act.

(vi) *Written decision.* (A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

(vii) *Effects of determination*—(A) *Binding.* A determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section:

(*1*) Is binding upon the parties, in the absence of fraud or evidence of intentional misrepresentation of material facts presented to the certified IDR entity regarding the claim; and

(*2*) Is not subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9, United States Code.

(B) *Suspension of certain subsequent IDR requests.* In the case of a determination made by a certified IDR entity under paragraph (c)(4)(ii) of this section, the party that submitted the initial notification under paragraph (b)(2) of this section may not submit a subsequent notification involving the same other party with respect to a claim for the same or similar item or service that was the subject of the initial notification during the 90-calendar-day period following the determination.

(C) *Subsequent submission of requests permitted.* If the end of the open negotiation period specified in paragraph (b)(1) of this section occurs during the 90-calendar-day suspension period regarding claims for the same or similar item or service that were the subject of the initial notice of IDR determination as described in paragraph (c)(4)(vi) of this section, either party may initiate the Federal IDR process for those claims by submitting a notification as specified in paragraph (b)(2) of this section during the 30-business-day period beginning on the day after the last day of the 90-calendar-day suspension period.

(viii) *Recordkeeping requirements.* The certified IDR entity must maintain records of all claims and notices associated with the Federal IDR process with respect to any determination for 6 years. The certified IDR entity must make these records available for examination by the plan, issuer, FEHB carrier, provider, facility, or provider of air ambulance services, or a State or Federal oversight agency upon request, except to the extent the disclosure would violate either State or Federal privacy law.

(ix) *Payment.* If applicable, the amount of the offer selected by the certified IDR entity (less the sum of the initial payment and any cost sharing paid or owed by the participant or beneficiary) must be paid directly to the provider, facility, or provider of air ambulance services not later than 30 calendar days after the determination by the certified IDR entity. If the offer selected by the certified IDR entity is less than the sum of the initial payment and any cost sharing paid by the

participant or beneficiary, the provider, facility, or provider of air ambulance services will be liable to the plan or issuer for the difference. The provider, facility, or provider of air ambulance services must pay the difference directly to the plan or issuer not later than 30 calendar days after the determination by the certified IDR entity.

(d) *Costs of IDR process*—(1) *Certified IDR entity fee.* (i) With respect to the Federal IDR process described in paragraph (c) of this section, the party whose offer submitted to the certified IDR entity under paragraph (c)(4)(ii)(A) of this section is not selected is responsible for the payment to the certified IDR entity of the predetermined fee charged by the certified IDR entity.

(ii) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must pay the predetermined certified IDR entity fee charged by the certified IDR entity to the certified IDR entity at the time the parties submit their offers under (c)(4)(i) of this section. The certified IDR entity fee paid by the prevailing party whose offer is selected by the certified IDR entity will be returned to that party within 30 business days following the date of the certified IDR entity's determination.

(2) *Administrative fee.* (i) Each party to a determination for which a certified IDR entity is selected under paragraph (c)(1) of this section must, at the time the certified IDR entity is selected under paragraph (c)(1) of this section, pay to the certified IDR entity a non-refundable administrative fee due to the Secretary for participating in the Federal IDR process described in this section.

(ii) The administrative fee amount will be established through notice and comment rulemaking no more frequently than once per calendar year in a manner such that the total administrative fees paid for a year are estimated to be equal to the amount of expenditures estimated to be made by the Secretaries of the Treasury, Labor, and Health and Human Services for the year in carrying out the Federal IDR process. The administrative fee amount will remain in effect until changed by notice and comment rulemaking. For disputes initiated on or after January 22, 2024, the administrative fee amount is $115 per party per dispute.

(3) *Severability.* (i) Any provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) of this section held to be invalid or unenforceable as applied to any person or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this paragraph (d) or paragraphs (e)(2)(vii) and (viii) and shall not affect the remainder thereof.

(ii) The provisions in this paragraph (d) and paragraphs (e)(2)(vii) and (viii) of this section are intended to be severable from each other.

(e) *Certification of IDR entity*—(1) *In general.* In order to be selected under paragraph (c)(1) of this section—

(i) An IDR entity must meet the standards described in this paragraph (e) and be certified by the Secretary, jointly with the Secretaries of Labor and the Treasury, as set forth in this paragraph (e) of this section and guidance promulgated by the Secretary. Once certified, the IDR entity will be provided with a certified IDR entity number.

(ii) An IDR entity must provide written documentation to the Secretary regarding general company information (such as contact information, Taxpayer Identification Number, and website), as well as the applicable service area in which the IDR entity intends to conduct payment determinations under the Federal IDR process. IDR entities may choose to submit their application for all States or self-limit to a particular subset of States.

(iii) An IDR entity that the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, certifies must enter into an agreement as a condition of certification. The agreement shall include specified provisions encompassed by this section, including, but not limited to, the requirements applicable to certified

IDR entities when making payment determinations as well as the requirements regarding certification and revocation (such as specifications for wind down activities and reallocation of certified IDR entity fees, where warranted).

(2) *Requirements.* An IDR entity must provide written documentation to the Secretary through the Federal IDR portal that demonstrates that the IDR entity satisfies the following standards to be a certified IDR entity under this paragraph (e):

(i) Possess (directly or through contracts or other arrangements) sufficient arbitration and claims administration of health care services, managed care, billing and coding, medical and legal expertise to make the payment determinations described in paragraph (c) of this section within the time prescribed in paragraph (c)(4)(ii) of this section.

(ii) Employ (directly or through contracts or other arrangements) a sufficient number of personnel to make the determinations described in paragraph (c) of this section within the time prescribed by (c)(4)(ii) of this section. To satisfy this standard, the written documentation must include a description of the IDR entity's organizational structure and capabilities, including an organizational chart and the credentials, responsibilities, and number of personnel employed to make determinations described in paragraph (c) of this section.

(iii) Maintain a current accreditation from a nationally recognized and relevant accrediting organization, such as URAC, or ensure that it otherwise possesses the requisite training to conduct payment determinations (for example, providing documentation that personnel employed by the IDR entity have completed arbitration training by the American Arbitration Association, the American Health Law Association, or a similar organization).

(iv) Have a process to ensure that no conflict of interest, as defined in paragraph (a)(2) of this section, exists between the parties and the personnel the certified IDR entity assigns to a payment determination to avoid violating paragraph (c)(1)(ii) of this section, including policies and procedures for conducting ongoing audits for conflicts of interest, to ensure that should any arise, the certified IDR entity has procedures in place to inform the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, of the conflict of interest and to mitigate the risk by reassigning the dispute to other personnel in the event that any personnel previously assigned have a conflict of interest.

(v) Have a process to maintain the confidentiality of IIHI obtained in the course of conducting determinations. A certified IDR entity's responsibility to comply with these confidentiality requirements shall survive revocation of the IDR entity's certification for any reason, and IDR entities must comply with the record retention and disposal requirements described in this section. Under this process, once certified, the certified IDR entity must comply with the following requirements:

(A) *Privacy.* The certified IDR entity may create, collect, handle, disclose, transmit, access, maintain, store, and/or use IIHI, only to perform:

(*1*) The certified IDR entity's required duties described in this section; and

(*2*) Functions related to carrying out additional obligations as may be required under applicable Federal or State laws or regulations.

(B) *Security.* (*1*) The certified IDR entity must ensure the confidentiality of all IIHI it creates, obtains, maintains, stores, and transmits;

(*2*) The certified IDR entity must protect against any reasonably anticipated threats or hazards to the security of this information;

(*3*) The certified IDR entity must ensure that IIHI is securely destroyed or disposed of in an appropriate and reasonable manner 6 years from either the date of its creation or the first date on which the certified IDR entity had access to it, whichever is earlier.

(*4*) The certified IDR entity must implement policies and procedures to prevent, detect, contain, and correct security violations in the event of a breach of IIHI;

(C) *Breach notification.* The certified IDR entity must, following the discovery of a breach of unsecured IIHI,

notify of the breach the provider, facility, or provider of air ambulance services; the plan and issuer; the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor; and each individual whose unsecured IIHI has been, or is reasonably believed to have been, subject to the breach, to the extent possible.

(*1*) *Breaches treated as discovered.* For purposes of this paragraph (e)(2)(v)(C), a breach shall be treated as discovered by a certified IDR entity as of the first day on which the breach is known to the certified IDR entity or, by exercising reasonable diligence, would have been known to the certified IDR entity. A certified IDR entity shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the certified IDR entity;

(*2*) *Timing of notification.* A certified IDR entity must provide the notification required by this paragraph (e)(2)(v)(C) without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(*3*) *Content of notification.* The notification required by this paragraph (e)(2)(v)(C) must include, to the extent possible:

(*i*) The identification of each individual whose unsecured IIHI has been, or is reasonably believed by the certified IDR entity to have been, subject to the breach;

(*ii*) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, to the extent known;

(*iii*) A description of the types of unsecured IIHI that were involved in the breach (for example whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(*iv*) A brief description of what the certified IDR entity involved is doing to investigate the breach, to mitigate harm to the affected parties, and to protect against any further breaches; and

(*v*) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, email address, website, or postal address.

(*4*) *Method for providing notification.* A certified IDR entity must submit the notification required by this paragraph (e)(2)(v)(C) in written form (in clear and understandable language) either on paper or electronically through the Federal IDR portal or electronic mail.

(D) *Application to contractor and subcontractors.* The certified IDR entity must ensure compliance with this paragraph (e)(2)(v) of this section by any contractor or subcontractor with access to IIHI performing any duties related to the Federal IDR process.

(vi) Meet appropriate indicators of fiscal integrity and stability by demonstrating that the certified IDR entity has a system of safeguards and controls in place to prevent and detect improper financial activities by its employees and agents to assure fiscal integrity and accountability for all certified IDR entity fees and administrative fees received, held, and disbursed and by submitting 3 years of financial statements or, if not available, other information to demonstrate fiscal stability of the IDR entity.

(vii) Provide, no more frequently than once per calendar year, a fixed fee for single determinations and a separate fixed fee for batched determinations, as well as an additional fixed tiered fee for batched determinations, if applicable, within the upper and lower limits for each, as established by the Secretary in notice and comment rulemaking. The certified IDR entity fee ranges established by the Secretary in rulemaking will remain in effect until changed by notice and comment rulemaking. The certified IDR entity may not charge a fee outside the limits set forth in rulemaking unless the certified IDR entity or IDR entity seeking certification receives advance written approval from the Secretary to charge a fixed fee beyond the upper or lower limits by following the process described in paragraph (e)(2)(vii)(A) of this section. A certified IDR entity may also seek advance written approval from the Secretary to update its fees one additional time per calendar year by meeting the requirements described in paragraph (e)(2)(vii)(A). The

Secretary will approve a request to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year if, in their discretion, they determine the information submitted by a certified IDR entity or IDR entity seeking certification demonstrates that the proposed change to the certified IDR entity fee would ensure the financial viability of the certified IDR entity or IDR entity seeking certification and would not impose on parties an undue barrier to accessing the Federal IDR process.

(A) In order for the certified IDR entity or IDR entity seeking certification to receive the Secretary's written approval to charge a fixed fee beyond the upper or lower limits for fees as set forth in rulemaking or to update the fixed fee during the calendar year, the certified IDR entity or IDR entity seeking certification must submit to the Secretary, in the form and manner specified by the Secretary:

(*1*) The fixed fee the certified IDR entity or IDR entity seeking certification believes is appropriate for the certified IDR entity or IDR entity seeking certification to charge;

(*2*) A description of the circumstances that require the alternative fixed fee, or that require a change to the fixed fee during the calendar year, as applicable; and

(*3*) A detailed description that reasonably explains how the alternative fixed fee or the change to the fixed fee during the calendar year, as applicable, will be used to mitigate the effects of those circumstances.

(B) [Reserved]

(viii) For disputes initiated on or after January 22, 2024, certified IDR entities are permitted to charge a fixed certified IDR entity fee for single determinations within the range of $200 to $840, and a fixed certified IDR entity fee for batched determinations within the range of $268 to $1,173, unless a fee outside such ranges is approved by the Secretary, pursuant to paragraph (e)(2)(vii)(A) of this section. As part of the batched determination fee, certified IDR entities are permitted to charge an additional fixed tiered fee within the range of $75 to $250 for every additional 25 line items within a batched dispute, beginning with the 26th line item. The ranges for the certified IDR entity fees for single and batched determinations will remain in effect until changed by notice and comment rulemaking.

(ix) Have a procedure in place to retain the certified IDR entity fees described in paragraph (d)(1) of this section paid by both parties in a trust or escrow account and to return the certified IDR entity fee paid by the prevailing party of an IDR payment determination, or half of each party's certified IDR entity fee in the case of an agreement described in paragraph (c)(2)(i) of this section, within 30 business days following the date of the determination.

(x) Have a procedure in place to retain the administrative fees described in paragraph (d)(2) of this section and to remit the administrative fees to the Secretary in accordance with the timeframe and procedures set forth in guidance published by the Secretary.

(xi) Discharge its responsibilities in accordance with paragraph (c) of this section, including not making any determination with respect to which the certified IDR entity would not be eligible for selection pursuant to paragraph (c)(1) of this section.

(xii) Collect the information required to be reported to the Secretary under paragraph (f) of this section and report the information on a timely basis in the form and manner provided in guidance published by the Secretary.

(3) Conflict-of-interest standards. In addition to the general standards set forth in paragraph (e)(2)(iv) of this section, an IDR entity must provide written documentation that the IDR entity satisfies the standards to be a certified IDR entity under this paragraph (e)(3).

(i) The IDR entity must provide an attestation indicating that it does not have a conflict of interest as defined in paragraph (a)(2) of this section;

(ii) The IDR entity must have procedures in place to ensure that personnel assigned to a determination do not have any conflicts of interest regarding any party to the dispute within the 1 year immediately preceding an assignment of dispute determination, similar to the requirements laid out in 18

U.S.C. 207(b). In order to satisfy this requirement, if certified, the IDR entity must ensure that any personnel assigned to a determination do not have any conflicts of interest as defined in paragraph (a)(2) of this section.

(iii) Following certification under this paragraph (e), if a certified IDR entity acquires control of, becomes controlled by, or comes under common control with any entity described in paragraph (e)(3)(i) of this section, the certified IDR entity must notify the Secretary in writing no later than 3 business days after the acquisition or exercise of control and shall be subject to the revocation of certification under paragraph (e)(6)(ii) of this section.

(4) *Period of certification.* Subject to paragraphs (e)(5) and (6) of this section, each certification (including a recertification) of a certified IDR entity under the process described in paragraph (e)(1) of this section will be effective for a 5-year period.

(5) *Petition for denial or revocation*—(i) *In general.* An individual, provider, facility, provider of air ambulance services, plan, or issuer may petition for a denial of a certification for an IDR entity or a revocation of a certification for a certified IDR entity for failure to meet a requirement of this section using the standard form and manner set forth in guidance to be issued by the Secretary. The petition for denial of a certification must be submitted within the timeframe set forth in guidance issued by the Secretary.

(ii) *Content of petition.* The individual, provider, facility, provider of air ambulance services, plan, or issuer seeking denial or revocation of certification must submit a written petition using the standard form issued by the Secretary including the following information:

(A) The identity of the IDR entity seeking certification or certified IDR entity that is the subject of the petition;

(B) The reason(s) for the petition;

(C) Whether the petition seeks denial or revocation of a certification;

(D) Documentation to support the reasons outlined in the petition; and

(E) Other information as may be required by the Secretary.

(iii) *Process.* (A) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor will acknowledge receipt of the petition within 10 business days of receipt of the petition.

(B) If the Secretary finds that the petition adequately shows a failure of the IDR entity seeking certification or the certified IDR entity to follow the requirements of this paragraph (e), the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will notify the IDR entity seeking certification or the certified IDR entity by providing a de-identified copy of the petition. Following the notification, the IDR entity seeking certification or certified IDR entity will have 10 business days to provide a response. After the time period for providing the response has passed, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will review the response (if any), determine whether a denial or revocation of a certification is warranted, and issue a notice of the decision to the IDR entity or certified IDR entity and to the petitioner. This decision will be subject to the appeal requirements of paragraph (e)(6)(v) of this section.

(C) Effect on certification under petition. Regarding a petition for revocation of a certified IDR entity's certification, if the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, finds that the petition adequately shows a failure to comply with the requirements of this paragraph (e), following the Secretary's notification of the failure to the certified IDR entity under paragraph (e)(5)(iii)(B) of this section, the certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations until the Secretary issues a notice of the decision to the certified IDR entity finding that a revocation of certification is not warranted.

(6) *Denial of IDR entity certification or revocation of certified IDR entity certification*—(i) *Denial of IDR entity certification.* The Secretary, jointly with the

Secretary of the Treasury and the Secretary of Labor, may deny the certification of an IDR entity under paragraph (e)(1) of this section if, during the process of certification, including as a result of a petition described in paragraph (e)(5) of this section, the Secretary determines the following:

(A) The IDR entity fails to meet the applicable standards set forth under this paragraph (e);

(B) The IDR entity has committed or participated in fraudulent or abusive activities, including, during the certification process, submitting fraudulent data, or submitting information or data the IDR entity knows to be false to the Secretary, the Secretary of the Treasury or the Secretary of Labor;

(C) The IDR entity has failed to comply with requests for information from the Secretary, the Secretary of the Treasury, or the Secretary of Labor as part of the certification process;

(D) In conducting payment determinations, including those outside the Federal IDR process, the IDR entity has failed to meet the standards that applied to those determinations or reviews, including standards of independence and impartiality; or

(E) The IDR entity is otherwise not fit or qualified to make determinations under the Federal IDR process.

(ii) *Revocation of certification of a certified IDR entity.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may revoke the certification of a certified IDR entity under paragraph (e)(1) of this section if, as a result of an audit, a petition described in paragraph (e)(5) of this section, or otherwise, the Secretary determines the following:

(A) The certified IDR entity has a pattern or practice of noncompliance with any requirements of this paragraph (e);

(B) The certified IDR entity is operating in a manner that hinders the efficient and effective administration of the Federal IDR process;

(C) The certified IDR entity no longer meets the applicable standards for certification set forth under this paragraph (e);

(D) The certified IDR entity has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data to the Secretary, the Secretary of the Treasury, or the Secretary of Labor;

(E) The certified IDR entity lacks the financial viability to provide arbitration under the Federal IDR process;

(F) The certified IDR entity has failed to comply with requests from the Secretary, the Secretary of the Treasury, or the Secretary of Labor made as part of an audit, including failing to submit all records of the certified IDR entity that pertain to its activities within the Federal IDR process; or

(G) The certified IDR entity is otherwise no longer fit or qualified to make determinations.

(iii) *Notice of denial or revocation.* The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a written notice of denial to the IDR entity or revocation to the certified IDR entity within 10 business days of the Secretary's decision, including the effective date of denial or revocation, the reason(s) for denial or revocation, and the opportunity to request appeal of the denial or revocation.

(iv) *Request for appeal of denial or revocation.* To request an appeal, the IDR entity or certified IDR entity must submit a request for appeal to the Secretary within 30 business days of the date of the notice under paragraph (e)(6)(iii) of this section of denial or revocation and in the manner prescribed by the instructions to the notice. During this time period, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will not issue a notice of final denial or revocation and a certified IDR entity may continue to work on previously assigned determinations but may not accept new determinations. If the IDR entity or certified IDR entity does not timely submit a request for appeal of the denial or revocation, the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, will issue a notice of final denial or revocation to the IDR entity or certified IDR entity (if applicable) and the petitioner.

(v) *Denial or final revocation.* Upon notice of denial or final revocation, the IDR entity shall not be considered a certified IDR entity and therefore shall

not be eligible to accept payment determinations under the Federal IDR process. Moreover, after a notice of final revocation, the IDR entity may not re-apply to be a certified IDR entity until on or after the 181st day after the date of the notice of denial or final revocation.

(f) *Reporting of information relating to the Federal IDR process*—(1) *Reporting of information*. Within 30 business days of the close of each month, for qualified IDR items and services furnished on or after January 1, 2022, each certified IDR entity must, in a form and manner specified by the Secretary, report:

(i) The number of notices of IDR initiation submitted under paragraph (b)(2) of this section to the certified IDR entity during the immediately preceding month;

(ii) The size of the provider practices and the size of the facilities submitting notices of IDR initiation under paragraph (b)(2) of this section during the immediately preceding month, as required to be provided to the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section;

(iii) The number of such notices of IDR initiation with respect to which a determination was made under paragraph (c)(4)(ii) of this section;

(iv) The number of times during the month that the out-of-network rate determined (or agreed to) under this section has exceeded the qualifying payment amount, specified by qualified IDR items and services;

(v) With respect to each notice of IDR initiation under paragraph (b)(2) of this section for which such a determination was made, the following information:

(A) A description of the qualified IDR items and services included with respect to the notification, including the relevant billing and service codes;

(B) The relevant geographic region for purposes of the qualifying payment amount for the qualified IDR items and services with respect to which the notification was provided;

(C) The amount of the offer submitted under paragraph (c)(4)(i) of this section by the plan or issuer (as applicable) and by the provider or facility (as applicable) expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under paragraph (c)(4) of this section was the offer submitted by the plan or issuer (as applicable) or by the provider or facility (as applicable);

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section;

(G) The practice specialty or type of each provider or facility, respectively, involved in furnishing each qualified IDR item or service;

(H) The identity for each plan or issuer, and provider or facility, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the determination of the out-of-network rate by the certified IDR entity.

(vi) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph (d)(1) of this section during the month.

(2) [Reserved]

(g) *Extension of time periods for extenuating circumstances*—(1) *General*. The time periods specified in this section (other than the time for payment, if applicable, under paragraph (c)(4)(ix) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension*. The parties may request an extension by submitting a request for extension due to extenuating circumstances through

the Federal IDR portal if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years or in the individual market policy years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

[86 FR 56124, Oct. 7, 2021, as amended at 87 FR 52652, Aug. 26, 2022; 88 FR 88525, Dec. 21, 2023; 89 FR 4548, Jan. 24, 2024]

§ 149.520 Independent dispute resolution process for air ambulance services.

(a) *Definitions.* Unless otherwise stated, the definitions in §149.30 apply.

(b) *Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process*—(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of §149.510, except that references in §149.510 to the additional circumstances in §149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

(i) The quality and outcomes measurements of the provider that furnished the services.

(ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

(iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.

(iv) Ambulance vehicle type, including the clinical capability level of the vehicle.

(v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

(vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under §149.510(c)(4)(iii)(A) or other credible information under §149.510(c)(4)(iii)(B) through (D), except that the additional circumstances in §149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(4) *Reporting of information relating to the IDR process.* In applying the requirements of §149.510(f), within 30 business days of the close of each month, for services furnished on or after January 1, 2022, the information the certified IDR entity must report, in a form and manner specified by the

Secretary, with respect to the Federal IDR process involving air ambulance services is:

(i) The number of notices of IDR initiation submitted under the Federal IDR process to the certified IDR entity that pertain to air ambulance services during the immediately preceding month;

(ii) The number of such notices of IDR initiation with respect to which a final determination was made under §149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section);

(iii) The number of times the payment amount determined (or agreed to) under this subsection has exceeded the qualifying payment amount, specified by services;

(iv) With respect to each notice of IDR initiation under §149.510(b)(2) of this part (as applied by paragraph (b)(1) of this section) for which a determination was made, the following information:

(A) A description of each air ambulance service included in such notification, including the relevant billing and service codes;

(B) The point of pick-up (as defined in 42 CFR 414.605) for the services included in such notification;

(C) The amount of the offers submitted under §149.510(c)(4)(i) (as applied by paragraph (b)(1) of this section) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider of air ambulance services, expressed as a dollar amount and as a percentage of the qualifying payment amount;

(D) Whether the offer selected by the certified IDR entity under §149.510(c)(4)(ii) (as applied by paragraph (b)(1) of this section) to be the payment amount applied was the offer submitted by the plan or issuer (as applicable) or by the provider of air ambulance services;

(E) The amount of the selected offer expressed as a dollar amount and as a percentage of the qualifying payment amount;

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and §149.510(c)(4)(iii)(C) and (D);

(G) Air ambulance vehicle type, including the clinical capability level of such vehicle (to the extent this information has been provided to the certified IDR entity);

(H) The identity for each plan or issuer and provider of air ambulance services, with respect to the notification. Specifically, each certified IDR entity must provide each party's name and address, as applicable; and

(I) For each determination, the number of business days elapsed between selection of the certified IDR entity and the selection of the payment amount by the certified IDR entity.

(v) The total amount of certified IDR entity fees paid to the certified IDR entity under paragraph §149.510(d)(1) (as applied by paragraph (b)(1) of this section) during the month for determinations involving air ambulance services.

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years, or in the individual market, policy years, beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

[86 FR 56124, Oct. 7, 2021, as amended at 87 FR 52654, Aug. 26, 2022]

Subpart G—Protection of Uninsured or Self-Pay Individuals

SOURCE: 86 FR 56134, Oct. 7, 2021, unless otherwise noted.

§ 149.610 Requirements for provision of good faith estimates of expected charges for uninsured (or self-pay) individuals.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for health care providers and health care facilities related to the issuance of good faith estimates of expected charges for uninsured (or self-pay) individuals (or their authorized representatives), upon request or upon scheduling an item or service.

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

(i) *Authorized representative* means an individual authorized under State law to provide consent on behalf of the uninsured (or self-pay) individual, provided that the individual is not a provider affiliated with a facility or an employee of a provider or facility represented in the good faith estimate, unless such provider or employee is a family member of the uninsured (or self-pay) individual.

(ii) *Convening health care provider or convening health care facility (convening provider or convening facility)* means the provider or facility who receives the initial request for a good faith estimate from an uninsured (or self-pay) individual and who is or, in the case of a request, would be responsible for scheduling the primary item or service.

(iii) *Co-health care provider or co-health care facility (co-provider or co-facility)* means a provider or facility other than a convening provider or a convening facility that furnishes items or services that are customarily provided in conjunction with a primary item or service.

(iv) *Diagnosis code* means the code that describes an individual's disease, disorder, injury, or other related health conditions using the International Classification of Diseases (ICD) code set.

(v) *Expected charge* means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.

(vi) *Good faith estimate* means a notification of expected charges for a scheduled or requested item or service, including items or services that are reasonably expected to be provided in conjunction with such scheduled or requested item or service, provided by a convening provider, convening facility, co-provider, or co-facility.

(vii) *Health care facility (facility)* means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

(viii) *Health care provider (provider)* means a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law, including a provider of air ambulance services.

(ix) *Items or services* has the meaning given in 45 CFR 147.210(a)(2).

(x) *Period of care* means the day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.

(xi) *Primary item or service* means the item or service to be furnished by the convening provider or convening facility that is the initial reason for the visit.

(xii) *Service code* means the code that identifies and describes an item or service using the Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis-Related Group (DRG) or National Drug Codes (NDC) code sets.

(xiii) *Uninsured (or self-pay) individual* means:

(A) An individual who does not have benefits for an item or service under a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code; or

(B) An individual who has benefits for such item or service under a group health plan, or individual or group health insurance coverage offered by a health insurance issuer, or a health benefits plan under chapter 89 of title 5, United States Code but who does not seek to have a claim for such item or service submitted to such plan or coverage.

(b) *Requirements of providers and facilities*—(1) *Requirements for convening providers and convening facilities.* A convening provider or convening facility must determine if an individual is an uninsured (or self-pay) individual by:

(i) Inquiring if an individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, Federal health care program (as defined in section 1128B(f) of the Social Security Act), or a health benefits plan under chapter 89 of title 5, United States Code;

(ii) Inquiring whether an individual who is enrolled in a group health plan, or group or individual health insurance coverage offered by a health insurance issuer or a health benefits plan under chapter 89 of title 5, United States Code is seeking to have a claim submitted for the primary item or service with such plan or coverage; and

(iii) Informing all uninsured (or self-pay) individuals of the availability of a good faith estimate of expected charges upon scheduling an item or service or upon request; information regarding the availability of good faith estimates for uninsured (or self-pay) individuals must be:

(A) Written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur;

(B) Orally provided when scheduling an item or service or when questions about the cost of items or services occur; and

(C) Made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with such convening provider or convening facility.

(iv) Convening providers and convening facilities shall consider any discussion or inquiry regarding the potential costs of items or services under consideration as a request for a good faith estimate;

(v) Upon the request for a good faith estimate from an uninsured (or self-pay) individual or upon scheduling a primary item or service to be furnished for such an individual, the convening provider or convening facility must contact, no later than 1 business day of such scheduling or such request, all co-providers and co-facilities who are reasonably expected to provide items or services in conjunction with and in support of the primary item or service and request that the co-providers or co-facilities submit good faith estimate information (as specified in paragraphs (b)(2) and (c)(2) of this section) to the convening provider or facility; the request must also include the date that good faith estimate information must be received by the convening provider or facility;

(vi) Provide a good faith estimate (as specified in paragraph (c)(1) of this section) to uninsured (or self-pay) individuals within the following timeframes:

(A) When a primary item or service is scheduled at least 3 business days before the date the item or service is scheduled to be furnished: Not later than 1 business day after the date of scheduling;

(B) When a primary item or service is scheduled at least 10 business days before such item or service is scheduled to be furnished: Not later than 3 business days after the date of scheduling; or

(C) When a good faith estimate is requested by an uninsured (or self-pay) individual: Not later than 3 business days after the date of the request.

(vii) A convening provider or convening facility must provide an uninsured (or self-pay) individual who has

scheduled an item or service with a new good faith estimate if a convening provider, convening facility, co-provider, or co-facility anticipates or is notified of any changes to the scope of a good faith estimate (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities) previously furnished at the time of scheduling; a new good faith estimate must be issued to the uninsured (or self-pay) individual no later than 1 business day before the items or services are scheduled to be furnished.

(viii) If any changes in expected providers or facilities represented in a good faith estimate occur less than 1 business day before the item or service is scheduled to be furnished, the replacement provider or facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the items or services being furnished that was provided by the replaced provider or facility.

(ix) For good faith estimates provided upon request of an uninsured (or self-pay) individual, upon scheduling of the requested item or service, the convening provider or convening facility must provide the uninsured (or self-pay) individual with a new good faith estimate for the scheduled item or service within the timeframes specified in paragraphs (b)(1)(vi)(A) and (B) of this section; and

(x) A convening provider or convening facility may issue a single good faith estimate for recurring primary items or services if the following requirements are met, in addition to the requirements under this section:

(A) The good faith estimate for recurring items or services must include, in a clear and understandable manner, the expected scope of the recurring primary items or services (such as timeframes, frequency, and total number of recurring items or services); and

(B) The scope of a good faith estimate for recurring primary items or services must not exceed 12 months. If additional recurrences of furnishing such items or services are expected beyond 12 months (or as specified under paragraph (b)(vii) of this section), a convening provider or convening facility must provide an uninsured (or self-pay) individual with a new good faith estimate, and communicate such changes (such as timeframes, frequency, and total number of recurring items or services) upon delivery of the new good faith estimate to help patients understand what has changed between the initial good faith estimate and the new good faith estimate.

(2) *Requirements for co-providers and co-facilities.* (i) Co-providers and co-facilities must submit good faith estimate information (as specified in paragraph (c)(2) of this section) upon the request of the convening provider or convening facility. The co-provider or co-facility must provide, and the convening provider or convening facility must receive, the good faith estimate information no later than 1 business day after the co-provider or co-facility receives the request from the convening provider or convening facility.

(ii) Co-providers and co-facilities must notify and provide new good faith estimate information to a convening provider or convening facility if the co-provider or co-facility anticipates any changes to the scope of good faith estimate information previously submitted to a convening provider or convening facility (such as anticipated changes to the expected charges, items, services, frequency, recurrences, duration, providers, or facilities).

(iii) If any changes in the expected co-providers or co-facilities represented in a good faith estimate occur less than 1 business day before that the item or service is scheduled to be furnished, the replacement co-provider or co-facility must accept as its good faith estimate of expected charges the good faith estimate for the relevant items or services included in the good faith estimate for the item or service being furnished that was provided by the replaced provider or facility.

(iv) In the event that an uninsured (or self-pay) individual separately schedules or requests a good faith estimate from a provider or facility that would otherwise be a co-provider or co-facility, that provider or facility is considered a convening provider or convening facility for such item or service and must meet all requirements in

paragraphs (b)(1) and (c)(1) of this section for issuing a good faith estimate to an uninsured (or self-pay) individual.

(c) *Content requirements of a good faith estimate issued to an uninsured (or self-pay) individual.* (1) A good faith estimate issued to an uninsured (or self-pay) individual must include:

(i) Patient name and date of birth;

(ii) Description of the primary item or service in clear and understandable language (and if applicable, the date the primary item or service is scheduled);

(iii) Itemized list of items or services, grouped by each provider or facility, reasonably expected to be furnished for the primary item or service, and items or services reasonably expected to be furnished in conjunction with the primary item or service, for that period of care including:

(A) Items or services reasonably expected to be furnished by the convening provider or convening facility for the period of care; and

(B) Items or services reasonably expected to be furnished by co-providers or co-facilities (as specified in paragraphs (b)(2) and (c)(2) of this section);

(iv) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(v) Name, National Provider Identifier, and Tax Identification Number of each provider or facility represented in the good faith estimate, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by such provider or facility;

(vi) List of items or services that the convening provider or convening facility anticipates will require separate scheduling and that are expected to occur before or following the expected period of care for the primary item or service. The good faith estimate must include a disclaimer directly above this list that includes the following information: Separate good faith estimates will be issued to an uninsured (or self-pay) individual upon scheduling or upon request of the listed items or services; notification that for items or services included in this list, information such as diagnosis codes, service codes, expected charges and provider or facility identifiers do not need to be included as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services; and include instructions for how an uninsured (or self-pay) individual can obtain good faith estimates for such items or services;

(vii) [Reserved]

(viii) A disclaimer that informs the uninsured (or self-pay) individual that there may be additional items or services the convening provider or convening facility recommends as part of the course of care that must be scheduled or requested separately and are not reflected in the good faith estimate;

(ix) A disclaimer that informs the uninsured (or self-pay) individual that the information provided in the good faith estimate is only an estimate regarding items or services reasonably expected to be furnished at the time the good faith estimate is issued to the uninsured (or self-pay) individual and that actual items, services, or charges may differ from the good faith estimate; and

(x) A disclaimer that informs the uninsured (or self-pay) individual of the uninsured (or self-pay) individual's right to initiate the patient-provider dispute resolution process if the actual billed charges are substantially in excess of the expected charges included in the good faith estimate, as specified in § 149.620; this disclaimer must include instructions for where an uninsured (or self-pay) individual can find information about how to initiate the patient-provider dispute resolution process and state that the initiation of the patient-provider dispute resolution process will not adversely affect the quality of health care services furnished to an uninsured (or self-pay) individual by a provider or facility; and

(xi) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the providers or facilities identified in the good faith estimate.

(2) [Reserved]

(d) *Content Requirements for Good Faith Estimate Information Submitted by*

Co-Providers or Co-Facilities to Convening Providers or Convening Facilities. (1) Good faith estimate information submitted to convening providers or convening facilities by co-providers or co-facilities for inclusion in the good faith estimate (described in paragraph (c)(1) of this section) must include:

(i) Patient name and date of birth;

(ii) Itemized list of items or services expected to be provided by the co-provider or co-facility that are reasonably expected to be furnished in conjunction with the primary item or service as part of the period of care;

(iii) Applicable diagnosis codes, expected service codes, and expected charges associated with each listed item or service;

(iv) Name, National Provider Identifiers, and Tax Identification Numbers of the co-provider or co-facility, and the State(s) and office or facility location(s) where the items or services are expected to be furnished by the co-provider or co-facility; and

(v) A disclaimer that the good faith estimate is not a contract and does not require the uninsured (or self-pay) individual to obtain the items or services from any of the co-providers or co-facilities identified in the good faith estimate.

(2) [Reserved]

(e) *Required Methods for Providing Good Faith Estimates for Uninsured (or Self-Pay) Individuals.* (1) A good faith estimate must be provided in written form either on paper or electronically, pursuant to the uninsured (or self-pay) individual's requested method of delivery, and within the timeframes described in paragraph (b) of this section. Good faith estimates provided electronically must be provided in a manner that the uninsured (or self-pay) individual can both save and print. A good faith estimate must be provided and written using clear and understandable language and in a manner calculated to be understood by the average uninsured (or self-pay) individual.

(2) To the extent that an uninsured (or self-pay) individual requests a good faith estimate in a method other than paper or electronically (for example, by phone or orally in person), the convening provider may orally inform the uninsured (or self-pay) individual of information contained in the good faith estimate using the method requested by the uninsured (or self-pay) individual; however, in order for a convening provider or convening facility to meet the requirements of this section, the convening provider or convening facility must issue the good faith estimate to the uninsured (or self-pay) individual in written form as specified in paragraph (e)(1) of this section.

(f) *Additional compliance provisions.* (1) A good faith estimate issued to uninsured (or self-pay) individual under this section is considered part of the patient's medical record and must be maintained in the same manner as a patient's medical record. Convening providers and convening facilities must provide a copy of any previously issued good faith estimate furnished within the last 6 years to an uninsured (or self-pay) individual upon the request of the uninsured (or self-pay) individual.

(2) Providers or facilities that issue good faith estimates issued under State processes that do not meet the requirements set forth in this section fail to comply with the requirements of this section.

(3) A provider or facility will not fail to comply with this section solely because, despite acting in good faith and with reasonable due diligence, the provider or facility makes an error or omission in a good faith estimate required under this section, provided that the provider or facility corrects the information as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in §149.620).

(4) To the extent compliance with this section requires a provider or facility to obtain information from any other entity or individual, the provider or facility will not fail to comply with this section if it relied in good faith on the information from the other entity, unless the provider or facility knows, or reasonably should have known, that

the information is incomplete or inaccurate. If the provider or facility learns that the information is incomplete or inaccurate, the provider or facility must provide corrected information to the uninsured (or self-pay) individual as soon as practicable. If items or services are furnished before an error in a good faith estimate is addressed, the provider or facility may be subject to patient-provider dispute resolution if the actual billed charges are substantially in excess of the good faith estimate (as described in § 149.620).

(g) *Applicability*—(1) *Applicability date.* The requirements of this section are applicable for good faith estimates requested on or after January 1, 2022 or for good faith estimates required to be provided in connection with items or services scheduled on or after January 1, 2022.

(2) *Applicability with other laws.* Nothing in this section alters or otherwise affects a provider's or facility's requirement to comply with other applicable State or Federal laws, including those governing the accessibility, privacy, or security of information required to be disclosed under this section, or those governing the ability of properly authorized representatives to access uninsured (or self-pay) individuals' information held by providers or facilities, except to the extent a state law prevents the application of this section.

§ 149.620 Requirements for the patient-provider dispute resolution process.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements for the patient-provider dispute resolution process, under which an uninsured (or self-pay) individual, with respect to eligible items or services under paragraph (b) of this section, may submit notification under paragraph (c) of this section to initiate the patient-provider dispute resolution process. This section sets forth in paragraph (d) of this section the certification requirements for a dispute resolution entity to become a Selected Dispute Resolution (SDR) entity contracted to resolve the patient-provider dispute, and the process for HHS to select SDR entities for patient-provider disputes under paragraph (e) of this section. This section sets forth in paragraph (f) the process and requirements regarding how SDR entities will determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility. This section also sets forth requirements for an administrative fee under paragraph (g) of this section and minimum requirements under paragraph (h) of this section for states that wish to establish processes for performing patient-provider dispute resolution in place of the Federal process.

(2) *Definitions.* Unless otherwise stated, the definitions in § 149.610(a)(2) apply to this section. Definitions related to confidentiality set forth in § 149.510(a)(2), including the definitions for *breach, individually identifiable health information (IIHI),* and *unsecured IIHI* also apply to this section. Additionally, for purposes of this section, the following definitions apply:

(i) *Billed charge(s)* means the amount billed by a provider or facility for an item or service.

(ii) *Substantially in excess* means, with respect to the total billed charges by a provider or facility, an amount that is at least $400 more than the total amount of expected charges listed on the good faith estimate for the provider or facility.

(iii) *Total billed charge(s)* means the total of billed charges, by a provider or-facility, for all primary items or services and all other items or services furnished in conjunction with the primary items or services to an uninsured (or self-pay) individual, regardless of whether such items or services were included in the good faith estimate.

(b) *Eligibility for patient-provider dispute resolution*—(1) *In general.* In general, an item or service provided by a convening provider, convening facility, co-provider, or co-facility is eligible for the patient-provider dispute resolution process if the total billed charges (by the particular convening provider, convening facility, or co-provider or co-facility listed in the good faith estimate), are substantially in excess of the total expected charges for that specific provider or facility listed on the good faith estimate, as required under § 149.610.

(2) *Special rule for co-provider or co-facility substitution.* If a co-provider or co-facility that provided an estimate of the expected charge for an item or service in the good faith estimate is substituted for a different co-provider or co-facility, an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution if the billed charge is substantially in excess of the total expected charges included in the good faith estimate for the original co-provider or co-facility. If the replacement provider or facility provides the uninsured (or self-pay) individual with a new good faith estimate in accordance with §149.610(b)(2), then the determination of whether an item or service billed by the replacement co-provider or co-facility is eligible for dispute resolution is based on whether the total billed charge for the replacement co-provider or co-facility is substantially in excess of the total expected charges included in the good faith estimate provided by the replacement co-provider or co-facility.

(c) *Initiation of the Patient Provider dispute resolution process*—(1) *In general.* With respect to an item or service that meets the requirements in paragraph (b) of this section, an uninsured (or self-pay) individual (or their authorized representative, excluding any providers directly represented in the good faith estimate, providers associated with these providers, non-clinical staff associated with these providers, or individuals employed or associated with a facility that had included services in the good faith estimate) may initiate the patient-provider dispute resolution process by submitting a notification (initiation notice) to HHS as specified in paragraph (c)(2) of this section postmarked within 120 calendar days of receiving the initial bill containing charges for the item or service that is substantially in excess of the expected charges in the good faith estimate. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(2) *Initiation notice*—(i) *Content.* The notice to initiate the patient-provider dispute resolution process must include:

(A) Information sufficient to identify the item or service under dispute, including the date the item or service was provided, and a description of the item or service;

(B) A copy of the provider or facility bill for the item and service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(C) A copy of the good faith estimate for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(D) If not included on the good faith estimate, contact information of the provider or facility involved, including, if available, name, email address, phone number, and mailing address;

(E) The State where the items or services in dispute were furnished; and

(F) The uninsured (or self-pay) individual's communication preference, through the Federal IDR portal, or electronic or paper mail.

(ii) *Manner.* The uninsured (or self-pay) individual or their authorized representative must submit the initiation notice, to the Secretary by submitting the notice via the Federal IDR portal, electronically, or on paper, in the form and manner specified by the Secretary. The date of initiation of the patient-provider dispute resolution process will be the date the Secretary receives such initiation notice. In addition, the uninsured (or self-pay) individual must submit an administrative fee as described in paragraph (g) of this section to the SDR entity in an amount and in a manner that will be clarified in guidance by HHS.

(3) *Notification of SDR entity receipt.* Upon receipt of the initiation notice described in paragraph (c)(1) of this section, HHS will select an SDR entity according to the process described in paragraph (e) of this section. Upon selection, the SDR entity will, through the Federal IDR portal, or electronic or paper mail, notify the uninsured (or self-pay) individual, and the provider or facility that a patient-provider dispute resolution request has been received and is under review. Such notice shall also include:

(i) Sufficient information to identify the item or service under dispute;

(ii) The date the initiation notice was received;

(iii) Notice of the additional requirements for providers or facilities specified in paragraphs (c)(5) and (6) of this section while the patient-provider dispute resolution process is pending; and

(iv) Information to the uninsured (or self-pay) individual about the availability of consumer assistance resources that can assist the individual with the dispute.

(4) *Validation of initiation notice.* After the selection of the SDR entity, as described in paragraph (c)(2) of this section, the SDR entity shall review the initiation notice to ensure the items or services in dispute meet the eligibility criteria described in paragraph (b) of this section and the initiation notice contains the required information described in paragraph (c)(2). The SDR entity will notify the uninsured (or self-pay) individual of the outcome of the review, including, if applicable, providing the individual with 21 calendar days to submit supplemental information when the initiation notice is determined to be incomplete or the items or services are determined ineligible for dispute resolution.

(i) If the SDR entity determines that the item or service meets the eligibility criteria, and the initiation notice contains the required information, the SDR entity will notify the uninsured (or self-pay) individual and the provider or facility that the that the item or service has been determined eligible for dispute resolution. The SDR entity shall request the provider or facility provide the information described in paragraph (f)(2) of this section within 10 business days.

(ii) If the SDR entity determines that the item or service does not meet the eligibility criteria or that the initiation notice does not contain the required information, the SDR entity will provide an insufficiency notice to the uninsured (or self-pay) individual of the determination and the reasons for the determination and will notify the uninsured (or self-pay) individual that the individual may submit supplemental information, postmarked within 21 calendar days, to resolve any deficiencies identified. If the insufficiency notice is not made available to an individual in a format that is accessible to individuals with disabilities or with low-English proficiency within 14 calendar days of such a request from the individual, a 14-calendar-day extension will be granted so that the individual will have a total of 35 calendar days to submit supplemental information.

(5) *Prohibitions on collections.* While the patient-provider dispute resolution process is pending, the provider or facility must not move the bill for the disputed item or service into collection or threaten to do so, or if the bill has already moved into collection, the provider or facility should cease collection efforts. The provider or facility must also suspend the accrual of any late fees on unpaid bill amounts until after the dispute resolution process has concluded.

(6) *Prohibitions on retributive action.* The provider or facility must not take or threaten to take any retributive action against an uninsured (or self-pay) individual for utilizing the patient-provider dispute resolution process to seek resolution for a disputed item or service.

(d) *Certification of SDR entities*—(1) *In general.* The Secretary shall contract with and certify only that number of SDR entities the Secretary believes will be necessary to timely resolve the volume of patient-provider disputes. As part of the contract process with HHS, a potential SDR entity must satisfy the Federal IDR entity certification criteria specified in §149.510(e), subject to the exceptions set forth in paragraphs (d)(2) of this section. In addition, the SDR entity must also meet the conflict-of-interest mitigation policy requirements specified in paragraph (d)(3) of this section. Through this contract process, HHS will assess the dispute resolution entity for compliance with all applicable SDR entity certification requirements.

(2) *Exception for SDR entity certification.* With respect to certified IDR entity requirements that do not apply to an SDR entity, potential SDR entities are not required to make the following submissions:

(i) Information regarding the service area(s) for which the entity will arbitrate cases, however, a potential SDR entity will need to submit information on their ability to operate nationwide through the contract process;

(ii) Fee schedule for batched and non-batched claims;

(iii) Policies and procedures to hold dispute resolution entity fees in a trust or escrow account, however, a potential SDR entity must submit policies and procedures to hold administrative fees, as described in paragraph (g) of this section, and remit them to HHS in a manner specified by HHS.

(3) *Conflict of interest mitigation policies.* A potential SDR entity must also provide additional information on the SDR entity's conflict-of-interest policies and procedures, including outlining a mitigation plan in the event of an entity-level conflict of interest, under which no dispute resolution personnel affiliated with the SDR entity can fairly and impartially adjudicate a case, in compliance with the standards in Federal Acquisition Regulation-subpart 9.5 (48 CFR subpart 9.5). Such conflict of interest mitigation plan could include utilizing a subcontractor without a conflict of interest that meets SDR entity requirements to conduct the patient-provider dispute resolution for the case.

(e) *Selection of an SDR entity.* (1) After the Secretary has received the initiation notice as described in paragraph (c) of this section, the Secretary will assign an SDR entity that is certified and contracted under paragraph (d) of this section to conduct the dispute resolution process for the item or service. Upon receiving an assignment from the Secretary to make a determination for an item or service as described in paragraph (c)(3) of this section, the SDR entity shall ensure that no conflict of interest exists, and in such case, shall notify the uninsured (or self-pay) individual and the provider or facility of the selection of the SDR entity.

(2) Should a conflict of interest exist, the SDR entity must submit notice to the Secretary of such conflict no later than 3 business days following selection by the Secretary. The Secretary will then automatically select a new SDR entity to conduct the patient-provider dispute resolution process for the item or service. In the event that no SDR entities are available to resolve the dispute, the initially-selected SDR entity will be required to initiate their entity-level conflict of interest mitigation plan as described in paragraph (d)(3) of this section. If no other contracted SDR entity, and no subcontracted entity, is able to provide the patient-provider dispute resolution services due to conflicts of interest that cannot be sufficiently mitigated or any other reason, HHS may seek to contract with an additional SDR entity as needed. In the event that HHS needs to contract with an additional SDR entity, the time periods specified in this section may be extended at HHS' discretion to allow for HHS to contract with that SDR entity.

(3) Conflict of interest means, with respect to a party to a payment determination, or SDR entity, a material relationship, status, or condition of the party, or SDR entity that impacts the ability of the SDR entity to make an unbiased and impartial payment determination. For purposes of this section, a conflict of interest exists when an SDR entity is:

(i) A provider or a facility;

(ii) An affiliate or a subsidiary of a provider or facility;

(iii) An affiliate or subsidiary of a professional or trade association representing a provider or facility; or

(iv) An SDR entity, or any personnel assigned to a determination has a material familial, financial, or professional relationship with a party to the payment determination being disputed, or with any officer, director, or management employee of the provider, the provider's group or practice association, or the facility that is a party to the dispute.

(4) Either party to the dispute resolution process (the uninsured (or self-pay) individual, or the provider or facility) may attest that a conflict of interest exists in relation to the SDR entity assigned to a payment dispute, in which case the SDR entity must notify the Secretary of HHS no later than 3 business days receiving the attestation.

(f) *Payment determination for Patient-Provider dispute resolution*—(1) *Determination of payment amount through settlement*—(i) *In general.* If the parties to a dispute resolution process agree on a payment amount (through either an offer of financial assistance or an offer of a lower amount, or an agreement by the uninsured (or self-pay) individual to pay the billed charges in full) after the dispute resolution process has been initiated but before the date on which a determination is made under paragraph (f)(3) of this section, the provider or facility will notify the SDR entity through the Federal IDR Portal, electronically, or in paper form as soon as possible, but no later than 3 business days after the date of the agreement. The settlement notification must contain at a minimum, the settlement amount, the date of such settlement, and documentation demonstrating that the provider or facility and uninsured (or self-pay) individual have agreed to the settlement. The settlement notice must also document that the provider or facility has applied a reduction to the uninsured (or self-pay) individual's settlement amount equal to at least half the amount of the administrative fee paid as set forth in paragraph (g) of this section. Once the SDR entity receives the settlement notice, the SDR entity shall close the dispute resolution case as settled and the agreed upon payment amount will apply for the items or services.

(ii) *Treatment of payments made prior to determination.* Payment of the billed charges (or a portion of the billed charges) by the uninsured (or self-pay) individual (or by another party on behalf of the uninsured (or self-pay) individual) prior to a determination under paragraph (f)(3) of this section does not demonstrate agreement by the uninsured (or self-pay) individual to settle at that amount or any other amount.

(2) *Determination of payment amount through the patient-provider dispute resolution process*—(i) *In general.* With respect to an item or service to which an agreement described in paragraph (f)(1) of this section does not apply, not later than 10 business days after the receipt of the selection notice from the SDR entity described in paragraph (c)(4)(i) of this section, the provider or facility must submit to the SDR entity:

(A) A copy of the good faith estimate provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable);

(B) A copy of the billed charges provided to the uninsured (or self-pay) individual for the item or service under dispute (the copy can be a photocopy or an electronic image so long as the document is readable); and

(C) If available, documentation demonstrating that the difference between the billed charge and the expected charges in the good faith estimate reflects the cost of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Timeframe for SDR entity determination.* Not later than 30 business days after receipt of the information described in paragraph (f)(2)(i) of this section, the SDR entity must make a determination regarding the amount to be paid by such uninsured (or self-pay) individual, taking into account the requirements in paragraph (f)(3) of this section.

(3) *Payment determination by an SDR entity*—(i) *In general.* The SDR entity must review any documentation submitted by the uninsured (or self-pay) individual, and the provider or the facility, and make a separate determination for each unique item or service charged as to whether the provider or facility has provided credible information to demonstrate that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided.

(ii) *Definition of credible information.* Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(iii) *Payment determination process.* (A) For an item or service that appears on the good faith estimate:

(*1*) If the billed charge is equal to or less than the expected charge for the item or service in the good faith estimate, the SDR entity must determine the amount to be paid for the item or service as the billed charge.

(*2*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility does not provide credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine the amount to be paid for the item or service to be equal to the expected charge for the item or service in the good faith estimate.

(*3*) If the billed charge for the item or service is greater than the expected charge in the good faith estimate, and the SDR entity determines that information submitted by the provider or facility provides credible information that the difference between the billed charge and the expected charge for the item or service in the good faith estimate reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must determine as the amount to be paid for the item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in §149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in §149.140(a)(3) using the methodology described in §149.140(c)(3), except that in cases where the amount determined by an independent database is determined to be less than the expected charge for the item or service listed on the good faith estimate, the amount to be paid will equal to the expected charge for the item or service listed on the good faith estimate. When comparing the billed charge with the amount contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(B) For an item or service that does not appear on the good faith estimate (new item or service):

(*1*) If the SDR entity determines that the information submitted by the provider or facility does not provide credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, then the SDR entity must determine that amount to be paid for the new item or service to be equal to $0.

(*2*) If the SDR entity determines that the information submitted by the provider or facility provides credible information that the billed charge for the new item or service reflects the costs of a medically necessary item or service and is based on unforeseen circumstances that could not have reasonably been anticipated by the provider or facility when the good faith estimate was provided, the SDR entity must select as the amount to be paid for the new item or service, the lesser of:

(*i*) The billed charge; or

(*ii*) The median payment amount paid by a plan or issuer for the same or similar service, by a same or similar provider in the geographic area as defined in §149.140(a)(7) where the services were provided, that is reflected in an independent database as defined in §149.140(a)(3) using the methodology described in §149.140(c)(3). When comparing the billed charge with the amounts contained in an independent database, the SDR entity should account for any discounts offered by the provider or facility.

(C) To calculate the final payment determination amount, the SDR entity

must add together the amounts to be paid for all items or services subject to the determination. In cases where the final amount determined by the SDR entity is lower than the billed charges, the SDR entity must reduce the total amount determined by the amount paid by the individual for the administrative fee described in paragraph (g) of this section to calculate the final payment determination amount to be paid by the individual for the items or services. Once the final payment determination amount has been calculated, the SDR entity will inform the uninsured (or self-pay) individual and the provider or facility, through the Federal IDR portal, or by electronic or paper mail, of such determination, the determination amount and the SDR entity's justification for making the determination. After such notification is made, the SDR entity will close the case.

(4) *Effects of determination.* A determination made by an SDR entity under this paragraph (f) will be binding upon the parties involved, in the absence of a fraud or evidence of misrepresentation of facts presented to the selected SDR entity regarding the claim, except that the provider or facility may provide financial assistance or agree to an offer for a lower payment amount than the SDR entity's determination, the uninsured (or self-pay) individual may agree to pay the billed charges in full, or the uninsured (or self-pay) individual and the provider or facility may agree to a different payment amount.

(g) *Costs of patient-provider dispute resolution process*—(1) *Administrative fee to participate in the patient-provider dispute resolution process.* (i) The uninsured (or self-pay) individual shall pay to the SDR entity the administrative fee amount described in section (g)(2) of this section at the initiation of the patient-provider dispute resolution process described in paragraph (c) of this section. The SDR entity shall remit all administrative fees collected to the Secretary upon receiving an invoice from HHS.

(ii) In cases where the SDR entity issues a determination and the provider or facility is the non-prevailing party as described in section (g)(1)(iv) of this section, the provider or facility must pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iii) If the SDR entity issues a determination and the provider or facility is the prevailing party as described in paragraph (g)(1)(iv) of this section, the provider or facility is not required to pay an amount equal to the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied by the SDR entity to the final payment determination amount as described in paragraph (f)(3) of this section.

(iv) For purposes of paragraphs (g)(1)(ii) and (iii) of this section, the prevailing party is the provider or facility in cases where the SDR entity determines the amount to be paid as equal to the billed charges; and the prevailing party is the uninsured (or self-pay) individual in cases where the SDR entity determines the-amount to be paid as less than the billed charges.

(v) Allocation of administrative fee in the case of settlement. In case of a settlement described in paragraph (f)(1) of this section, the provider or facility must pay an amount equal to half of the administrative fee to the uninsured (or self-pay) individual in the form of a reduction in the payment amount that is applied to the final settlement amount. The provider or facility will document in the settlement notice described in paragraph (f)(1) that it has applied a payment reduction of at least half of the administrative fee amount to the uninsured (or self-pay) individual's settlement amount.

(2) Establishment of the administrative fee. The amount of the administrative fee described in paragraph (g)(1) of this section will be specified by the Secretary through guidance.

(h) *Deferral to State patient-provider dispute resolution processes*—(1) *In general.* If the Secretary determines that a-state law provides a process to determine the amount to be paid by an uninsured (or self-pay) individual to a provider or facility, and that such process

meets or exceeds the requirements in paragraph (h)(2) of this section, the Secretary shall defer to the State process and direct any patient-provider dispute resolution requests received from uninsured (or self-pay) individuals in such state to the State process to adjudicate the dispute resolution initiation request.

(2) *Minimum Federal requirements.* A State process described in paragraph (h)(1) of this section shall at a minimum:

(i) Be binding, unless the provider or facility offer for the uninsured (or self-pay) individual to pay a lower payment amount than the determination amount;

(ii) Take into consideration a good faith estimate, that meets the minimum standards established in §149.160, provided by the provider or facility to the uninsured (or self-pay) individual;

(iii) If the State has a fee charged to uninsured (or self-pay) individuals to participate in the patient-provider dispute resolution process, the fee must be equal to or less than the Federal administrative fee-established in paragraph (g) of this section; and

(iv) Have in place conflict-of-interest standards that at a minimum meets the requirements set forth in paragraphs (d) and (e) of this section.

(3) *HHS determination of State process.* HHS will review the State process to determine whether it meets or exceeds the minimum Federal requirements set forth in paragraph (h)(2) of this section—HHS will communicate with the state and determine whether such process meets or exceeds such requirements. HHS will notify the state in writing of such determination.

(4) *HHS review of State process.* HHS will review changes to the State process on an annual basis (or at other times if HHS receives information from the state that would indicate the state process no longer meets the minimum Federal requirements) to ensure the state process continues to meet or exceed the minimum Federal standards set forth in this section.

(5) *State process termination.* In the event that the State process is terminated, or HHS determines that the State process no longer meets the minimum Federal requirements described in paragraph (h)(2) of this section, HHS will make the Federal process available to uninsured (or self-pay) individuals in that State to ensure that the state's residents have access to a patient-provider dispute resolution process that meets the minimum Federal requirements.

(i) *Extension of time periods for extenuating circumstances*—(1) *In general.* The time periods specified in this section (other than the time for payment of the administrative fees under paragraph (d)(2) of this section) may be extended in extenuating circumstances at the Secretary's discretion if:

(i) An extension is necessary to address delays due to matters beyond the control of the parties or for good cause; and

(ii) The parties attest that prompt action will be taken to ensure that the determination under this section is made as soon as administratively practicable under the circumstances.

(2) *Process to request an extension.* The time periods specified in this section may be extended in the case of extenuating circumstances at HHS' discretion. The parties may request an extension by submitting a request for extension due to extenuating circumstances through the Federal IDR portal, or electronic or paper mail if the extension is necessary to address delays due to matters beyond the control of the parties or for good cause.

(j) *Applicability date.* The provisions of this section are applicable to uninsured (or self-pay) individuals; providers (including providers of air ambulance services) and facilities; and SDR entities, generally beginning on or after January 1, 2022. The provisions regarding SDR entity certification in paragraphs (a) and (d) of this section, are applicable beginning on October 7, 2021.

Subpart H—Prescription Drug and Health Care Spending

SOURCE: 86 FR 66702, Nov. 23, 2021, unless otherwise noted.

§ 149.710 Definitions.

For purposes of this subpart, the following definitions apply in addition to the definitions in §149.30:

Brand prescription drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), or under section 351 of the PHS Act (42 U.S.C. 262), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes a drug with Emergency Use Authorization issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), and that is generally marketed under a proprietary, trademark-protected name. The term ''brand prescription drug'' includes drugs that the U.S. Food and Drug Administration determines to be interchangeable biosimilar products under sections 351(i)(3) and 351(k)(4) of the PHS Act (42 U.S.C. 262).

Dosage unit means the smallest form in which a pharmaceutical product is administered or dispensed, such as a pill, tablet, capsule, ampule, or measurement of grams or milliliters.

Enrollee means an individual who is enrolled, within the meaning of §144.103 of this subchapter, in group health insurance coverage, or an individual who is covered by individual health insurance coverage, at any time during the reference year, and includes dependents.

Federal Employees Health Benefits (FEHB) line of business refers to all health benefit plans that are offered to eligible enrollees pursuant to a contract between the Office of Personnel Management and Federal Employees Health Benefits (FEHB) Program carriers. Such plans are Federal governmental plans offered pursuant to 5 U.S.C. chapter 89.

Life-years means the total number of months of coverage for participants and beneficiaries, or for enrollees, as applicable, divided by 12.

Market segment means one of the following: The individual market (excluding the student market), the student market, the fully-insured small group market, the fully-insured large group market (excluding the FEHB line of business), self-funded plans offered by small employers, self-funded plans offered by large employers, and the FEHB line of business.

Premium amount means, with respect to individual health insurance coverage and fully-insured group health plans, earned premium as that term is defined in §158.130 of this subchapter, excluding the adjustments specified in §158.130(b)(5). Premium amount means, with respect to self-funded group health plans and other arrangements that do not rely exclusively or primarily on payments of premiums as defined in §158.130 of this subchapter, the premium equivalent amount representing the total cost of providing and maintaining coverage, including claims costs, administrative costs, and stop-loss premiums, as applicable.

Prescription drug (drug) means a set of pharmaceutical products that have been assigned a National Drug Code (NDC) by the Food and Drug Administration and are grouped by name and ingredient in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

Prescription drug rebates, fees, and other remuneration means all remuneration received by or on behalf of a plan or issuer, its administrator or service provider, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the plan or issuer, with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, as applicable, regardless of the source of the remuneration (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates, fees, and other remuneration also include, for example, discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits. Prescription drug rebates, fees, and other remuneration include bona fide service fees. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the plan or issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer

would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of the entity, whether or not the entity takes title to the drug.

Reference year means the calendar year immediately preceding the calendar year in which data submissions under this section are required.

Reporting entity means an entity that submits some or all of the information required under this subpart with respect to a plan or issuer, and that may be different from the plan or issuer that is subject to the requirements of this subpart.

Student market has the meaning given in §158.103 of this subchapter.

Therapeutic class means a group of pharmaceutical products that have similar mechanisms of action or treat the same types of conditions, grouped in the manner specified by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, in guidance. The Secretary may require plans and issuers to classify drugs according to a commonly available public or commercial therapeutic classification system, a therapeutic classification system provided by the Secretary, or a combination thereof.

Total annual spending means incurred claims, as that term is defined in §158.140 of this subchapter, excluding the adjustments specified in §158.140(b)(1)(i), (b)(2)(iv), and (b)(4), and including cost sharing. With respect to prescription drugs, total annual spending is net of prescription drug rebates, fees, and other remuneration.

§149.720 Reporting requirements related to prescription drug and health care spending.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit an annual report to the Secretary, the Secretary of the Treasury, and the Secretary of Labor, on prescription drug and health care spending, premiums, and enrollment under the plan or coverage.

(b) *Timing and form of report.* The report for the 2020 reference year must be submitted to the Secretary by December 27, 2021. Beginning with the 2021 reference year, the report for each reference year is due by June 1 of the year following the reference year. The report must be submitted in the form and manner prescribed by the Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor.

(c) *Transfer of business.* Issuers that acquire a line or block of business from another issuer during a reference year are responsible for submitting the information and report required by this section for the acquired business for that reference year, including for the part of the reference year that was prior to the acquisition.

(d) *Reporting entities and special rules to prevent unnecessary duplication*—(1) *Special rule for insured group health plans.* To the extent coverage under a group health plan consists of group health insurance coverage, the plan may satisfy the requirements of paragraph (a) of this section if the plan requires the health insurance issuer offering the coverage to report the information required by this section in compliance with this subpart pursuant to a written agreement. Accordingly, if a health insurance issuer and a group health plan sponsor enter into a written agreement under which the issuer agrees to provide the information required under paragraph (a) of this section in compliance with this section, and the issuer fails to do so, then the issuer, but not the plan, violates the reporting requirements of paragraph (a) of this section with respect to the relevant information.

(2) *Other contractual arrangements.* A group health plan or health insurance issuer offering group or individual health insurance coverage may satisfy the requirements under paragraph (a) of this section by entering into a written agreement under which one or more other parties (such as health insurance issuers, pharmacy benefit managers, third-party administrators, or other third parties) report some or all of the information required under paragraph (a) of this section in compliance with this section. Notwithstanding the preceding sentence, if a group health plan or health insurance issuer chooses to enter into such an agreement and

the party with which it contracts fails to provide the information in accordance with paragraph (a) of this section, the plan or issuer violates the reporting requirements of paragraph (a) of this section.

(e) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.730 Aggregate reporting.

(a) *General requirement.* A group health plan or a health insurance issuer offering group or individual health insurance coverage must submit, or arrange to be submitted, the information required in § 149.740(b) separately for each State in which group health coverage or group or individual health insurance coverage was provided in connection with the group health plan or by the health insurance issuer. The report must include the experience of all plans and policies in the State during the reference year covered by the report, and must include the experience separately for each market segment as defined in § 149.710.

(b) *Aggregation by reporting entity*—(1) *In general.* If a reporting entity submits data on behalf of more than one group health plan in a State and market segment, the reporting entity may aggregate the data required in § 149.740(b) for the group health plans for each market segment in the State.

(2) *Multiple reporting entities.* (i) If multiple reporting entities submit the required data related to one or more plans or issuers in a State and market segment, the data submitted by each of these reporting entities must not be aggregated at a less granular level than the aggregation level used by the reporting entity that submits the data on total annual spending on health care services, as required by § 149.740(b)(4), on behalf of these plans or issuers.

(ii) The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance alternative or additional aggregation methods for data submitted by multiple reporting entities, to ensure a balance between compliance burdens and a data aggregation level that facilitates the development of the biannual public report required under section 2799A–10(b) of the PHS Act.

(3) *Group health insurance coverage with dual contracts.* If a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, the plan's out-of-network experience may be treated as if it were all related to the contract provided by the in-network issuer.

(c) *Aggregation by State.* (1) Experience with respect to each fully-insured policy must be included on the report for the State where the contract was issued, except as specified in paragraphs (c)(3) and (4) of this section.

(2) Experience with respect to each self-funded group health plan must be included on the report for the State where the plan sponsor has its principal place of business.

(3) For individual market business sold through an association, experience must be attributed to the issue State of the certificate of coverage.

(4) For health coverage provided to plans through a group trust or multiple employer welfare arrangement, the experience must be included in the report for the State where the employer (if the plan is sponsored at the individual employer level) or the association (if the association qualifies as an employer under ERISA section 3(5)) has its principal place of business or the State where the association is incorporated, in the case of an association with no principal place of business.

(d) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

§ 149.740 Required information.

(a) *Information for each plan or coverage.* The report required under § 149.720 must include the following information for each plan or coverage, at the plan or coverage level:

(1) The identifying information for plans, issuers, plan sponsors, and any other reporting entities.

(2) The beginning and end dates of the plan year that ended on or before the last day of the reference year.

(3) The number of participants, beneficiaries, and enrollees, as applicable,

covered on the last day of the reference year.

(4) Each State in which the plan or coverage is offered.

(b) *Information for each state and market segment.* The report required under §149.720 must include the following information with respect to plans or coverage for each State and market segment for the reference year, unless otherwise specified:

(1) The 50 brand prescription drugs most frequently dispensed by pharmacies, and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most frequently dispensed drugs must be determined according to total number of paid claims for prescriptions filled during the reference year for each drug.

(2) The 50 most costly prescription drugs and for each such drug, the data elements listed in paragraph (b)(5) of this section. The most costly drugs must be determined according to total annual spending on each drug.

(3) The 50 prescription drugs with the greatest increase in expenditures between the year immediately preceding the reference year and the reference year, and for each such drug: The data elements listed in paragraph (b)(5) of this section for the year immediately preceding the reference year, and the data elements listed in paragraph (b)(5) of this section for the reference year. The drugs with the greatest increase in expenditures must be determined based on the increase in total annual spending from the year immediately preceding the reference year to the reference year. A drug must be approved for marketing or issued an Emergency Use Authorization by the Food and Drug Administration for the entirety of the year immediately preceding the reference year and for the entirety of the reference year to be included in the data submission as one of the drugs with the greatest increase in expenditures.

(4) Total annual spending on health care services by the plan or coverage and by participants, beneficiaries, and enrollees, as applicable, broken down by the type of costs, including—

(i) Hospital costs;

(ii) Health care provider and clinical service costs, for primary care and specialty care separately;

(iii) Costs for prescription drugs, separately for drugs covered by the plan's or issuer's pharmacy benefit and drugs covered by the plan's or issuer's hospital or medical benefit; and

(iv) Other medical costs, including wellness services.

(5) Prescription drug spending and utilization, including—

(i) Total annual spending by the plan or coverage;

(ii) Total annual spending by the participants, beneficiaries, and enrollees, as applicable, enrolled in the plan or coverage, as applicable;

(iii) The number of participants, beneficiaries, and enrollees, as applicable, with a paid prescription drug claim;

(iv) Total dosage units dispensed; and

(v) The number of paid claims.

(6) Premium amounts, including—

(i) Average monthly premium amount paid by employers and other plan sponsors on behalf of participants, beneficiaries, and enrollees, as applicable;

(ii) Average monthly premium amount paid by participants, beneficiaries, and enrollees, as applicable; and

(iii) Total annual premium amount and the total number of life-years.

(7) Prescription drug rebates, fees, and other remuneration, including—

(i) Total prescription drug rebates, fees, and other remuneration, and the difference between total amounts that the plan or issuer pays the entity providing pharmacy benefit management services to the plan or issuer and total amounts that such entity pays to pharmacies.

(ii) Prescription drug rebates, fees, and other remuneration, excluding bona fide service fees, broken down by the amounts passed through to the plan or issuer, the amounts passed through to participants, beneficiaries, and enrollees, as applicable, and the amounts retained by the entity providing pharmacy benefit management services to the plan or issuer; and the data elements listed in paragraph (b)(5) of this section—

(A) For each therapeutic class; and

(B) For each of the 25 prescription drugs with the greatest amount of total prescription drug rebates and other price concessions for the reference year.

(8) The method used to allocate prescription drug rebates, fees, and other remuneration, if applicable.

(9) The impact of prescription drug rebates, fees, and other remuneration on premium and cost sharing amounts.

(c) *Applicability date.* The provisions of this section are applicable beginning December 27, 2021.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

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AUTHORITY: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

SOURCE: 64 FR 45795, Aug. 20, 1999, unless otherwise noted.

Subpart A—General Provisions

§ 150.101 Basis and scope.

(a) *Basis.* CMS's enforcement authority under sections 2723 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group heath plans.* The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures described in §150.301 *et seq.*

(2) *Enforcement with respect to health insurance issuers.* The states have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a state is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in parts 146, 147, and 148 of this subchapter, CMS enforces them under subpart C of this part.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13439, Feb. 27, 2013]

§ 150.103 Definitions.

The definitions that appear in part 144 of this subchapter apply to this part 150, unless stated otherwise. As used in this part:

Amendment, *endorsement*, or *rider* means a document that modifies or changes the terms or benefits of an individual policy, group policy, or certificate of insurance.

Application means a signed statement of facts by a potential insured that an issuer uses as a basis for its decision whether, and on what basis to insure an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

Certificate of insurance means the document issued to a person or entity covered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in PHS Act requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in §144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to the requirements of parts 147 and 148 of this subchapter. The term ''individual health insurance policy'' includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of parts 146 and 147 of this subchapter.

PHS Act requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146, 147, and 148 of this subchapter.

Plan document means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any

State as defined in §144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13439, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce PHS Act Requirement

§ 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces PHS Act requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces PHS Act requirement to the extent warranted (as determined by CMS) in any of the following circumstances:

(a) *Notification by State.* A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing PHS Act requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a State may not be substantially enforcing PHS Act requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with §148.128 of this subchapter instead of complying with the guaranteed availability requirements of §148.120, CMS's determination focuses on the following:

(1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§148.101 through 148.126 and §148.170 of this subchapter.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.205 Sources of information triggering an investigation of State enforcement.

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

(a) A complaint received by CMS.

(b) Information learned during informal contact between CMS and State officials.

(c) A report in the news media.

(d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of PHS Act requirements.

(e) Information obtained during periodic review of State health care legislation. CMS may review State health care and insurance legislation and regulations to determine whether they are:

(1) Consistent with PHS Act requirements.

(2) Not pre-empted as provided in §146.143 (relating to group market provisions) and §148.120 (relating to individual market requirements) on the basis that they prevent the application of a PHS Act requirement.

(f) Any other information that indicates a possible failure to substantially enforce.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.207 Procedure for determining that a State fails to substantially enforce PHS Act requirements.

Sections 150.209 through 150.219 describe the procedures CMS follows to

determine whether a State is substantially enforcing PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If CMS receives a complaint or other information indicating that a State is failing to enforce PHS Act requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.211 Notice to the State.

If CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce PHS Act requirements, CMS sends, in writing, the notice described in § 150.213 of this part, to the following State officials:

(a) The governor or chief executive officer of the State.

(b) The insurance commissioner or chief insurance regulatory official.

(c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

(a) Identifies the PHS Act requirement or requirements that have allegedly not been substantially enforced.

(b) Describes the factual basis for the allegation of a failure or failures to enforce PHS Act requirements.

(c) Explains that the consequence of a State's failure to substantially enforce PHS Act requirements is that CMS enforces them.

(d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in § 150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.215 Extension for good cause.

CMS may extend, for good cause, the time the State has for responding to the notice described in § 150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

§ 150.217 Preliminary determination.

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the PHS Act requirements described in the notice, CMS takes the following actions:

(a) Consults with the appropriate State officials identified in § 150.211 (or their designees).

(b) Notifies the State of CMS's preliminary determination that the State has failed to substantially enforce the requirements and that the failure is continuing.

(c) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.219 Final determination.

If, after providing notice and a reasonable opportunity for the State to show that it has corrected any failure to substantially enforce, CMS finds that the failure to substantially enforce has not been corrected, it will send the State a written notice of its final determination. The notice includes the following:

(a) Identification of the PHS Act requirements that CMS is enforcing.

(b) The effective date of CMS's enforcement.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.221 Transition to State enforcement.

(a) If CMS determines that a State for which it has assumed enforcement authority has enacted and implemented legislation to enforce PHS Act requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to ensure that a transition is effected with respect to the following:

(1) Consumer complaints and inquiries.

(2) Instructions to issuers.

(3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that will assume enforcement responsibility.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

Subpart C—CMS Enforcement With Respect to Issuers and Non-Federal Governmental Plans—Civil Money Penalties

§ 150.301 General rule regarding the imposition of civil money penalties.

If any health insurance issuer that is subject to CMS's enforcement authority under § 150.101(b)(2), or any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) that is subject to CMS's enforcement authority under § 150.101(b)(1), fails to comply with PHS Act requirements, it may be subject to a civil money penalty as described in this subpart.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.303 Basis for initiating an investigation of a potential violation.

(a) *Information.* Any information that indicates that any issuer may be failing to meet the PHS Act requirements or that any non-Federal governmental plan that is a group health plan as defined in section 2791(a)(1) of the PHS Act and 45 CFR § 144.103 may be failing to meet an applicable PHS Act requirement, may warrant an investigation. CMS may consider, but is not limited to, the following sources or types of information:

(1) Complaints.

(2) Reports from State insurance departments, the National Association of Insurance Commissioners, and other Federal and State agencies.

(3) Any other information that indicates potential noncompliance with PHS Act requirements.

(b) *Who may file a complaint.* Any entity or individual, or any entity or personal representative acting on that individual's behalf, may file a complaint with CMS if he or she believes that a right to which the aggrieved person is entitled under PHS Act requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of an issuer or other responsible entity as defined in § 150.305.

(c) *Where a complaint should be directed.* A complaint may be directed to any CMS regional office.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.305 Determination of entity liable for civil money penalty.

If a failure to comply is established under this part, the responsible entity, as determined under this section, is liable for any civil money penalty imposed.

(a) *Health insurance issuer is responsible entity*—(1) *Group health insurance policy.* To the extent a group health insurance policy issued, sold, renewed, or offered to a private plan sponsor or a non-Federal governmental plan sponsor is subject to applicable PHS Act requirements, a health insurance issuer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraphs (b) or (c) of this section, if the policy itself or the manner in which the policy is marketed or administered fails to comply with an applicable PHS Act requirement.

(2) *Individual health insurance policy.* To the extent an individual health insurance policy is subject to an applicable PHS Act requirement, a health insurance issuer is subject to a civil money penalty if the policy itself, or the manner in which the policy is marketed or administered, violates any applicable PHS Act requirement.

(b) *Non-Federal governmental plan is responsible entity*—(1) *Basic rule.* If a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable PHS Act requirement, the plan is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The plan is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, an employer sponsoring the plan, or a third-party administrator.

(2) *Exception.* In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (b) does not apply to the extent that the non-Federal governmental employers have elected under §146.180 to exempt the plan from applicable PHS Act requirements.

(c) *Employer is responsible entity*—(1) *Basic rule.* If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable PHS Act requirement, the employer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The employer is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, the employer, or a third-party administrator.

(2) *Exception.* In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (c) does not apply to the extent the non-Federal governmental employer has elected under §146.180 to exempt the plan from applicable PHS Act requirements.

(d) *Actions or inactions of agent.* A principal is liable for penalties assessed for the actions or inactions of its agent.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.307 Notice to responsible entities.

If an investigation under §150.303 indicates a potential violation, CMS provides written notice to the responsible entity or entities identified under §150.305. The notice does the following:

(a) Describes the substance of any complaint or other information.

(b) Provides 30 days from the date of the notice for the responsible entity or entities to respond with additional information, including documentation of compliance as described in §150.311.

(c) States that a civil money penalty may be assessed.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005]

§ 150.309 Request for extension.

In circumstances in which an entity cannot prepare a response to CMS within the 30 days provided in the notice, the entity may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. If CMS grants the extension, the responsible entity must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.311 Responses to allegations of noncompliance.

In determining whether to impose a civil money penalty, CMS reviews and considers documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with PHS Act requirements. The following are examples of documentation that a potential responsible entity may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any individual policy, group policy, certificate of insurance, application, rider, amendment, endorsement, certificate of creditable coverage, advertising material, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the responsible entity to refute the complaint or allegation.

(b) Any other evidence that refutes an alleged noncompliance.

(c) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(d) Documentation that the policies, certificates of insurance, or non-Federal governmental plan documents have been amended to comply with PHS Act requirements either by revision of the contracts or by the development of riders, amendments, or endorsements.

(e) Documentation of the entity's issuance of conforming policies, certificates of insurance, plan documents, or amendments to policyholders or certificate holders before the issuance of the notice to the responsible entity or entities described in §150.307.

(f) Evidence documenting the development and implementation of internal policies and procedures by an issuer, or non-Federal governmental health plan or employer, to ensure compliance with PHS Act requirements. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's, or non-Federal governmental health plan's or employer's, commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with PHS Act requirements and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(g) Evidence documenting the entity's record of previous compliance with PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005; 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§150.313 Market conduct examinations.

(a) *Definition.* A market conduct examination means the examination of health insurance operations of an issuer, or the operation of a non-Federal governmental plan, involving the review of one or more (or a combination) of a responsible entity's business or operational affairs, or both, to verify compliance with PHS Act requirements.

(b) *General.* If, based on the information described in §150.303, CMS finds evidence that a specific entity may be in violation of a PHS Act requirement, CMS may initiate a market conduct examination to determine whether the entity is out of compliance. CMS may conduct the examinations either at the site of the issuer or other responsible entity or a site CMS selects. When CMS selects a site, it may direct the issuer or other responsible entity to forward any documentation CMS considers relevant for purposes of the examination to that site.

(c) *Appointment of examiners.* When CMS identifies an issue that warrants investigation, CMS will appoint one or more examiners to perform the examination and instruct them as to the scope of the examination.

(d) *Appointment of professionals and specialists.* When conducting an examination under this part, CMS may retain attorneys, independent actuaries, independent market conduct examiners, or other professionals and specialists as examiners.

(e) *Report of market conduct examination*—(1) *CMS review.* When CMS receives a report, it will review the report, together with the examination work papers and any other relevant information, and prepare a final report. The final examination report will be provided to the issuer or other responsible entity.

(2) *Response from issuer or other responsible entity.* With respect to each

examination issue identified in the report, the issuer or other responsible entity may:

(i) Concur with CMS's position(s) as outlined in the report, explaining the plan of correction to be implemented.

(ii) Dispute CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

(3) *CMS's reply to a response from an issuer or other responsible entity*. Upon receipt of a response from the issuer or other responsible entity, CMS will provide a letter containing its reply to each examination issue. CMS's reply will consist of one of the following:

(i) Concurrence with the issuer's or non-Federal governmental plan's position.

(ii) Approval of the issuer's or non-Federal governmental plan's proposed plan of correction.

(iii) Conditional approval of the issuer's or non-Federal governmental plan's proposed plan of correction, which will include any modifications CMS requires.

(iv) Notice to the issuer or non-Federal governmental plan that there exists a potential violation of PHS Act requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013; 86 FR 24286, May 5, 2021]

§ 150.315 Amount of penalty—General.

A civil money penalty for each violation of 42 U.S.C. 300gg *et seq.* may not exceed $100 as adjusted annually under 45 CFR part 102 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

[64 FR 45795, Aug. 20, 1999, as amended at 81 FR 61581, Sept. 6, 2016]

§ 150.317 Factors CMS uses to determine the amount of penalty.

In determining the amount of any penalty, CMS takes into account the following:

(a) *The entity's previous record of compliance*. This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation or violations, CMS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of PHS Act requirements.

(2) Documentation that the responsible entity has submitted its policy forms to CMS for compliance review.

(3) Evidence that the responsible entity has never had a complaint for noncompliance with PHS Act requirements filed with a State or CMS.

(4) Such other factors as justice may require.

(b) *The gravity of the violation*. This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.319 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 150.315 to reflect that fact. As guidelines for taking into account the factors listed in § 150.317, CMS considers the following:

(a) *Record of prior compliance*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 150.307, implemented and followed a compliance plan as described in § 150.311(f).

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s)*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with PHS Act requirements so that the following occur:

(i) All employers, employees, individuals and non-Federal governmental entities are identified that are or were issued any policy, certificate of insurance or plan document, or any form used in connection therewith that failed to comply.

(ii) All employers, employees, individuals, and non-Federal governmental plans are identified that were denied coverage or were denied a right provided under PHS Act requirements.

(iii) Each employer, employee, individual, or non-Federal governmental plan adversely affected by the violation has been, for example, offered coverage or provided a certificate of creditable coverage in a manner that complies with PHS Act requirements that were violated so that, to the extent practicable, that employer, employee, individual, or non-Federal governmental entity is in the same position that he, she, or it would have been in had the violation not occurred.

(iv) The adjustments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.321 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 150.323 Determining the amount of penalty—other matters as justice may require.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

§ 150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity

or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 150.343 Notice of proposed penalty.

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the PHS Act requirements that CMS has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which CMS based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§ 150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with § 150.347.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

§ 150.345 Appeal of proposed penalty.

Any entity against which CMS has assessed a penalty may appeal that penalty in accordance with § 150.401 *et seq*.

§ 150.347 Failure to request a hearing.

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in § 150.343, CMS may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. CMS notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 unless the responsible entity can show good cause, as determined under § 150.405(b), for failing to timely exercise its right to a hearing.

Subpart D—Administrative Hearings

§ 150.401 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services.

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

Party means CMS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to § 150.343.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.403 Scope of ALJ's authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedure Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§ 150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with § 150.407(a), within 30 days after the

date of issuance of either CMS's notice of proposed assessment under §150.343 or notice that an alternative dispute resolution process has terminated. The request for hearing should be addressed as instructed in the notice of proposed determination. ''Date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 150.407 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) The request for hearing must identify the relevant notice of assessment by date and attach a copy of the notice.

§ 150.409 Amendment of notice of assessment or request for hearing.

The ALJ may permit CMS to amend its notice of assessment, or permit the respondent to amend a request for hearing that complies with §150.407(a), if the ALJ finds that no undue prejudice to either party will result.

§ 150.411 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by §150.405(a) or any extension of time granted by the ALJ pursuant to §150.405(b).

(b) The request for hearing fails to meet the requirements of §150.407.

(c) The entity that filed the request for hearing is not a respondent under §150.401.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 150.413 Settlement.

CMS has exclusive authority to settle any issue or any case, without the consent of the administrative law judge at any time before or after the administrative law judge's decision.

§ 150.415 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor or the IRS may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

§ 150.417 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Applies the factors that are identified in § 150.317.

(2) May consider evidence of record relating to any factor that CMS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that CMS assessed.

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.421 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 150.423 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 150.425 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as ''Motion for Discovery'').

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.429 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time

begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in §150.401) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in section §150.405(b)).

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

[86 FR 24286, May 5, 2021]

§ 150.435 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in §150.437(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by §150.437 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 150.437 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in §150.431, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment that the respondent did not

identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document (respondent's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 150.439 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 150.437 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 150.441 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 150.437 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 150.441 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 150.437 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.443 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 150.445 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §§ 150.317 and 150.323 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether CMS's notice sent in accordance with §§ 150.307 and 150.343 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after CMS's notice under § 150.307.

§ 150.447 The record.

(a) Any testimony that is taken in-person by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

[64 FR 45795, Aug. 20, 1999, as amended at 86 FR 24286, May 5, 2021]

§ 150.449 Cost of transcripts.

Generally, each party is responsible for 50 percent of the transcript cost. Where there is an intervenor, the ALJ determines what percentage of the transcript cost is to be paid for by the intervenor.

§ 150.451 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§ 150.453 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 150.457.

§ 150.455 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§ 150.457 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this subsection may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 150.453.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 150.459 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to CMS.

(b) *Certification of administrative record.* CMS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of CMS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 150.461 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 150.463 Final order not subject to review.

In an action brought under § 150.461, the validity and appropriateness of the final order described in § 150.459 is not subject to review.

§ 150.465 Collection and use of penalty funds.

(a) Any funds collected under § 150.461 are paid to CMS.

(b) The funds are available without appropriation until expended.

(c) The funds may be used only for the purpose of enforcing the PHS Act requirements for which the penalty was assessed.

[64 FR 45795, Aug. 20, 1999, as amended at 78 FR 13440, Feb. 27, 2013]

PART 151 [RESERVED]

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

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AUTHORITY: Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 45029, July 30, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 152.1 Statutory basis.

(a) *Basis.* This part establishes provisions needed to implement section 1101 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which requires the Secretary of the Department of Health and Human Services to establish a temporary high risk health insurance pool program to provide health insurance coverage for individuals described in § 152.14 of this part.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for the temporary high risk health insurance pool program, hereafter referred to as the ''Pre-Existing Condition Insurance Plan'' (PCIP) program.

§ 152.2 Definitions.

For purposes of this part the following definitions apply:

Creditable coverage means coverage of an individual as defined in section 2701(c)(1) of the Public Health Service Act as of March 23, 2010 and 45 CFR 146.113(a)(1).

Enrollee means an individual receiving coverage from a PCIP established under this section.

Lawfully present means

(1) A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Act (PRWORA) (8 U.S.C. 1641);

(2) An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;

(3) An alien who has been paroled into the United States pursuant to section 212(d)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) An alien who belongs to one of the following classes:

(i) Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. 1160 or 1255a, respectively);

(ii) Aliens currently under Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. 1254a), and pending applicants for TPS who have been granted employment authorization;

(iii) Aliens who have been granted employment authorization under 8 CFR 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);

(iv) Family Unity beneficiaries pursuant to section 301 of Public Law 101–649 as amended;

(v) Aliens currently under Deferred Enforced Departure (DED) pursuant to a decision made by the President;

(vi) Aliens currently in deferred action status;

(vii) Aliens whose visa petitions have been approved and who have a pending application for adjustment of status;

(5) A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. 1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. 1231) or under the Convention Against Torture who has been granted employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days;

(6) An alien who has been granted withholding of removal under the Convention Against Torture; or

(7) A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. 1101(a)(27)(J)).

(8) *Exception*. An individual with deferred action under the Department of Homeland Security's deferred action for childhood arrivals process, as described in the Secretary of Homeland Security's June 15, 2012, memorandum, shall not be considered to be lawfully present with respect to any of the above categories in paragraphs (1) through (7) of this definition.

Out-of-pocket costs means the sum of the annual deductible and the other annual out-of-pocket expenses, other than for premiums, required to be paid under the program.

Pre-Existing condition exclusion has the meaning given such term in 45 CFR 144.103.

Pre-Existing Condition Insurance Plan (PCIP) means the temporary high risk health insurance pool plan (sometimes referred to as a ''qualified high risk pool'') that provides coverage in a State, or combination of States, in accordance with the requirements of section 1101 of the Affordable Care Act and this part. The term ''PCIP program'' is generally used to describe the national program the Secretary is charged with carrying out, under which States or non-profit entities operate individual PCIPs.

Resident means an individual who has been legally domiciled in a State.

Service Area refers to the geographic area encompassing an entire State or States in which PCIP furnishes benefits.

State refers each of the 50 States and the District of Columbia.

[75 FR 45029, July 30, 2010, as amended at 77 FR 52616, Aug. 30, 2012]

EFFECTIVE DATE NOTE: At 89 FR 39436, May 8, 2024, §152.2 was amended by revising the

definition of ''Lawfully present'', effective Nov. 1, 2024. For the convenience of the user, the revised text is set forth as follows:

§ 152.2 Definitions.

* * * * *

Lawfully present has the meaning given the term at 45 CFR 155.20.

* * * * *

Subpart B—PCIP Program Administration

§ 152.6 Program administration.

(a) *General rule.* Section 1101(b)(1) of the Affordable Care Act requires that HHS carry out the Pre-Existing Condition Insurance Plan program directly or through contracts with eligible entities, which are States or nonprofit private entities.

(b) *Administration by State.* A State (or its designated non-profit private entity) may submit a proposal to enter into a contract with HHS to establish and administer a PCIP in accordance with section 1101 of the Affordable Care Act and this part.

(1) At the Secretary's discretion, a State may designate a nonprofit entity or entities to contract with HHS to administer a PCIP.

(2) As part of its administrative approach, a State or designated entity may subcontract with either a for-profit or nonprofit entity.

(c) *Administration by HHS.* If a State or its designated entity notifies HHS that it will not establish or continue to administer a PCIP, or does not submit an acceptable or timely proposal to do so, HHS will contract with a nonprofit private entity or entities to administer a PCIP in that State.

(d) *Transition in administration.* The Secretary may consider a request from a State to transition from administration by HHS to administration by a State or from administration by a State to administration by HHS. Such transitions shall be approved only if the Secretary determines that the transition is in the best interests of the PCIP enrollees and potential PCIP enrollees in that state, consistent with §152.7(b) of this part.

§ 152.7 PCIP proposal process.

(a) *General.* A proposal from a State or nonprofit private entity to contract with HHS shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

(b) *Special rules for transitions in administration.* (1) Transitions from HHS administration of a PCIP to State administration must take effect on January 1 of a given year.

(2) A State's proposal to administer a PCIP must meet all the requirements of this section.

(3) Transitions from State administration to HHS administration must comply with the termination procedures of the PCIP contract in effect with the State or its designated entity.

(4) The Secretary may establish other requirements needed to ensure a seamless transition of coverage for all existing enrollees.

Subpart C—Eligibility and Enrollment

§ 152.14 Eligibility.

(a) *General rule.* An individual is eligible to enroll in a PCIP if he or she:

(1) Is a citizen or national of the United States or lawfully present in the United States;

(2) Subject to paragraph (b) of this section, has not been covered under creditable coverage for a continuous 6-month period of time prior to the date on which such individual is applying for PCIP;

(3) Has a pre-existing condition as established under paragraph (c) of this section; and

(4) Is a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP. A PCIP may not establish any standards with regard to the duration of residency in the PCIP service area.

(b) *Satisfaction of 6-month creditable coverage requirement when an enrollee leaves the PCIP service area.* An individual who becomes ineligible for a PCIP on the basis of no longer residing

in the PCIP's service area as described in paragraph (a)(4) of this section is deemed to have satisfied the requirement in paragraph (a)(2) of this section for purposes of applying to enroll in a PCIP in the new service area.

(c) *Pre-existing condition requirement.* For purposes of establishing a process for determining eligibility, and subject to HHS approval, a PCIP may elect to apply any one or more of the following criteria in determining whether an individual has a pre-existing condition for purposes of this section:

(1) *Refusal of coverage.* Documented evidence that an insurer has refused, or a clear indication that the insurer would refuse, to issue coverage to an individual on grounds related to the individual's health.

(2) *Exclusion of coverage.* Documented evidence that such individual has been offered coverage but only with a rider that excludes coverage of benefits associated with an individuals' identified pre-existing condition.

(3) *Medical or health condition.* Documented evidence of the existence or history of certain medical or health condition, as approved or specified by the Secretary.

(4) *Other.* Other criteria, as defined by a PCIP and approved by HHS.

§ 152.15 Enrollment and disenrollment process.

(a) *Enrollment process.* (1) A PCIP must establish a process for verifying eligibility and enrolling an individual that is approved by HHS.

(2) A PCIP must allow an individual to remain enrolled in the PCIP unless:

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual obtains other creditable coverage;

(iii) The PCIP program terminates, or is terminated; or

(iv) As specified by the PCIP program and approved by HHS.

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

(i) Verifying the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security as applicable; or

(ii) By requiring the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(iii) The PCIP must provide an individual who is applying to enroll in the PCIP with a disclosure specifying if the information will be shared with the Department of Health and Human Services, Social Security Administration, and if necessary, Department of Homeland Security for purposes of establishing eligibility.

(b) *Disenrollment process.* (1) A PCIP must establish a disenrollment process that is approved by HHS.

(2) A PCIP may disenroll an individual if the monthly premium is not paid on a timely basis, following notice and a reasonable grace period, not to exceed 61 days from when payment is due, as defined by the PCIP and approved by HHS.

(3) A PCIP must disenroll an individual in any of the following circumstances:

(i) The individual no longer resides in the PCIP service area.

(ii) The individual obtains other creditable coverage.

(iii) Death of the individual.

(iv) Other exceptional circumstances established by HHS.

(c) *Effective dates.* A PCIP must establish rules governing the effective date of enrollment and disenrollment that are approved by HHS. A complete enrollment request submitted by an eligible individual by the 15th day of a month, where the individual is determined to be eligible for enrollment, must take effect by the 1st day of the following month, except in exceptional circumstances that are subject to HHS approval.

(d) *Funding limitation.* A PCIP may stop taking applications for enrollment to comply with funding limitations established by the HHS under section 1101(g) of Public Law 111–148 and § 152.35 of this part. Accordingly, a PCIP may employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, and other measures, as defined by the PCIP and approved by HHS, including measures specified under § 152.35(b).

Subpart D—Benefits

§ 152.19 Covered benefits.

(a) *Required benefits.* Each benefit plan offered by a PCIP shall cover at least the following categories and the items and services:

(1) Hospital inpatient services

(2) Hospital outpatient services

(3) Mental health and substance abuse services

(4) Professional services for the diagnosis or treatment of injury, illness, or condition

(5) Non-custodial skilled nursing services

(6) Home health services

(7) Durable medical equipment and supplies

(8) Diagnostic x-rays and laboratory tests

(9) Physical therapy services (occupational therapy, physical therapy, speech therapy)

(10) Hospice

(11) Emergency services, consistent with §152.22(b), and ambulance services

(12) Prescription drugs

(13) Preventive care

(14) Maternity care

(b) *Excluded services.* Benefit plans offered by a PCIP shall not cover the following services:

(1) Cosmetic surgery or other treatment for cosmetic purposes except to restore bodily function or correct deformity resulting from disease.

(2) Custodial care except for hospice care associated with the palliation of terminal illness.

(3) In vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy.

(4) Abortion services except when the life of the woman would be endangered or when the pregnancy is the result of an act of rape or incest.

(5) Experimental care except as part of an FDA-approved clinical trial.

§ 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.

(a) *Pre-existing condition exclusions.* A PCIP must provide all enrollees with health coverage that does not impose any pre-existing condition exclusions (as defined in §152.2) with respect to such coverage.

(b) *Waiting periods.* A PCIP may not impose a waiting period with respect to the coverage of services after the effective date of enrollment.

§ 152.21 Premiums and cost-sharing.

(a) *Limitation on enrollee premiums.* (1) The premiums charged under the PCIP may not exceed 100 percent of the premium for the applicable standard risk rate that would apply to the coverage offered in the State or States. The PCIP shall determine a standard risk rate by considering the premium rates charged for similar benefits and cost-sharing by other insurers offering health insurance coverage to individuals in the applicable State or States. The standard risk rate shall be established using reasonable actuarial techniques, that are approved by the Secretary, and that reflect anticipated experience and expenses. A PCIP may not use other methods of determining the standard rate, except with the approval of the Secretary.

(2) Premiums charged to enrollees in the PCIP may vary on the basis of age by a factor not greater than 4 to 1.

(b) *Limitation on enrollee costs.* (1) The PCIP's average share of the total allowed costs of the PCIP benefits must be at least 65 percent of such costs.

(2) The out-of-pocket limit of coverage for cost-sharing for covered services under the PCIP may not be greater than the applicable amount described in section 223(c)(2) of the Internal Revenue code of 1986 for the year involved. If the plan uses a network of providers, this limit may be applied only for in-network providers, consistent with the terms of PCIP benefit package.

(c) *Prohibition on balance billing in the PCIP administered by HHS.* A facility or provider that accepts payment under §152.35(c)(2) for a covered service furnished to an enrollee may not bill the enrollee for an amount greater than the cost-sharing amount for the covered service calculated by the PCIP.

[75 FR 45029, July 30, 2010, as amended at 78 FR 30226, May 22, 2013]

§ 152.22 Access to services.

(a) *General rule.* A PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it

has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees.

(b) *Emergency services.* In the case of emergency services, such services must be covered out of network if:

(1) The enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and

(2) The services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted.

Subpart E—Oversight

§ 152.26 Appeals procedures.

(a) *General.* A PCIP shall establish and maintain procedures for individuals to appeal eligibility and coverage determinations.

(b) *Minimum requirements.* The appeals procedure must, at a minimum, provide:

(1) A potential enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding PCIP eligibility, including a determination of whether the individual is a citizen or national of the United States, or is lawfully present in the United States.

(2) An enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding the coverage of a service or the amount paid by the PCIP for a service.

(3) An enrollee with the right to a timely reconsideration of a redetermination made under paragraph (b)(2) of this section by an entity independent of the PCIP.

§ 152.27 Fraud, waste, and abuse.

(a) *Procedures.* The PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse, and to appropriate law enforcement authorities instances of fraud. Such procedures shall include identifying situations in which enrollees or potential enrollees (or their family members) are employed, and may have, or have had, access to other coverage such as group health coverage, but were discouraged from enrolling.

(b) *Cooperation.* The PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report to appropriate authorities situations in which enrollment in other coverage may have been discouraged.

§ 152.28 Preventing insurer dumping.

(a) *General rule.* If it is determined based on the procedures and criteria set forth in paragraph (b) of this section that a health insurance issuer or group health plan has discouraged an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status, if the individual subsequently enrolls in a PCIP under this part, the issuer or health plan will be responsible for any medical expenses incurred by the PCIP with respect to the individual.

(b) *Procedures and criteria for a determination of dumping.* A PCIP shall establish procedures to identify and report to HHS instances in which health insurance issuers or employer-based group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. Such procedures shall include methods to identify the following circumstances, either through the PCIP enrollment application form or other vehicles:

(1) Situations where an enrollee or potential enrollee had prior coverage obtained through a group health plan or issuer, and the individual was provided financial consideration or other rewards for disenrolling from their coverage, or disincentives for remaining enrolled.

(2) Situations where enrollees or potential enrollees had prior coverage obtained directly from an issuer or a group health plan and either of the following occurred:

(i) The premium for the prior coverage was increased to an amount that exceeded the premium required by the PCIP (adjusted based on the age factors

applied to the prior coverage), and this increase was not otherwise explained;

(ii) The health plan, issuer or employer otherwise provided money or other financial consideration to disenroll from coverage, or disincentive to remain enrolled in such coverage. Such considerations include payment of the PCIP premium for an enrollee or potential enrollee.

(c) *Remedies*. If the Secretary determines, based on the criteria in paragraph (b) of this section, that the rule in paragraph (a) of this section applies, an issuer or a group health plan will be billed for the medical expenses incurred by the PCIP. The issuer or group health plan also will be referred to appropriate Federal and State authorities for other enforcement actions that may be warranted based on the behavior at issue.

(d) *Other*. Nothing in this section may be construed as constituting exclusive remedies for violations of this section or as preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers.

Subpart F—Funding

§ 152.32 Use of funds.

(a) *Limitation on use of funding*. All funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program.

(b) *Limitation on administrative expenses*. No more than 10 percent of available funds shall be used for administrative expenses over the life of the contract with the PCIP, absent approval from HHS.

§ 152.33 Initial allocation of funds.

HHS will establish an initial ceiling for the amount of the $5 billion in Federal funds allocated for PCIPs in each State using a methodology consistent with that used to established allocations under the Children's Health Insurance Program, as set forth under 42 CFR part 457, subpart F, Payment to States.

§ 152.34 Reallocation of funds.

If HHS determines, based on actual and projected enrollment and claims experience, that the PCIP in a given State will not make use of the total estimated funding allocated to that State, HHS may reallocate unused funds to other States, as needed.

§ 152.35 Insufficient funds.

(a) *Adjustments by a PCIP to eliminate a deficit*. In the event that a PCIP determines, based on actual and projected enrollment and claims data, that its allocated funds are insufficient to cover projected PCIP expenses, the PCIP shall report such insufficiency to HHS, and identify and implement necessary adjustments to eliminate such deficit, subject to HHS approval.

(b) *Adjustment by the Secretary*. If the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit.

(c) *Payment rates for covered services furnished beginning June 15, 2013 to enrollees in the PCIP administered by HHS*. (1) Covered services furnished under the prescription drug, organ/tissue transplant, dialysis and durable medical equipment benefits will be paid at the payment rates that are in effect on June 15, 2013.

(2) With respect to all other covered services, the payment rates will be—

(i) 100 percent of Medicare payment rates; or

(ii) Where Medicare payment rates cannot be implemented by the federally-administered PCIP, 50 percent of billed charges or a rate using a relative value scale pricing methodology.

[75 FR 45029, July 30, 2010, as amended at 78 FR 30226, May 22, 2013]

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General*. A State that enters into a contract with HHS under this part must demonstrate, subject to approval

by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts.* In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND HHS RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

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153.720 Establishment and usage of masked enrollee identification numbers.
153.730 Deadline for submission of data.
153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

AUTHORITY: 42 U.S.C. 18031, 18041, and 18061 through 18063.

SOURCE: 77 FR 17245, Mar. 23, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 153.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act (Pub. L. 111–148, 24 Stat. 119):

(1) Section 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(2) Section 1341. Transitional reinsurance program for individual market in each State.

(3) Section 1342. Establishment of risk corridors for plans in individual and small group markets.

(4) Section 1343. Risk adjustment.

(b) *Scope.* This part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors program, and a permanent risk adjustment program.

§ 153.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of a Federally certified risk adjustment methodology that has not yet been certified by HHS.

Applicable reinsurance entity means a not-for-profit organization that is exempt from taxation under Chapter 1 of the Internal Revenue Code of 1986 that carries out reinsurance functions under this part on behalf of the State. An entity is not an applicable reinsurance entity to the extent it is carrying out reinsurance functions under subpart C of this part on behalf of HHS.

Attachment point means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits in a benefit year, after which threshold the claims costs for such benefits are eligible for reinsurance payments.

Benefit year has the meaning given to the term in § 155.20 of this subchapter.

Calculation of payments and charges means the methodology applied to plan average actuarial risk to determine risk adjustment payments and charges for a risk adjustment covered plan.

Calculation of plan average actuarial risk means the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustments for variable rating and the specification of the risk pool from which average actuarial risk is to be calculated.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for claims costs incurred for an enrolled individual's covered benefits in a benefit year after the attachment point and before the reinsurance cap.

Contributing entity means—

(1) A health insurance issuer; or

(2) For the 2014 benefit year, a self-insured group health plan (including a group health plan that is partially self-

insured and partially insured, where the health insurance coverage does not constitute major medical coverage), whether or not it uses a third party administrator; and for the 2015 and 2016 benefit years, a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) that uses a third party administrator in connection with claims processing or adjudication (including the management of internal appeals) or plan enrollment for services other than for pharmacy benefits or excepted benefits within the meaning of section 2791(c) of the PHS Act. Notwithstanding the foregoing, a self-insured group health plan that uses an unrelated third party to obtain provider network and related claim repricing services, or uses an unrelated third party for up to 5 percent of claims processing or adjudication or plan enrollment, will not be deemed to use a third party administrator, based on either the number of transactions processed by the third party, or the value of the claims processing and adjudication and plan enrollment services provided by the third party. A self-insured group health plan that is a contributing entity is responsible for the reinsurance contributions, although it may elect to use a third party administrator or administrative services-only contractor for transfer of the reinsurance contributions.

Contribution rate means, with respect to a benefit year, the per capita amount each contributing entity must pay for a reinsurance program established under this part with respect to each reinsurance contribution enrollee who resides in that State.

Exchange has the meaning given to the term in §155.20 of this subchapter.

Federally certified risk adjustment methodology means a risk adjustment methodology that either has been developed and promulgated by HHS, or has been certified by HHS.

Grandfathered health plan has the meaning given to the term in §147.140(a) of this subchapter.

Group health plan has the meaning given to the term in §144.103 of this subchapter.

Health insurance coverage has the meaning given to the term in §144.103 of this subchapter.

Health insurance issuer or *issuer* has the meaning given to the term in §144.103 of this subchapter.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given to the term in §144.103 of this subchapter.

Individual risk score means a relative measure of predicted health care costs for a particular enrollee that is the result of a risk adjustment model.

Major medical coverage means, for purposes only of the requirements related to reinsurance contributions under section 1341 of the Affordable Care Act, a catastrophic plan, an individual or a small group market plan subject to the actuarial value requirements under §156.140 of this subchapter, or health coverage for a broad range of services and treatments provided in various settings that provides minimum value as defined in §156.145 of this subchapter.

Qualified employer has the meaning given to the term in §155.20 of this subchapter.

Qualified individual has the meaning given to the term in §155.20 of this subchapter.

Reinsurance cap means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits, after which threshold, the claims costs for such benefits are no longer eligible for reinsurance payments.

Reinsurance contribution enrollee means an individual covered by a plan for which reinsurance contributions must be made pursuant to §153.400.

Reinsurance-eligible plan means, for the purpose of the reinsurance program, any health insurance coverage offered in the individual market, except for grandfathered plans and health insurance coverage not required to submit reinsurance contributions under §153.400(a).

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group

health insurance coverage described in §146.145(b) of this subchapter, individual health insurance coverage described in §148.220 of this subchapter, and any plan determined not to be a risk adjustment covered plan in the applicable Federally certified risk adjustment methodology.

Risk adjustment data means all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Risk adjustment data collection approach means the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, and validated and the applicable timeframes, data formats, and privacy and security standards.

Risk adjustment methodology means the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program.

Risk adjustment model means an actuarial tool used to predict health care costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the State-wide population across which risk is distributed.

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

State has the meaning given to the term in §155.20 of this subchapter.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013; 78 FR 54133, Aug. 30, 2013; 78 FR 65093, Oct. 30, 2013; 79 FR 13834, Mar. 11, 2014; 79 FR 36432, June 27, 2014; 81 FR 94174, Dec. 22, 2016; 84 FR 17561, Apr. 25, 2019]

Subpart B—State Notice of Benefit and Payment Parameters

§ 153.100 State notice of benefit and payment parameters.

(a) *General requirement for reinsurance.* A State establishing a reinsurance program must issue an annual notice of benefit and payment parameters specific to that State if that State elects to:

(1) Modify the data requirements for health insurance issuers to receive reinsurance payments from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Collect additional reinsurance contributions under §153.220(d)(1) or use additional funds for reinsurance payments under §153.220(d)(2); or

(3) Use more than one applicable reinsurance entity; or

(b) *Risk adjustment requirements.* A State operating a risk adjustment program must issue an annual notice of benefit and payment parameters specific to that State setting forth the risk adjustment methodology and data validation standards it will use.

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters for a particular benefit year, it must do so by the later of March 1 of the calendar year prior to the applicable benefit year, or by the 30th day following the publication of the final HHS notice of benefit and payment parameters for that benefit year.

(d) *State failure to publish notice.* Any State establishing a reinsurance program or operating a risk adjustment program that fails to publish a State notice of benefit and payment parameters within the period specified in paragraph (c) of this section must—

(1) Adhere to the data requirements for health insurance issuers to receive reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of additional reinsurance contributions under §153.220(d)(1) and the use of additional funds for reinsurance payments under §153.220(d)(2);

(3) Forgo the use of more than one applicable reinsurance entity;

(4) Adhere to the risk adjustment methodology and data validation standards published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013; 80 FR 10862, Feb. 27, 2015]

§ 153.110 Standards for the State notice of benefit and payment parameters.

(a) *Data requirements.* If a State that establishes a reinsurance program elects to modify the data requirements for health insurance issuers to receive reinsurance payments from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State notice of benefit and payment parameters must specify those modifications.

(b) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds under §153.220(d)(1) or use additional funds for reinsurance payments under §153.220(d)(2), the State must publish in the State notice of benefit and payment parameters the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments made under §153.232, administrative costs, or both;

(2) The additional contribution rate at which the funds will be collected; and

(3) If the purpose of the additional collection includes reinsurance payments (or if the State is using additional funds for reinsurance payments under §153.220(d)(2)), the State supplemental reinsurance payment parameters required under §153.232.

(c) *Multiple reinsurance entities.* If a State plans to use more than one applicable reinsurance entity, the State must publish in the State notice of benefit and payment parameters, for each applicable reinsurance entity—

(1) The geographic boundaries for that entity;

(2) An estimate of the number of enrollees in the individual market within those boundaries;

(3) An estimate of the amount of reinsurance payments that will be made to issuers with respect to enrollees within those boundaries.

(d) *Risk adjustment content.* A State operating a risk adjustment program must provide the information set forth in §153.330(a) and the data validation standards set forth pursuant to §153.350 in the State notice of benefit and payment parameters.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013]

Subpart C—State Standards Related to the Reinsurance Program

§ 153.200 [Reserved]

§ 153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State is eligible to establish a reinsurance program for the years 2014 through 2016.

(1) If a State establishes a reinsurance program, the State must enter into a contract with one or more applicable reinsurance entities to carry out the provisions of this subpart.

(2) If a State contracts with or establishes more than one applicable reinsurance entity, the State must ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity.

(3) A State may permit an applicable reinsurance entity to subcontract specific administrative functions required under this subpart and subpart E of this part.

(4) A State must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures of administrative funds collected under this subpart.

(5) A State must ensure that the applicable reinsurance entity completes all reinsurance-related activities for benefit years 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single entity to serve as an applicable reinsurance entity for each State. In such a case, the reinsurance programs for those States must be operated as separate programs.

(c) *Non-electing States.* HHS will establish a reinsurance program for each State that does not elect to establish its own reinsurance program.

(d) *Oversight.* Each State that establishes a reinsurance program must ensure that the applicable reinsurance

entity complies with all provisions of this subpart and subpart E of this part throughout the duration of its contract.

(e) *Reporting to HHS.* Each State that establishes a reinsurance program must ensure that each applicable reinsurance entity provides information regarding requests for reinsurance payments under the national contribution rate made under § 153.410 for all reinsurance-eligible plans for each quarter during the applicable benefit year in a manner and timeframe established by HHS.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 15525, Mar. 11, 2013]

§ 153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, HHS will collect all reinsurance contributions from all contributing entities for that State under the national contribution rate.

(b) *Contribution funding.* Reinsurance contributions collected must fund the following:

(1) Reinsurance payments that will total, on a national basis, $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016;

(2) U.S. Treasury contributions that will total, on a national basis, $2 billion in 2014, $2 billion in 2015, and $1 billion in 2016; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(c) *National contribution rate.* HHS will set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the national contribution rate and the proportion of contributions collected under the national contribution rate to be allocated to:

(1) Reinsurance payments;

(2) Payments to the U.S. Treasury as described in paragraph (b)(2) of this section; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(d) *Additional State collections.* If a State establishes a reinsurance program:

(1) The State may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

(i) Funding for administrative expenses of the applicable reinsurance entity; or

(ii) Additional funds for reinsurance payments.

(2) A State may use additional funds which were not collected as additional reinsurance contributions under this part for reinsurance payments under the State supplemental payment parameters under § 153.232.

[77 FR 17245, Mar. 23, 2012, as amended at 77 FR 29236, May 17, 2012, 78 FR 15525, Mar. 11, 2013; 78 FR 66655, Nov. 6, 2013]

§ 153.230 Calculation of reinsurance payments made under the national contribution rate.

(a) *Eligibility for reinsurance payments under the national reinsurance parameters.* A health insurance issuer of a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions collected under the national contribution rate when its claims costs for an individual enrollee's covered benefits in a benefit year exceed the national attachment point.

(b) *National reinsurance payment parameters.* The national reinsurance payment parameters for each benefit year commencing in 2014 and ending in 2016 set forth in the annual HHS notice of benefit and payment parameters for each applicable benefit year will apply with respect to reinsurance payments made from contributions received under the national contribution rate.

(c) *National reinsurance payments.* Each reinsurance payment made from contributions received under the national contribution rate will be calculated as the product of the national coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs in the applicable benefit year between the national attachment point and the national reinsurance cap.

(d) *Uniform adjustment to national reinsurance payments.* If HHS determines

that all reinsurance payments requested under the national payment parameters from all reinsurance-eligible plans in all States for a benefit year will not be equal to the amount of all reinsurance contributions collected for reinsurance payments under the national contribution rate in all States for an applicable benefit year, HHS will determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments for all States. Each applicable reinsurance entity, or HHS on behalf of a State, must reduce or increase the reinsurance payment amounts for the applicable benefit year by any adjustment required under this paragraph (d).

[78 FR 15526, Mar. 11, 2013, as amended at 78 FR 66655, Nov. 6, 2013; 79 FR 13835, Mar. 11, 2014]

§ 153.232 Calculation of reinsurance payments made under a State additional contribution rate.

(a) *State supplemental reinsurance payment parameters.* (1) If a State establishes a reinsurance program and elects to collect additional contributions under §153.220(d)(1)(ii) or use additional funds for reinsurance payments under §153.220(d)(2), the State must set supplemental reinsurance payment parameters using one or more of the following methods:

(i) Decreasing the national attachment point;

(ii) Increasing the national reinsurance cap; or

(iii) Increasing the national coinsurance rate.

(2) The State must ensure that additional reinsurance contributions and funds projected to be received under §153.220(d)(1)(ii) and §153.220(d)(2), as applicable, for any applicable benefit year are reasonably calculated to cover additional reinsurance payments that are projected to be made only under the State supplemental reinsurance payment parameters (that will not be paid under the national payment parameters) for the given benefit year.

(3) All applicable reinsurance entities in a State collecting additional reinsurance contributions must apply the State supplemental reinsurance payment parameters established under paragraph (a)(1) of this section when calculating reinsurance payments.

(b) *General requirement for payments under State supplemental reinsurance parameters.* Contributions collected under §153.220(d)(1)(ii) or funds under §153.220(d)(2), as applicable, must be applied towards requests for reinsurance payments made under the State supplemental reinsurance payments parameters for each benefit year commencing in 2014 and ending in 2016.

(c) *Eligibility for reinsurance payments under State supplemental reinsurance parameters.* If a State establishes State supplemental reinsurance payment parameters under §153.232(a)(1), a reinsurance-eligible plan becomes eligible for reinsurance payments from contributions under §153.220(d)(1)(ii) or funds under §153.220(d)(2), as applicable, if its incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year:

(1) Exceed the State supplemental attachment point set forth in the State notice of benefit and payment parameters for the applicable benefit year if a State has established such a supplemental attachment point under §153.232(a)(1)(i);

(2) Exceed the national reinsurance cap set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a State supplemental reinsurance cap under §153.232(a)(1)(ii); or

(3) Exceed the national attachment point set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year if a State has established a supplemental coinsurance rate under §153.232(a)(1)(iii).

(d) *Payments under State supplemental reinsurance parameters.* Each reinsurance payment made from contributions received under §153.220(d)(1)(ii) or funds under §153.220(d)(2), as applicable, will be calculated with respect to an issuer's incurred claims costs for an individual enrollee's covered benefits in the applicable benefit year as the sum of the following:

(1) If the State has established a State supplemental attachment point, to the extent the issuer's incurred

claims costs for such benefits in the applicable benefit year exceed the State supplemental attachment point but do not exceed the national attachment point, the product of such claims costs between the State supplemental attachment point and the national attachment point multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate);

(2) If the State has established a State supplemental reinsurance cap, to the extent the issuer's incurred claims costs for such benefits in the applicable benefit year exceed the national reinsurance cap but do not exceed the State supplemental reinsurance cap, the product of such claims costs between the national reinsurance cap and the State supplemental reinsurance cap multiplied by the national coinsurance rate (or, if the State has established a State supplemental coinsurance rate, the State supplemental coinsurance rate); and

(3) If the State has established a State supplemental coinsurance rate, the product of the issuer's incurred claims costs for such benefits in the applicable benefit year between the national attachment point and the national reinsurance cap multiplied by the difference between the State supplemental coinsurance rate and the national coinsurance rate.

(e) *Uniform adjustment to payments under State supplemental reinsurance payment parameters.* If all requested reinsurance payments under the State supplemental reinsurance parameters calculated in accordance with paragraph (a)(1) of this section from all reinsurance-eligible plans in a State for a benefit year will exceed all reinsurance contributions collected under §153.220(d)(1)(ii) or funds under §153.220(d)(2) for the applicable benefit year, the State must determine a uniform pro rata adjustment to be applied to all such requests for reinsurance payments. Each applicable reinsurance entity in the State must reduce all such requests for reinsurance payments for the applicable benefit year by that adjustment.

(f) *Limitations on payments under State supplemental reinsurance parameters.* A State must ensure that:

(1) The payments made to issuers must not exceed the issuer's total paid amount for the reinsurance-eligible claim(s); and

(2) Any remaining additional funds for reinsurance payments collected under §153.220(d)(1)(ii) must be used for reinsurance payments under the State supplemental reinsurance payment parameters in subsequent benefit years.

[78 FR 15526, Mar. 11, 2013]

§ 153.234 Eligibility under health insurance market rules.

A reinsurance-eligible plan's covered claims costs for an enrollee incurred prior to the application of the following provisions do not count towards either the national reinsurance payment parameters or the State supplemental reinsurance payment parameters: 45 CFR 147.102, 147.104 (subject to 147.145), 147.106 (subject to 147.145), 156.80, and subpart B of part 156.

[78 FR 15527, Mar. 11, 2013]

§ 153.235 Allocation and distribution of reinsurance contributions

(a) *Allocation of reinsurance contributions.* HHS will allocate and disburse to each State operating reinsurance (and will distribute directly to issuers if HHS is operating reinsurance on behalf of a State), reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments. The disbursed funds would be based on the total requests for reinsurance payments made under the national reinsurance payment parameters in all States and submitted under §153.410, net of any adjustment under §153.230(d).

(b) *Excess reinsurance contributions.* Any reinsurance contributions collected from contributing entities under the national contribution rate for reinsurance payments for any benefit year but unused for the applicable benefit year will be used for reinsurance payments under the national reinsurance payment parameters for subsequent benefit years.

[78 FR 15527, Mar. 11, 2013]

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity:

(1) Collects data required to determine reinsurance payments as described in §§ 153.230 and 153.232, as applicable, from an issuer of reinsurance-eligible plans or is provided access to such data, according to the data requirements specified by the State in the State notice of benefit and payment parameters described in subpart B of this part.

(2) Makes reinsurance payments to the issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer in accordance with the requirements of § 153.410.

(3) Provides a process through which an issuer of a reinsurance-eligible plan that does not generate individual enrollee claims in the normal course of business may use estimated claims costs to make a request for payment (or to submit data to be considered for reinsurance payments) in accordance with the requirements of § 153.410. The State must ensure that such requests for reinsurance payment (or a subset of such requests) are subject to validation.

(b) *Notification of reinsurance payments.* For each applicable benefit year,

(1) A State, or HHS on behalf of the State, must notify issuers annually of:

(i) Reinsurance payments under the national payment parameters, and

(ii) Reinsurance payments under the State supplemental payment parameters if applicable, to be made for the applicable benefit year no later than June 30 of the year following the applicable benefit year.

(2) A State must provide to each issuer of a reinsurance-eligible plan the calculation of total reinsurance payment requests, on a quarterly basis during the applicable benefit year in a timeframe and manner specified by HHS, made under:

(i) The national reinsurance payment parameters, and

(ii) State supplemental reinsurance payments parameters if applicable.

(c) *Maintenance of records.* If a State establishes a reinsurance program, the State must maintain documents and records relating to the reinsurance program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated reinsurance program's compliance with Federal standards. The State must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Privacy and security.* (1) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity's collection of personally identifiable information is limited to information reasonably necessary for use in the calculation of reinsurance payments, and that use and disclosure of personally identifiable information is limited to those purposes for which the personally identifiable information was collected (including for purposes of data validation).

(2) If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity implements security standards that provide administrative, physical, and technical safeguards for the personally identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15527, Mar. 11, 2013; 78 FR 65093, Oct. 30, 2013]

§ 153.250 Coordination with high-risk pools.

(a) *General requirement.* The State must eliminate or modify any State high-risk pool to the extent necessary to carry out the reinsurance program established under this subpart.

(b) *Coordination with high-risk pools.* The State may coordinate the State high-risk pool with the reinsurance program to the extent that the State

high-risk pool conforms to the provisions of this subpart.

§ 153.260 General oversight requirements for State-operated reinsurance programs.

(a) *Accounting requirements.* A State that establishes a reinsurance program must ensure that its applicable reinsurance entity keeps an accounting for each benefit year of:

(1) All reinsurance contributions received from HHS for reinsurance payments and for administrative expenses;

(2) All claims for reinsurance payments received from issuers of reinsurance-eligible plans;

(3) All reinsurance payments made to issuers of reinsurance-eligible plans; and

(4) All administrative expenses incurred for the reinsurance program.

(b) *State summary report.* A State that establishes a reinsurance program must submit to HHS and make public a report on its reinsurance program operations for each benefit year in the manner and timeframe specified by HHS. The report must summarize the accounting for the benefit year kept pursuant to paragraph (a) of this section.

(c) *Independent external audit.* A State that establishes a reinsurance program must engage an independent qualified auditing entity to perform a financial and programmatic audit for each benefit year of its State-operated reinsurance program in accordance with generally accepted auditing standards (GAAS). The State must:

(1) Provide to HHS the results of the audit, in the manner and timeframe to be specified by HHS;

(2) Ensure that the audit addresses the prohibitions set forth in § 153.265;

(3) Identify to HHS any material weakness or significant deficiency identified in the audit, and address in writing to HHS how the State intends to correct any such material weakness or significant deficiency; and

(4) Make public a summary of the results of the audit, including any material weakness or significant deficiency and how the State intends to correct the material weakness or significant deficiency, in the manner and timeframe to be specified by HHS.

[78 FR 65093, Oct. 30, 2013]

§ 153.265 Restrictions on use of reinsurance funds for administrative expenses.

A State that establishes a reinsurance program must ensure that its applicable reinsurance entity does not use any funds for the support of reinsurance operations, including any reinsurance contributions provided under the national contribution rate for administrative expenses, for any of the following purposes:

(a) Staff retreats;

(b) Promotional giveaways;

(c) Excessive executive compensation; or

(d) Promotion of Federal or State legislative or regulatory modifications.

[78 FR 65093, Oct. 30, 2013]

§ 153.270 HHS audits of State-operated reinsurance programs.

(a) *Audits.* HHS or its designee may conduct a financial and programmatic audit of a State-operated reinsurance program to assess compliance with the requirements of this subpart or subpart B of this part. A State that establishes a reinsurance program must ensure that its applicable reinsurance entity and any relevant contractors, subcontractors, or agents cooperate with any audit under this section.

(b) *Action on audit findings.* If an audit results in a finding of material weakness or significant deficiency with respect to compliance with any requirement of this subpart or subpart B, the State must ensure that the applicable reinsurance entity:

(1) Within 60 calendar days of the issuance of the final audit report, provides a written corrective action plan to HHS for approval;

(2) Implements that plan; and

(3) Provides to HHS written documentation of the corrective actions once taken.

[79 FR 13835, Mar. 11, 2014]

Subpart D—State Standards Related to the Risk Adjustment Program

§ 153.300 [Reserved]

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program.* (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect to operate an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to operate an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(4) Beginning in 2015, any State that is approved to operate an Exchange and elects to operate risk adjustment but has not been approved by HHS to operate risk adjustment prior to publication of its State notice of benefit and payment parameters for the applicable benefit year, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities.* If a State is operating a risk adjustment program, the State may elect to have an entity other than the Exchange perform the State functions of this subpart, provided that the entity meets the standards promulgated by HHS to be an entity eligible to carry out Exchange functions.

(c) *State responsibility for risk adjustment.* (1) A State operating a risk adjustment program for a benefit year must administer the applicable Federally certified risk adjustment methodology through an entity that—

(i) Is operationally ready to implement the applicable Federally certified risk adjustment methodology and process the resulting payments and charges; and

(ii) Has experience relevant to operating the risk adjustment program.

(2) The State must ensure that the risk adjustment entity complies with all applicable provisions of subpart D of this part in the administration of the applicable Federally certified risk adjustment methodology.

(3) The State must conduct oversight and monitoring of its risk adjustment program.

(4) *Maintenance of records.* A State operating a risk adjustment program must maintain documents and records relating to the risk adjustment program, whether paper, electronic, or in other media, for each benefit year for at least 10 years, and make them available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity. The documents and records must be sufficient to enable the evaluation of the State-operated risk adjustment program's compliance with Federal standards. A State operating a risk adjustment program must also ensure that its contractors, subcontractors, and agents similarly maintain and make relevant documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity.

(d) *Approval for a State to operate risk adjustment.* (1) To be approved by HHS to operate risk adjustment under a particular Federally certified risk adjustment methodology for a benefit year, a State must establish that it and its risk adjustment entity meet the standards set forth in paragraph (c) of this section.

(2) To obtain such approval, the State must submit to HHS, in a form and manner specified by HHS, evidence that its risk adjustment entity meets these standards.

(3) In addition to requirements set forth in paragraphs (d)(1) and (2) of this section, to obtain re-approval from HHS to operate risk adjustment for a third benefit year, the State must, in the first benefit year for which it operates risk adjustment, provide to HHS an interim report, in a manner specified by HHS, including a detailed summary of its risk adjustment activities

in the first 10 months of the benefit year, no later than December 31 of the applicable benefit year.

(4) To obtain re-approval from HHS to operate risk adjustment for each benefit year after the third benefit year, each State operating a risk adjustment program must submit to HHS and make public a detailed summary of its risk adjustment program operations for the most recent benefit year for which risk adjustment operations have been completed, in the manner and timeframe specified by HHS.

(i) The summary must include the results of a programmatic and financial audit for each benefit year of the State-operated risk adjustment program conducted by an independent qualified auditing entity in accordance with generally accepted auditing standards (GAAS).

(ii) The summary must identify any material weakness or significant deficiency identified in the audit and address how the State intends to correct any such material weakness or significant deficiency.

(e) *Timeframes.* A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15527, Mar. 11, 2013; 78 FR 65093, Oct. 30, 2013]

§ 153.320 Federally certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in advance of the benefit year in rulemaking; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in the applicable annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices.* The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must include:

(1) A complete description of the risk adjustment model, including—

(i) Draft factors to be employed in the model, including but not limited to, demographic factors, diagnostic factors, and utilization factors, if any, the dataset(s) to be used to calculate final coefficients, and the date by which final coefficients will be released in guidance;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in notice-and-comment rulemaking by HHS in advance of the applicable benefit year, the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

(d) *State flexibility to request reductions to transfers.* For the 2020 through 2023 benefit years, States can request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50 percent in States where HHS operates the risk adjustment program. For the 2024 benefit year only, only prior participants, as defined in paragraph (d)(5) of this section, may request to reduce risk adjustment transfers in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by up to 50

percent in States where HHS operates the risk adjustment program.

(1) *State requests.* State requests for a reduction to transfers must include:

(i) Supporting evidence and analysis demonstrating the State-specific factors that warrant an adjustment to more precisely account for the differences in actuarial risk in the State market risk pool;

(ii) The adjustment percentage of up to 50 percent requested for the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool; and

(iii) For the 2020 through 2023 benefit years, a justification for the reduction requested demonstrating the State-specific factors that warrant an adjustment to more precisely account for relative risk differences in the State individual catastrophic, individual non-catastrophic, small group, or merged market risk pool, or demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments; or

(iv) For the 2024 benefit year only, a justification for the requested reduction demonstrating the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(2) *Timeframe to submit reduction requests.* States must submit requests for a reduction to transfers in the individual catastrophic, individual non-catastrophic, small group, or merged market risk pool by August 1 of the benefit year that is 2 calendar years prior to the applicable benefit year, in the form and manner specified by HHS.

(3) *Publication of reduction requests.* HHS will publish State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters rule and make the supporting evidence available to the public for comment, except to the extent the State requests HHS not publish certain supporting evidence because it contains trade secrets or confidential commercial or financial information as defined in HHS' Freedom of Information regulations under 45 CFR 5.31(d). HHS will publish any approved or denied State reduction requests in the applicable benefit year's HHS notice of benefit and payment parameters final rule.

(4) *HHS approval.* (i) Subject to paragraph (d)(4)(ii) of this section, HHS will approve State reduction requests if HHS determines, based on the review of the information submitted as part of the State's request, along with other relevant factors, including the premium impact of the transfer reduction for the State market risk pool, and relevant public comments:

(A) For the 2020 through 2023 benefit years, that State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and support the percentage reduction to risk adjustment transfers requested; or State-specific rules or other relevant factors warrant an adjustment to more precisely account for relative risk differences in the State's individual catastrophic, individual non-catastrophic, small group, or merged market risk pool and the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(B) For the 2024 benefit year only, that the requested reduction would have *de minimis* impact on the necessary premium increase to cover the transfers for issuers that would receive reduced transfer payments.

(ii) HHS may approve a reduction amount that is lower than the amount requested by the State if the supporting evidence and analysis do not fully support the requested reduction amount. HHS will assess other relevant factors, including the premium impact of the transfer reduction for the applicable State market risk pool.

(5) *Exception for prior participants.* As used in paragraph (d) of this section, prior participants mean States that submitted a State reduction request in the State's individual catastrophic, individual non-catastrophic, small group,

or merged market risk pool in the 2020, 2021, 2022, or 2023 benefit year.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013; 81 FR 94174, Dec. 22, 2016; 83 FR 17059, Apr. 17, 2018; 84 FR 17561, Apr. 25, 2019; 86 FR 24286, May 5, 2021; 87 FR 27387, May 6, 2022; 88 FR 25916, Apr. 27, 2023]

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.* (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in health care costs of a given population;

(ii) Links risk factors to daily clinical practice and is clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality, and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *Evaluation criteria for alternate risk adjustment methodology.* An alternate risk adjustment methodology will be certified by HHS as a Federally certified risk adjustment methodology based on the following criteria:

(1) The criteria listed in paragraph (a)(2) of this section;

(2) Whether the methodology complies with the requirements of this subpart D;

(3) Whether the methodology accounts for risk selection across metal levels; and

(4) Whether each of the elements of the methodology are aligned.

(c) *State renewal of alternate methodology.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* If a State is operating a risk adjustment program, the State must collect risk adjustment data.

(b) *Minimum standards.* (1) If a State is operating a risk adjustment program, the State may vary the amount and type of data collected, but the State must collect or calculate individual risk scores generated by the risk adjustment model in the applicable Federally certified risk adjustment methodology;

(2) If a State is operating a risk adjustment program, the State must require that issuers offering risk adjustment covered plans in the State comply with data privacy and security standards set forth in the applicable risk adjustment data collection approach; and

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State. Use and disclosure of personally identifiable information is limited to those purposes for which

the personally identifiable information was collected (including for purposes of data validation).

(4) If a State is operating a risk adjustment program, the State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement.* The State, or HHS on behalf of the State, must ensure proper implementation of any risk adjustment software and ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Adjustment to plan average actuarial risk.* The State, or HHS on behalf of the State, may adjust the plan average actuarial risk for a risk adjustment covered plan based on errors discovered with respect to implementation of risk adjustment software or as a result of data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments.* The State, or HHS on behalf of the State, may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

(d) *Appeals.* The State, or HHS on behalf of the State, must provide an administrative process to appeal findings with respect to the implementation of risk adjustment software or data validation.

§ 153.360 Application of risk adjustment to the small group market.

Enrollees in a risk adjustment covered plan must be assigned to the applicable risk pool in the State in which the employer's policy was filed and approved.

[78 FR 15528, Mar. 11, 2013]

§ 153.365 General oversight requirements for State-operated risk adjustment programs.

If a State is operating a risk adjustment program, it must keep an accounting of all receipts and expenditures related to risk adjustment payments and charges and the administration of risk adjustment-related functions and activities for each benefit year.

[78 FR 65094, Oct. 30, 2013]

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement.* Each contributing entity must make reinsurance contributions annually: at the national contribution rate for all reinsurance contribution enrollees, in a manner specified by HHS; and at the additional State supplemental contribution rate if the State has elected to collect additional contributions under §153.220(d)(1), in a manner specified by the State.

(1) In general, reinsurance contributions are required for major medical coverage that is considered to be part of a commercial book of business, but are not required to be paid more than once with respect to the same covered life. In order to effectuate that principle, a contributing entity must make reinsurance contributions for lives covered by its self-insured group health plans and health insurance coverage except to the extent that:

(i) Such plan or coverage is not major medical coverage, subject to paragraph (a)(3) of this section.

(ii) In the case of health insurance coverage, such coverage is not considered to be part of an issuer's commercial book of business;

(iii) Such plan or coverage is expatriate health coverage, as defined by the Secretary, or for the 2015 and 2016 benefit years only, is a self-insured group health plan with respect to which enrollment is limited to participants who reside outside of their home country for at least 6 months of the

plan year, and any covered dependents; or

(iv) In the case of employer-provided health coverage, such coverage applies to individuals with respect to which benefits under Title XVIII of the Act (Medicare) are primary under the Medicare Secondary Payor rules under section 1862(b) of the Act and the regulations issued thereunder.

(v) Such plan or coverage applies to individuals with primary residence in a territory that does not operate a reinsurance program.

(vi) In the case of employer-provided group health coverage:

(A) Such coverage applies to individuals with individual market health insurance coverage for which reinsurance contributions are required; or

(B) Such coverage is supplemental or secondary to group health coverage for which reinsurance contributions must be made for the same covered lives.

(2) Accordingly, as specified in paragraph (a)(1) of this section, a contributing entity is not required to make contributions on behalf of the following:

(i) A self-insured group health plan or health insurance coverage that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act;

(ii) Coverage offered by an issuer under contract to provide benefits under any of the following titles of the Act:

(A) Title XVIII (Medicare);

(B) Title XIX (Medicaid); or

(C) Title XXI (Children's Health Insurance Program);

(iii) A Federal or State high-risk pool, including the Pre-Existing Condition Insurance Plan Program;

(iv) Basic health plan coverage offered by issuers under contract with a State as described in section 1331 of the Affordable Care Act;

(v) A health reimbursement arrangement within the meaning of IRS Notice 2002–45 (2002–2 CB 93) or any subsequent applicable guidance, that is integrated with a self-insured group health plan or health insurance coverage;

(vi) A health savings account within the meaning of section 223(d) of the Code;

(vii) A health flexible spending arrangement within the meaning of section 125 of the Code;

(viii) An employee assistance plan, disease management program, or wellness program that does not provide major medical coverage;

(ix) A stop-loss policy or an indemnity reinsurance policy;

(x) TRICARE and other military health benefits for active and retired uniformed services personnel and their dependents;

(xi) A plan or coverage provided by an Indian Tribe to Tribal members and their spouses and dependents (and other persons of Indian descent closely affiliated with the Tribe), in the capacity of the Tribal members as Tribal members (and not in their capacity as current or former employees of the Tribe or their dependents);

(xii) Health programs operated under the authority of the Indian Health Service; or

(xiii) A self-insured group health plan or health insurance coverage that consists solely of benefits for prescription drugs.

(3) Notwithstanding paragraph (a)(1)(i) of this section, a health insurance issuer must make reinsurance contributions for lives covered by its group health insurance coverage whether or not the insurance coverage constitutes major medical coverage, if—

(i) The group health plan provides health insurance coverage for those covered lives through more than one insurance policy that in combination constitute major medical coverage;

(ii) The lives are not covered by self-insured coverage of the group health plan (except for self-insured coverage limited to excepted benefits); and

(iii) The health insurance coverage under the policy offered by the health insurance issuer constitutes the greatest portion of inpatient hospitalization benefits under the group health plan.

(b) *Data requirements.* Each contributing entity must submit to HHS data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by HHS.

(c) *Determination of a debt.* Any amount owed to the Federal government by a self-insured group health plan (including a group health plan that is partially self-insured and partially insured, where the health insurance coverage does not constitute major medical coverage) and its affiliates for reinsurance is a determination of a debt.

[78 FR 15528, Mar. 11, 2013, as amended at 78 FR 65094, Oct. 30, 2013; 79 FR 13835, Mar. 11, 2014; 80 FR 10862, Feb. 27, 2015]

§ 153.405 Calculation of reinsurance contributions.

(a) *In general.* The reinsurance contribution required from a contributing entity for its reinsurance contribution enrollees during a benefit year is calculated by multiplying:

(1) The number of covered lives of reinsurance contribution enrollees during the applicable benefit year for all plans and coverage described in §153.400(a)(1) of the contributing entity; by

(2) The contribution rate for the applicable benefit year.

(b) *Annual enrollment count.* No later than November 15 of benefit year 2014, 2015, or 2016, as applicable, or, if such date is not a business day, the next business day, a contributing entity must submit an annual enrollment count of the number of covered lives of reinsurance contribution enrollees for the applicable benefit year to HHS. The count must be determined as specified in paragraphs (d) through (g) of this section, as applicable.

(c) *Notification and payment.* (1) Following submission of the annual enrollment count described in paragraph (b) of this section, HHS will notify the contributing entity of the reinsurance contribution amount allocated to reinsurance payments, administrative expenses, and the U.S. Treasury to be paid for the applicable benefit year.

(2) A contributing entity must remit reinsurance contributions to HHS no later than January 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making a combined contribution or the first payment of the bifurcated contribution, and no later than November 15, 2015, 2016, or 2017, as applicable, or, if such date is not a business day, the next business day, if making the second payment of the bifurcated contribution.

(d) *Procedures for counting covered lives for health insurance issuers.* A health insurance issuer must use the same method in a benefit year for all of its health insurance plans in the State (including both the individual and group markets) for which reinsurance contributions are required. To determine the number of covered lives of reinsurance contribution enrollees under all health insurance plans in a State for a benefit year, a health insurance issuer must use one of the following methods:

(1) Adding the total number of lives covered for each day of the first nine months of the benefit year and dividing that total by the number of days in the first nine months;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year, and dividing that total by the number of dates on which a count was made. For this purpose, the same months must be used for each quarter (for example January, April and July) and the date used for the second and third quarter must fall within the same week of the quarter as the corresponding date used for the first quarter; or

(3) Multiplying the average number of policies in effect for the first nine months of the benefit year by the ratio of covered lives per policy in effect, calculated using the prior National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit (or a form filed with the issuer's State of domicile for the most recent time period).

(e) *Procedures for counting covered lives for self-insured group health plans.* To determine the number of covered lives of reinsurance contribution enrollees under a self-insured group health plan for a benefit year, a plan must use one of the following methods:

(1) One of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section;

(2) Adding the total number of lives covered on any date (or more dates, if an equal number of dates are used for each quarter) during the same corresponding month in each of the first three quarters of the benefit year (provided that the date used for the second and third quarters must fall within the same week of the quarter as the corresponding date used for the first quarter), and dividing that total by the number of dates on which a count was made, except that the number of lives covered on a date is calculated by adding the number of participants with self-only coverage on the date to the product of the number of participants with coverage other than self-only coverage on the date and a factor of 2.35. For this purpose, the same months must be used for each quarter (for example, January, April, and July); or

(3) Using the number of lives covered for the most current plan year calculated based upon the ''Annual Return/Report of Employee Benefit Plan'' filed with the Department of Labor (Form 5500) for the last applicable time period. For purposes of this paragraph (e)(3), the number of lives covered for the plan year for a plan offering only self-only coverage equals the sum of the total participants covered at the beginning and end of the plan year, as reported on the Form 5500, divided by 2, and the number of lives covered for the plan year for a plan offering self-only coverage and coverage other than self-only coverage equals the sum of the total participants covered at the beginning and the end of the plan year, as reported on the Form 5500.

(f) *Procedures for counting covered lives for group health plans with a self-insured coverage option and an insured coverage option.* (1) To determine the number of covered lives of reinsurance contribution enrollees under a group health plan with a self-insured coverage option and an insured coverage option for a benefit year, a plan must use one of the methods specified in either paragraph (d)(1) or paragraph (d)(2) of this section.

(2) Notwithstanding paragraph (f)(1), a plan with multiple coverage options may use any of the counting methods specified for self-insured coverage or insured coverage, as applicable to each option, if it determines the number of covered lives under each option separately as if each coverage option provided major medical coverage (not including any coverage option that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement).

(g) *Multiple group health plans maintained by the same plan sponsor*—(1) *General rule.* If a plan sponsor maintains two or more group health plans (including one or more group health plans that provide health insurance coverage) that collectively provide major medical coverage for the same covered lives simultaneously, then those multiple plans must be treated as a single group health plan for purposes of calculating any reinsurance contribution amount due under this section. However, a plan sponsor may treat the multiple plans as separate group health plans for purposes of calculating any reinsurance contribution due under this section if it determines the number of covered lives under each separate group health plan as if the separate group health plan provided major medical coverage.

(2) *Plan sponsor.* For purposes of this paragraph (g), the term ''plan sponsor'' means:

(i) The employer, in the case of a plan established or maintained by a single employer;

(ii) The employee organization, in the case of a plan established or maintained by an employee organization;

(iii) The joint board of trustees, in the case of a multiemployer plan (as defined in section 414(f) of the Code);

(iv) The committee, in the case of a multiple employer welfare arrangement;

(v) The cooperative or association that establishes or maintains a plan established or maintained by a rural electric cooperative or rural cooperative association (as such terms are defined in section 3(40)(B) of ERISA);

(vi) The trustee, in the case of a plan established or maintained by a voluntary employees' beneficiary association (meaning that the association is

not merely serving as a funding vehicle for a plan that is established or maintained by an employer or other person);

(vii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, the person identified by the terms of the document under which the plan is operated as the plan sponsor, or the person designated by the terms of the document under which the plan is operated as the plan sponsor, provided that designation is made, and that person has consented to the designation, by no later than the date by which the count of covered lives for that benefit year is required to be provided, after which date that designation for that benefit year may not be changed or revoked, and provided further that a person may be designated as the plan sponsor only if the person is one of the persons maintaining the plan (for example, one of the employers that is maintaining the plan with one or more other employers or employee organizations); or

(viii) In the case of a plan, the sponsor of which is not described in paragraph (g)(2)(i) through (g)(2)(vi) of this section, and for which no identification or designation of a plan sponsor has been made under paragraph (g)(2)(i)(vii) of this section, each employer that maintains the plan (with respect to employees of that employer), each employee organization that maintains the plan (with respect to members of that employee organization), and each board of trustees, cooperative or association that maintains the plan.

(3) *Exception.* A plan sponsor is not required to include as part of a single group health plan as determined under paragraph (g)(1) of this section any group health plan that consists solely of excepted benefits as defined by section 2791(c) of the PHS Act, that only provides benefits related to prescription drugs, or that is a health reimbursement arrangement, health savings account, or health flexible spending arrangement.

(4) *Procedures for counting covered lives for multiple group health plans treated as a single group health plan.* The rules in this paragraph (g)(4) govern the determination of the average number of covered lives in a benefit year for any set of multiple self-insured group health plans or health insurance plans (or a combination of one or more self-insured group health plans and one or more health insurance plans) that are treated as a single group health plan under paragraph (g)(1) of this section.

(i) *Multiple group health plans including an insured plan.* If at least one of the multiple plans is an insured plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified in either paragraph (d)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor and reported to HHS.

(ii) *Multiple group health plans not including an insured plan.* If each of the multiple plans is a self-insured group health plan, the average number of covered lives of reinsurance contribution enrollees must be calculated using one of the methods specified either in paragraph (e)(1) or (2) of this section, applied across the multiple plans as a whole. The following information must be determined by the plan sponsor:

(A) The average number of covered lives calculated;

(B) The counting method used; and

(C) The names of the multiple plans being treated as a single group health plan as determined by the plan sponsor.

(h) *Maintenance of records.* A contributing entity must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the enrollment count submitted pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance contribution amounts.

(i) *Audits.* HHS or its designee may audit a contributing entity to assess its compliance with the requirements

of this subpart. A contributing entity that uses a third party administrator, administrative services-only contractor, or other third party to assist with its obligations under this subpart must ensure that the third party administrator, administrative services-only contractor, or other third party cooperates with any audit under this section.

[78 FR 15528, Mar. 11, 2013, as amended at 78 FR 66655, Nov. 6, 2013; 78 FR 65094, Oct. 30, 2013; 78 FR 66655, Nov. 6, 2014; 79 FR 13835, Mar. 11, 2014; 80 FR 10862, Feb. 27, 2015; 81 FR 12334, Mar. 8, 2016]

§ 153.410 Requests for reinsurance payment.

(a) *General requirement.* An issuer of a reinsurance-eligible plan may make a request for payment when that issuer's claims costs for an enrollee of that reinsurance-eligible plan has met the criteria for reinsurance payment set forth in subpart B of this part and the HHS notice of benefit and payment parameters and State notice of benefit and payment parameters for the applicable benefit year, if applicable.

(b) *Manner of request.* An issuer of a reinsurance-eligible plan must make requests for payment in accordance with the requirements of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

(c) *Maintenance of records.* An issuer of a reinsurance-eligible plan must maintain documents and records, whether paper, electronic, or in other media, sufficient to substantiate the requests for reinsurance payments made pursuant to this section for a period of at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, or, in a State where the State is operating reinsurance, the State or its designee, to any such entity, for purposes of verification, investigation, audit, or other review of reinsurance payment requests.

(d) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a reinsurance-eligible plan to assess its compliance with the applicable requirements of this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in §156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a reinsurance-eligible plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described in paragraph (d)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (d)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (d)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of reinsurance payments received that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (5)(i) of this section.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13835, Mar. 11, 2014; 86 FR 24286, May 5, 2021]

§ 153.420 Data collection.

(a) *Data requirement.* To be eligible for reinsurance payments, an issuer of a reinsurance-eligible plan must submit or make accessible all required reinsurance data in accordance with the reinsurance data collection approach established by the State, or by HHS on behalf of the State.

(b) *Deadline for submission of data.* An issuer of a reinsurance-eligible plan must submit or make accessible data to be considered for reinsurance payments for the applicable benefit year by April 30 of the year following the end of the applicable benefit year.

[78 FR 15530, Mar. 11, 2013]

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

§ 153.500 Definitions.

The following definitions apply to this subpart:

Adjustment percentage means, with respect to a QHP:

(1) For benefit year 2014—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium in a transitional State, the percentage specified by HHS for such QHPs in the transitional State; and otherwise

(ii) Zero percent.

(2) For benefit year 2015, for a QHP offered by a health insurance issuer in any State, 2 percent.

(3) For benefit year 2016—

(i) For a QHP offered by a health insurance issuer with allowable costs of at least 80 percent of after-tax premium, the percentage specified by HHS; and otherwise

(ii) Zero percent.

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, including taxes and regulatory fees.

After-tax premiums earned mean, with respect to a QHP, premiums earned with respect to the QHP minus taxes and regulatory fees.

Allowable administrative costs mean, with respect to a QHP, the sum of administrative costs of the QHP, other than taxes and regulatory fees, plus profits earned by the QHP, which sum is limited to the sum of 20 percent and the adjustment percentage of after-tax premiums earned with respect to the QHP (including any premium tax credit under any governmental program), plus taxes and regulatory fees.

Allowable costs means, with respect to a QHP, an amount equal to the pro rata portion of the sum of incurred claims

within the meaning of §158.140 of this subchapter (including adjustments for any direct and indirect remuneration), expenditures by the QHP issuer for the QHP for activities that improve health care quality as set forth in §158.150 of this subchapter, expenditures by the QHP issuer for the QHP related to health information technology and meaningful use requirements as set forth in §158.151 of this subchapter, and the adjustments set forth in §153.530(b); in each case for all of the QHP issuer's non-grandfathered health plans in a market within a State, allocated to the QHP based on premiums earned.

Charge means the flow of funds from QHP issuers to HHS.

Direct and indirect remuneration means prescription drug rebates received by a QHP issuer within the meaning of §158.140(b)(1)(i) of this subchapter.

Payment means the flow of funds from HHS to QHP issuers.

Premiums earned mean, with respect to a QHP, all monies paid by or for enrollees with respect to that plan as a condition of receiving coverage, including any fees or other contributions paid by or for enrollees, within the meaning of §158.130 of this subchapter.

Profits mean, with respect to a QHP, the greater of:

(1) The sum of three percent and the adjustment percentage of after-tax premiums earned; and

(2) Premiums earned of the QHP minus the sum of allowable costs and administrative costs of the QHP.

Qualified health plan or *QHP* means, with respect to the risk corridors program only —

(1) A qualified health plan, as defined at §155.20 of this subchapter;

(2) A health plan offered outside the Exchange by an issuer that is the same plan as a qualified health plan, as defined at §155.20 of this subchapter, offered through the Exchange by the issuer. To be the same plan as a qualified health plan (as defined at §155.20 of this subchapter) means that the health plan offered outside the Exchange has identical benefits, premium, cost-sharing structure, provider network, and service area as the qualified health plan (as defined at §155.20 of this subchapter); or

(3) A health plan offered outside the Exchange that is substantially the same as a qualified health plan, as defined at §155.20 of this subchapter, offered through the Exchange by the issuer. To be substantially the same as a qualified health plan (as defined at §155.20 of this subchapter) means that the health plan meets the criteria set forth in paragraph (2) of this definition with respect to the qualified health plan, except that its benefits, premium, cost-sharing structure, and provider network may differ from those of the qualified health plan (as defined at §155.20 of this subchapter) provided that such differences are tied directly and exclusively to Federal or State requirements or prohibitions on the coverage of benefits that apply differently to plans depending on whether they are offered through or outside an Exchange.

Risk corridors means any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount.

Target amount means, with respect to a QHP, an amount equal to the total premiums earned with respect to a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

Taxes and regulatory fees mean, with respect to a QHP, Federal and State licensing and regulatory fees paid with respect to the QHP as described in §158.161(a) of this subchapter, and Federal and State taxes and assessments paid with respect to the QHP as described in §158.162(a)(1) and (b)(1) of this subchapter.

Transitional State means a State that does not enforce compliance with §147.102, §147.104, §147.106, §147.150, §156.80, or subpart B of part 156 of this subchapter for individual market and small group health plans that renew for a policy year starting between January 1, 2014, and October 1, 2014, in accordance with the transitional policy outlined in the CMS letter dated November 14, 2013.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, 15550, Mar. 11, 2013; 78 FR 54133, Aug. 30, 2013; 79 FR 13835, Mar. 11, 2014; 79 FR 30341, May 27, 2014; 80 FR 10863, Feb. 27, 2015]

§ 153.510 Risk corridors establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the annual HHS notice of benefit and payment parameters for the establishment and administration of a program of risk corridors for calendar years 2014, 2015, and 2016.

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts, under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer an amount equal to 50 percent of the allowable costs in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS will pay to the QHP issuer an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts, under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and

(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

(d) *Charge submission deadline.* A QHP issuer must remit charges to HHS within 30 days after notification of such charges.

(e) A QHP issuer is not subject to the provisions of this subpart with respect to a stand-alone dental plan.

(f) *Eligibility under health insurance market rules.* The provisions of this subpart apply only for plans offered by a QHP issuer in the SHOP or the individual or small group market, as determined according to the employee counting method applicable under State law, that are subject to the following provisions: §§ 147.102, 147.104, 147.106, 147.150, 156.80, and subpart B of part 156 of this subchapter.

(g) *Adjustment to risk corridors payments and charges.* If an issuer reported a certified estimate of 2014 cost-sharing reductions on its 2014 MLR and Risk Corridors Annual Reporting Form that is lower than the actual value of cost-sharing reductions calculated under § 156.430(c) of this subchapter for the 2014 benefit year, HHS will make an adjustment to the amount of the issuer's 2015 benefit year risk corridors payment or charge measured by the full difference between the certified estimate of 2014 cost-sharing reductions reported and the actual value of cost-sharing reductions provided as calculated under § 156.430(c) for the 2014 benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 81 FR 12334, Mar. 8, 2016]

§ 153.520 Attribution and allocation of revenue and expense items.

(a) *Attribution to plans.* Each item of expense in the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP issuer's non-grandfathered health plans in a market within a State, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that a QHP issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of expense in the target amount must reflect an amount equal to the pro rata portion of the aggregate amount of such expense across all of the QHP issuer's non-grandfathered health plans in a market within a State, allocated to the QHP based on premiums earned.

(c) *Disclosure of attribution and allocation methods.* A QHP issuer must submit to HHS a report, in the manner and timeframe specified in the annual HHS notice of benefit and payment parameters, with a detailed description of the methods and specific bases used to perform the attributions and allocations set forth in paragraphs (a) and (b) of this section.

(d) *Attribution of reinsurance and risk adjustment to benefit year.* A QHP issuer must attribute reinsurance payments and risk adjustment payments and charges to allowable costs for the benefit year with respect to which the reinsurance payments or risk adjustment calculations apply.

(e) *Maintenance of records.* A QHP issuer must maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk corridors standards, for each benefit year for at least 10 years, and must make those documents and records available upon request from HHS, the OIG, the Comptroller General, or their designees, to any such entity, for purposes of verification, investigation, audit or other review.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15530, 15550, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013]

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in a manner specified by HHS.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS. For purposes of this subpart, allowable costs must be —

(1) Increased by any risk adjustment charges paid by the issuer for the non-grandfathered health plans under the risk adjustment program established under subpart D of this part.

(2) Reduced by —

(i) Any risk adjustment payments received by the issuer for the non-grandfathered health plans under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the non-grandfathered health plans under the transitional reinsurance program established under subpart C of this part;

(iii) A cost-sharing reduction amount equal to the amount of cost-sharing reductions for the benefit year as calculated under §156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service.

(iv) For the 2015 and 2016 benefit years, any difference between—

(A) The sum of unpaid claims reserves and claims incurred but not reported, as set forth in §§158.103 and 158.140(a)(2) and (3) of this subchapter, that were reported on the MLR and Risk Corridors Annual Reporting Form for the year preceding the benefit year; and

(B) The actual claims incurred during the year preceding the benefit year and paid between March 31 of the benefit year and March 31 of the year following the benefit year.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to the QHP issuer's non-grandfathered health plans in a market within a State in a manner specified by HHS.

(d) *Timeframes.* For each benefit year, a QHP issuer must submit all information required under paragraphs (a) through (c) of this section by July 31 of the year following the benefit year.

(e) *Requirement to submit enrollment data for risk corridors adjustment.* A health insurance issuer in the individual or small group market of a transitional State must submit, in a manner and timeframe specified by HHS, the following:

(1) A count of its total enrollment in the individual market and small group market; and

(2) A count of its total enrollment in individual market and small group market policies that meet the criteria

for transitional policies outlined in the CMS letter dated November 14, 2013.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013; 78 FR 65094, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 79 FR 37662, July 2, 2014; 81 FR 12334, Mar. 8, 2016]

§ 153.540 Compliance with risk corridors standards.

HHS or its designee may audit a QHP issuer to assess its compliance with the requirements of this subpart. HHS will conduct an audit in accordance with the procedures set forth in §158.402(a) through (e) of this subchapter.

[79 FR 13836, Mar. 11, 2014]

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.600 [Reserved]

§ 153.610 Risk adjustment issuer requirements.

(a) *Data requirements.* An issuer that offers risk adjustment covered plans must submit or make accessible all required risk adjustment data for those risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(b) *Risk adjustment data storage.* An issuer that offers risk adjustment covered plans must store all required risk adjustment data in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans that has a net balance of risk adjustment charges payable, including adjustments made pursuant to §153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

(f) *Assessment and collection of user fees for HHS risk adjustment operations.* Where HHS is operating risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan (other than a student health plan or a plan not subject to 45 CFR 147.102, 147.104, 147.106, 156.80, and subpart B of part 156) must, for each benefit year—

(1) Submit or make accessible to HHS its monthly enrollment for the risk adjustment covered plan for the benefit year through the risk adjustment data collection approach established at §153.610(a), in a manner and timeframe specified by HHS; and

(2) Remit to HHS an amount equal to the product of its monthly billable enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013; 81 FR 94174, Dec. 22, 2016]

§ 153.620 Compliance with HHS risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must also maintain documents and records, whether paper, electronic, or in other media, sufficient to enable the evaluation of the issuer's compliance with applicable risk adjustment standards, for each benefit year for at least 10 years, and must make those documents and records available upon request to HHS, the OIG, the

Comptroller General, or their designees, or in a State where the State is operating risk adjustment, the State or its designee to any such entity, for purposes of verification, investigation, audit or other review.

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer of a risk adjustment covered plan to assess its compliance with respect to the applicable requirements in this subpart and subpart H of this part. Compliance reviews conducted under this section will follow the standards set forth in §156.715 of this subchapter.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer of a risk adjustment covered plan.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the audit entrance conference described in paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraphs (c)(2)(ii) or (iii) of this section, as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding or observation in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following, if required by HHS:

(i) Within 45 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this subsection in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of the risk adjustment (including high-cost risk pool) payments that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any risk adjustment

(including high-cost risk pool) payments identified in paragraph (c)(5)(i) of this section.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 65095, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014; 86 FR 24287, May 5, 2021; 89 FR 26419, Apr. 15, 2024]

§ 153.630 Data validation requirements when HHS operates risk adjustment.

(a) *General requirement.* An issuer of a risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial and second validation audit performed on its risk adjustment data as described in this section.

(b) *Initial validation audit.* (1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS. The issuer must provide HHS with the identity of the initial validation auditor, and must attest to the absence of conflicts of interest between the initial validation auditor (or the members of its audit team, owners, directors, officers, or employees) and the issuer (or its owners, directors, officers, or employees), to its knowledge, following reasonable investigation, and must attest that it has obtained an equivalent representation from the initial validation auditor, in a timeframe and manner to be specified by HHS.

(2) The issuer must ensure that the initial validation auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

(3) The issuer must ensure that each initial validation auditor is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner and its impartiality is not reasonably open to question.

(4) The issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by HHS. The issuer must ensure that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

(5) An initial validation audit must be conducted by medical coders certified as such and in good standing by a nationally recognized accrediting agency.

(6) An issuer must provide the initial validation auditor and the second validation auditor with all relevant source enrollment documentation, all claims and encounter data, and medical record documentation from providers of services to each enrollee in the applicable sample without unreasonable delay and in a manner that reasonably assures confidentiality and security in transmission. Notwithstanding any other provision of this section, a qualified provider that is licensed to diagnose mental illness by the State and that is prohibited from furnishing a complete medical record by applicable State privacy laws concerning any enrollee's treatment for one or more mental or behavioral health conditions may furnish a signed mental or behavioral health assessment that, to the extent permissible under applicable Federal and State privacy laws, should contain: The enrollee's name; sex; date of birth; current status of all mental or behavioral health diagnoses; and dates of service. The mental or behavioral health assessment should be signed by the provider and submitted with an attestation that the provider is prohibited from furnishing a complete medical record by applicable State privacy laws.

(7) The risk score of each enrollee in the sample must be validated by—

(i) Validating the enrollee's enrollment data and demographic data in a manner to be determined by HHS.

(ii) Validating enrollee health status through review of all relevant medical record documentation. Medical record documentation must originate from the provider of the services and align with dates of service for the medical diagnoses, and reflect permitted providers and services. For purposes of this section, ''medical record documentation'' means clinical documentation of hospital inpatient or outpatient treatment or professional medical treatment from which enrollee health

status is documented and related to accepted risk adjustment services that occurred during a specified period of time. Medical record documentation must be generated under a face-to-face or telehealth visit documented and authenticated by a permitted provider of services;

(iii) Beginning in the 2018 benefit year, validating enrollee health status through review of all relevant paid pharmacy claims;

(iv) Validating medical records according to industry standards for coding and reporting; and

(v) Having a senior reviewer confirm any enrollee risk adjustment error discovered during the initial validation audit. For purposes of this section, a ''senior reviewer'' is a reviewer certified as a medical coder by a nationally recognized accrediting agency who possesses at least 5 years of experience in medical coding. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, a senior reviewer may possess 3 or more years of experience.

(8) The initial validation auditor must measure and report to the issuer and HHS, in a manner and timeframe specified by HHS, its inter-rater reliability rates among its reviewers. The initial validation auditor must achieve a consistency measure of at least 95 percent for his or her review outcomes, except that for validation of risk adjustment data for the 2015 and 2016 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) HHS may impose civil money penalties in accordance with the procedures set forth in §156.805(b) through (e) of this subchapter if an issuer of a risk adjustment covered plan—

(i) Fails to engage an initial validation auditor;

(ii) Fails to submit the results of an initial validation audit to HHS;

(iii) Engages in misconduct or substantial non-compliance with the risk adjustment data validation standards and requirements applicable to issuers of risk adjustment covered plans; or

(iv) Intentionally or recklessly misrepresents or falsifies information that it furnishes to HHS.

(10) If an issuer of a risk adjustment covered plan fails to engage an initial validation auditor or to submit the results of an initial validation audit to HHS, HHS will impose a default data validation charge.

(c) *Second validation audit.* HHS will select a subsample of the risk adjustment data validated by the initial validation audit for a second validation audit. The issuer must comply with, and must ensure the initial validation auditor complies with, standards for such audit established by HHS, and must cooperate with, and must ensure that the initial validation auditor cooperates with, HHS and the second validation auditor in connection with such audit.

(d) *Risk adjustment data validation disputes and appeals.* (1) Within 15 calendar days of notification of the initial validation audit sample determined by HHS, in the manner set forth by HHS, an issuer must confirm the sample or file a discrepancy report to dispute the initial validation audit sample determined by HHS.

(2) Within 15 calendar days of the notification of the findings of a second validation audit (if applicable) by HHS, in the manner set forth by HHS, an issuer must confirm the findings of the second validation audit (if applicable), or file a discrepancy report to dispute the findings of a second validation audit (if applicable).

(3) Within 30 calendar days of the notification by HHS of the calculation of a risk score error rate, in the manner set forth by HHS, an issuer must confirm the calculation of the risk score error rate as a result of risk adjustment data validation, or file a discrepancy report to dispute the calculation of a risk score error rate as a result of risk adjustment data validation.

(4) An issuer may appeal the findings of a second validation audit (if applicable) or the calculation of a risk score error rate as result of risk adjustment data validation, under the process set forth in §156.1220 of this subchapter.

(e) *Adjustment of payments and charges.* HHS may adjust payments and charges for issuers that do not comply with audit requirements and standards, as specified in paragraphs (b) and (c) of this section.

(f) *Data security and transmission.* (1) An issuer must submit the risk adjustment data and source documentation for the initial and second validation audits specified by HHS to HHS or its designee in the manner and timeframe specified by HHS.

(2) An issuer must ensure that it and its initial validation auditor comply with the security standards described at 45 CFR 164.308, 164.310, and 164.312 in connection with the initial validation audit, the second validation audit, and any appeal.

(g) *Exemptions.* An issuer of a risk adjustment covered plan will be exempted by HHS from the data validation requirement set forth in paragraph (b) of this section for a given benefit year if:

(1) The issuer has 500 or fewer billable member months of enrollment in the individual, small group and merged markets (as applicable) for the applicable benefit year, calculated on a Statewide basis;

(2) The issuer is at or below the materiality threshold as defined by HHS and is not selected by HHS to participate in the data validation requirements in an applicable benefit year under random and targeted sampling conducted approximately every 3 years (barring any risk-based triggers based on experience that will warrant more frequent audits); or

(3) The issuer is in liquidation, or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited, provided that:

(i) The issuer provides to HHS, in the manner and timeframe specified by HHS, an attestation that the issuer is in liquidation or will enter liquidation no later than April 30th of the benefit year that is 2 benefit years after the benefit year being audited that is signed by an individual with the authority to legally and financially bind the issuer; and

(ii) The issuer is not a positive error rate outlier under the error estimation methodology in risk adjustment data validation for the prior benefit year of risk adjustment data validation.

(iii) For purposes of this paragraph (g)(3), liquidation means that a State court has issued an order of liquidation for the issuer that fixes the rights and liabilities of the issuer and its creditors, policyholders, shareholders, members, and all other persons of interest.

(4) The issuer only offered small group market carryover coverage during the benefit year that is being audited.

(5) The issuer was the sole issuer in the state market risk pool during the benefit year that is being audited and did not participate in any other market risk pools in the State during the benefit year that is being audited.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13836, Mar. 11, 2014; 81 FR 94174, Dec. 22, 2016; 83 FR 17059, Apr. 17, 2018; 84 FR 17562, Apr. 25, 2019; 86 FR 24287, May 5, 2021; 88 FR 25916, Apr. 27, 2023]

Subpart H—Distributed Data Collection for HHS-Operated Programs

SOURCE: 78 FR 15531, Mar. 11, 2013, unless otherwise noted.

§ 153.700 Distributed data environment.

(a) *Dedicated distributed data environments.* For each benefit year in which HHS operates the risk adjustment or reinsurance program on behalf of a State, an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in the State, as applicable, must establish a dedicated data environment and provide data access to HHS, in a manner and timeframe specified by HHS, for any HHS-operated risk adjustment and reinsurance program.

(b) *Timeline.* An issuer must establish the dedicated data environment (and confirm proper establishment through successfully testing the environment to conform with applicable HHS standards for such testing) three months prior to the first date of full operation.

§ 153.710 Data requirements.

(a) *Enrollment, claims, and encounter data.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must provide to HHS, through the dedicated data environment, access to enrollee-level plan enrollment data, enrollee

claims data, and enrollee encounter data as specified by HHS.

(b) *Claims data.* All claims data submitted by an issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must have resulted in payment by the issuer (or payment of cost sharing by the enrollee).

(c) *Claims data from capitated plans.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, that does not generate individual enrollee claims in the normal course of business must derive the costs of all applicable provider encounters using its principal internal methodology for pricing those encounters. If the issuer does not have such a methodology, or has an incomplete methodology, it must supplement the methodology in a manner that yields derived claims that are reasonable in light of the specific service and insurance market that the plan is serving.

(d) *Final dedicated distributed data environment report.* Within 15 calendar days of the date of the final dedicated distributed data environment report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the information in the final report accurately reflects the data to which the issuer has provided access to HHS through its dedicated distributed data environment in accordance with §153.700(a) for the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(e) *Materiality threshold.* HHS will consider a discrepancy reported under paragraph (d)(2) of this section to be material if the amount in dispute is equal to or exceeds $100,000 or 1 percent of the total estimated transfer amount in the applicable State market risk pool, whichever is less.

(f) *Unresolved discrepancies.* If a discrepancy first identified in a final dedicated distributed data environment report in accordance with paragraph (d)(2) of this section remains unresolved after the issuance of the notification of risk adjustment payments and charges or reinsurance payments under §153.310(e) or §153.240(b)(1)(ii), respectively, an issuer of a risk adjustment covered plan or reinsurance-eligible plan may make a request for reconsideration regarding such discrepancy under the process set forth in §156.1220(a) of this subchapter.

(g) *Evaluation of dedicated distributed data.* If an issuer of a risk adjustment covered plan fails to provide sufficient required data, such that HHS cannot apply the applicable methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely or appropriate fashion, then HHS will assess a default risk adjustment charge under §153.740(b). If an issuer of a reinsurance eligible plan fails to provide data sufficient for HHS to calculate reinsurance payments, the issuer will forfeit reinsurance payments for claims it fails to submit.

(1) *Data quantity.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan must provide, in a format and on a timeline specified by HHS, data on its total enrollment and claims counts by market, which HHS may use in evaluating whether the issuer provided access in the dedicated distributed data environment to a sufficient quantity of data to meet reinsurance and risk adjustment data requirements.

(2) *Data quality.* If, following the deadline for submission of data specified in §153.730, HHS identifies an outlier that would cause the data that a risk adjustment covered plan or a reinsurance-eligible plan made available through a dedicated distributed data environment to fail HHS's data quality thresholds, the issuer may, within 10 calendar days of receiving notification of the outlier, submit an explanation of the outlier for HHS to consider in determining whether the issuer met the reinsurance and risk adjustment data requirements.

(h) *Risk corridors and MLR reporting.* Except as provided in paragraph (h)(3) of this section:

(1) Notwithstanding any discrepancy report made under paragraph (d)(2) of this section, any discrepancy filed

under §153.630(d)(2) or (3), or any request for reconsideration under §156.1220(a) of this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; reinsurance payment; cost-sharing reduction payment or charge; or risk corridors payment or charge, unless the dispute has been resolved, an issuer must report, for purposes of the risk corridors and medical loss ratio (MLR) programs:

(i) The risk adjustment payment to be made or charge assessed, including an assessment of risk adjustment user fees, by HHS in the notification provided under §153.310(e);

(ii) The reinsurance payment to be made by HHS in the notification provided under §153.240(b)(1)(ii);

(iii) A cost-sharing reduction amount equal to the actual amount of cost-sharing reductions for the benefit year as calculated under §156.430(c) of this subchapter, to the extent not reimbursed to the provider furnishing the item or service;

(iv) For medical loss ratio reporting only, the risk corridors payment to be made or charge assessed by HHS under §153.510; and

(v) The risk adjustment data validation adjustment calculated by HHS in the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers.

(2) An issuer must report during the current MLR and risk corridors reporting year any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge before August 15, or the next applicable business day, of the current MLR and risk corridors reporting year unless instructed otherwise by HHS. An issuer must report any adjustment made or approved by HHS for any risk adjustment payment or charge, including an assessment of risk adjustment user fees and risk adjustment data validation adjustments; any reinsurance payment; any cost-sharing reduction payment or charge; or any risk corridors payment or charge where such adjustment has not been accounted for in a prior MLR and Risk Corridors Annual Reporting Form, in the MLR and Risk Corridors Annual Reporting Form for the following reporting year.

(3) In cases where HHS reasonably determines that the reporting instructions in paragraph (h)(1) or (2) of this section would lead to unfair or misleading financial reporting, issuers must correct their data submissions in a form and manner to be specified by HHS.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13837, Mar. 11, 2014; 81 FR 12335, Mar. 8, 2016; 86 FR 24288, May 5, 2021; 87 FR 27387, May 6, 2022; 88 FR 25916, Apr. 27, 2023]

§153.720 Establishment and usage of masked enrollee identification numbers.

(a) *Enrollee identification numbers.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as applicable, must—

(1) Establish a unique masked enrollee identification number for each enrollee; and

(2) Maintain the same masked enrollee identification number for an enrollee across enrollments or plans within the issuer, within the State, during a benefit year.

(b) *Prohibition on personally identifiable information.* An issuer of a risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program on behalf of the State, as applicable, may not—

(1) Include enrollee's personally identifiable information in the masked enrollee identification number; or

(2) Use the same masked enrollee identification number for different enrollees enrolled with the issuer.

§153.730 Deadline for submission of data.

A risk adjustment covered plan or a reinsurance-eligible plan in a State in which HHS is operating the risk adjustment or reinsurance program, as

applicable, must submit data to be considered for risk adjustment payments and charges and reinsurance payments for the applicable benefit year by April 30 of the year following the applicable benefit year or, if such date is not a business day, the next applicable business day.

[87 FR 27387, May 6, 2022]

§ 153.740 Failure to comply with HHS-operated risk adjustment and reinsurance data requirements.

(a) *Enforcement actions.* If an issuer of a risk adjustment covered plan or reinsurance-eligible plan fails to establish a dedicated distributed data environment in a manner and timeframe specified by HHS; fails to provide HHS with access to the required data in such environment in accordance with §153.700(a) or otherwise fails to comply with the requirements of §§153.700 through 153.730; fails to adhere to the reinsurance data submission requirements set forth in §153.420; or fails to adhere to the risk adjustment data submission and data storage requirements set forth in §§153.610 through 153.630, HHS may impose civil money penalties in accordance with the procedures set forth in §156.805 of this subchapter. Civil monetary penalties will not be imposed for non-compliance with these requirements during the 2014 or 2015 calendar years under this paragraph if the issuer has made good faith efforts to comply with these requirements.

(b) *Default risk adjustment charge.* If an issuer of a risk adjustment covered plan fails to establish a dedicated distributed data environment or fails to provide HHS with access to the required data in such environment in accordance with §153.610(a), §153.700, §153.710, or §153.730 such that HHS cannot apply the applicable Federally certified risk adjustment methodology to calculate the risk adjustment payment transfer amount for the risk adjustment covered plan in a timely fashion, HHS will assess a default risk adjustment charge.

(c) *Information sharing.* HHS may consult with and share information about issuers of risk adjustment covered plans and reinsurance-eligible plans with other Federal and State regulatory and enforcement entities to the extent the consultation or information is necessary for purposes of Federal or State oversight and enforcement activities.

[78 FR 65095, Oct. 30, 2013, as amended at 80 FR 10863, Feb. 27, 2015]

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

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Subpart C—Effective Rate Review Programs

154.301 CMS's determinations of Effective Rate Review Programs.

AUTHORITY: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

SOURCE: 76 FR 29985, May 23, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope.* This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid

Services (CMS). This part further establishes the process by which it will be determined whether the rate increases are unreasonable rate increases as defined in this part.

§ 154.102 Definitions.

As used in this part:

CMS means the Centers for Medicare & Medicaid Services.

Effective Rate Review Program means a State program that CMS has determined meets the requirements set forth in §154.301(a) and (b) for the relevant market segment in the State.

Federal medical loss ratio standard means the applicable medical loss ratio standard for the State and market segment involved, determined under subpart B of 45 CFR part 158.

Health insurance coverage has the meaning given the term in section 2791(b)(1) of the PHS Act.

Health insurance issuer has the meaning given the term in section 2791(b)(2) of the PHS Act.

Individual market has the meaning given the term in §144.103 of this subchapter.

Plan has the meaning given the term in §144.103 of this subchapter.

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies offered in a State. The term product includes any product that is discontinued and newly filed within a 12-month period when the changes to the product meet the standards of §147.106(e)(2) or (3) of this subchapter (relating to uniform modification of coverage).

Rate increase means, with respect to rates filed—

(1) For coverage effective prior to January 1, 2017, any increase of the rates for a specific product offered in the individual or small group market.

(2) For coverage effective on or after January 1, 2017, any increase of the rates for a specific product or plan within a product offered in the individual or small group market.

Rate increase subject to review means a rate increase that meets the criteria set forth in §154.200.

Secretary means the Secretary of the Department of Health and Human Services.

Small group market has the meaning given the term in §144.103 of this subchapter.

State means each of the 50 States and the District of Columbia.

Unreasonable rate increase means:

(1) When CMS is conducting the review required by this part, a rate increase that CMS determines under §154.205 is:

(i) An excessive rate increase;

(ii) An unjustified rate increase; or

(iii) An unfairly discriminatory rate increase.

(2) When CMS adopts the determination of a State that has an Effective Rate Review Program, a rate increase that the State determines is excessive, unjustified, unfairly discriminatory, or otherwise unreasonable as provided under applicable State law.

[76 FR 29985, May 23, 2011, as amended at 76 FR 54976, Sept. 6, 2011; 79 FR 30342, May 27, 2014; 80 FR 10863, Feb. 27, 2015; 81 FR 94175, Dec. 22, 2016]

§ 154.103 Applicability.

(a) *In general.* The requirements of this part apply to health insurance issuers offering health insurance coverage in the individual market and small group market.

(b) *Exceptions.* The requirements of this part do not apply to—

(1) Grandfathered health plan coverage as defined in §147.140 of this subchapter;

(2) Excepted benefits as described in section 2791(c) of the PHS Act; and

(3) For coverage effective on or after July 1, 2018, student health insurance coverage as defined in §147.145 of this subchapter.

[76 FR 29985, May 23, 2011, as amended at 83 FR 17060, Apr. 17, 2018]

Subpart B—Disclosure and Review Provisions

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State, or effective in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 15 percent or more applicable to a 12-month period

that begins on January 1, as calculated under paragraph (b) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to a 12-month period that begins on January 1, as calculated under paragraph (b) of this section, determined by the Secretary. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that the data relating to such State-specific factors are available by August 1 of the preceding year. States interested in proposing a State-specific threshold greater than the Federal default stated in paragraph (a)(1) of this section are required to submit a proposal for approval of such threshold to the Secretary by August 1 of the preceding year, in the form and manner specified by the Secretary.

(b) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if the average increase, including premium rating factors described in §147.102 of this subchapter, for all enrollees weighted by premium volume for any plan within the product meets or exceeds the applicable threshold.

(c) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (b) of this section meets or exceeds the threshold when combined with a previous increase or increases during the 12-month period preceding the date on which the rate increase would become effective, then the rate increase must be considered to meet or exceed the threshold and is subject to review under §154.210, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

[83 FR 17060, Apr. 17, 2018]

§154.205 Unreasonable rate increases.

(a) When CMS reviews a rate increase subject to review under §154.210(a), CMS will determine that the rate increase is an unreasonable rate increase if the increase is an excessive rate increase, an unjustified rate increase, or an unfairly discriminatory rate increase.

(b) The rate increase is an excessive rate increase if the increase causes the premium charged for the health insurance coverage to be unreasonably high in relation to the benefits provided under the coverage. In determining whether the rate increase causes the premium charged to be unreasonably high in relationship to the benefits provided, CMS will consider:

(1) Whether the rate increase results in a projected medical loss ratio below the Federal medical loss ratio standard in the applicable market to which the rate increase applies, after accounting for any adjustments allowable under Federal law;

(2) Whether one or more of the assumptions on which the rate increase is based is not supported by substantial evidence; and

(3) Whether the choice of assumptions or combination of assumptions on which the rate increase is based is unreasonable.

(c) The rate increase is an unjustified rate increase if the health insurance issuer provides data or documentation to CMS in connection with the increase that is incomplete, inadequate or otherwise does not provide a basis upon which the reasonableness of an increase may be determined.

(d) The rate increase is an unfairly discriminatory rate increase if the increase results in premium differences between insureds within similar risk categories that:

(1) Are not permissible under applicable State law; or

(2) In the absence of an applicable State law, do not reasonably correspond to differences in expected costs.

§154.210 Review of rate increases subject to review by CMS or by a State.

(a) Except as provided in paragraph (b) of this section, CMS will review a rate increase subject to review to determine whether it is unreasonable, as required by this part.

(b) CMS will adopt a State's determination of whether a rate increase is an unreasonable rate increase, if the State:

(1) Has an Effective Rate Review Program as described in §154.301; and

(2) The State provides to CMS, on a form and in a manner prescribed by the Secretary, its final determination of

whether a rate increase is unreasonable, which must include a brief explanation of how its analysis of the relevant factors set forth in §154.301(a)(3) caused it to arrive at that determination, within five business days following the State's final determination.

(c) CMS will post and maintain on its Web site a list of the States with market segments that meet the requirements of paragraph (b) of this section.

§154.215 Submission of rate filing justification.

(a) A health insurance issuer must submit to CMS and to the applicable State (if the State accepts such submissions) the information specified below on a form and in a manner prescribed by the Secretary.

(1) For all single risk pool products, including new and discontinuing products, the Unified Rate Review Template, as described in paragraph (d) of this section;

(2) For each single risk pool product that includes a plan that is subject to a rate increase, regardless of the size of the increase, the unified rate review template and actuarial memorandum, as described in paragraph (f) of this section;

(3) For each single risk pool product that includes a plan with a rate increase that is subject to review under §154.210, all parts of the Rate Filing Justification, as described in paragraph (b) of this section

(b) A Rate Filing Justification includes one or more of the following:

(1) Unified rate review template (Part I), as described in paragraph (d) of this section.

(2) Written description justifying the rate increase (Part II), as described in paragraph (e) of this section.

(3) Rating filing documentation (Part III), as described in paragraph (f) of this section.

(c) [Reserved]

(d) Content of unified rate review template (Part I): The unified rate review template must include the following as determined appropriate by the Secretary:

(1) Historical and projected claims experience.

(2) Trend projections related to utilization, and service or unit cost.

(3) Any claims assumptions related to benefit changes.

(4) Allocation of the overall rate increase to claims and non-claims costs.

(5) Per enrollee per month allocation of current and projected premium.

(6) Three year history of rate increases for the product associated with the rate increase.

(e) Content of written description justifying the rate increase (Part II): The written description of the rate increase must include a simple and brief narrative describing the data and assumptions that were used to develop the rate increase and including the following:

(1) Explanation of the most significant factors causing the rate increase, including a brief description of the relevant claims and non-claims expense increases reported in the rate increase summary.

(2) Brief description of the overall experience of the policy, including historical and projected expenses, and loss ratios.

(f) Content of rate filing documentation (Part III): The rate filing documentation must include an actuarial memorandum that contains the reasoning and assumptions supporting the data contained in Part I of the Rate Filing Justification. Parts I and III must be sufficient to conduct an examination satisfying the requirements of §154.301(a)(3) and (4) and determine whether the rate increase is an unreasonable increase. Instructions concerning the requirements for the rate filing documentation will be provided in guidance issued by CMS.

(g) If the level of detail provided by the issuer for the information under paragraphs (d) and (f) of this section does not provide sufficient basis for CMS to determine whether the rate increase is an unreasonable rate increase when CMS reviews a rate increase subject to review under §154.210(a), CMS will request the additional information necessary to make its determination. The health insurance issuer must provide the requested information to CMS within 10 business days following its receipt of the request.

(h) Posting of the disclosure on the CMS Web site:

(1) CMS promptly will make available to the public on its Web site the information contained in Part II of each Rate Filing Justification.

(2) CMS will make available to the public on its website the information contained in Parts I and III of each Rate Filing Justification that is not a trade secret or confidential commercial or financial information as defined in HHS's Freedom of Information Act regulations, 45 CFR 5.31(d).

(3) CMS will include a disclaimer on its Web site with the information made available to the public that explains the purpose and role of the Rate Filing Justification.

(4) CMS will include information on its Web site concerning how the public can submit comments on the proposed rate increases that CMS reviews.

[78 FR 13440, Feb. 27, 2013, as amended at 80 FR 10864, Feb. 27, 2015; 81 FR 12335, Mar. 8, 2016; 83 FR 17060, Apr. 17, 2018]

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit applicable sections of the Rate Filing Justification for all single risk pool coverage in the individual or small group market, as follows:

(a) For rate increases for coverage effective prior to January 1, 2016:

(1) If a State requires that a proposed rate increase be filed with the State prior to the implementation of the rate, the health insurance issuer must submit to CMS and the applicable State the Rate Filing Justification on the date on which the health insurance issuer submits the proposed rate increase to the State.

(2) For all other States, the health insurance issuer must submit to CMS and the State the Rate Filing Justification prior to the implementation of the rate increase.

(b) For coverage effective on or after January 1, 2017, by the earlier of the following:

(1) The date by which the State requires submission of a rate filing; or

(2) The date specified in guidance by the Secretary.

[80 FR 10864, Feb. 27, 2015, as amended at 81 FR 12336, Mar. 8, 2016]

§ 154.225 Determination by CMS or a State of an unreasonable rate increase.

(a) When CMS receives a Rate Filing Justification for a rate increase subject to review and CMS reviews the rate increase under §154.210(a), CMS will make a timely determination whether the rate increase is an unreasonable rate increase.

(1) CMS will post on its Web site its final determination and a brief explanation of its analysis, consistent with the form and manner prescribed by the Secretary under §154.210(b)(2), within five business days following its final determination.

(2) If CMS determines that the rate increase is an unreasonable rate increase, CMS will also provide its final determination and brief explanation to the health insurance issuer within five business days following its final determination.

(b) If a State conducts a review under §154.210(b), CMS will adopt the State's determination of whether a rate increase is unreasonable and post on the CMS Web site the State's final determination described in §154.210(b)(2).

(c) If a State determines that the rate increase is an unreasonable rate increase and the health insurance issuer is legally permitted to implement the unreasonable rate increase under applicable State law, CMS will provide the State's final determination and brief explanation to the health insurance issuer within five business days following CMS's receipt thereof.

[76 FR 29985, May 23, 2011, as amended at 78 FR 13441, Feb. 27, 2013]

§ 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

(a) If a health insurance issuer receives from CMS a final determination by CMS or a State that a rate increase is an unreasonable rate increase, and the health insurance issuer declines to implement the rate increase or chooses to implement a lower increase, the health insurance issuer must submit to CMS timely notice that it will not implement the rate increase or that it will implement a lower increase on a form and in the manner prescribed by the Secretary.

(b) If a health insurance issuer implements a lower increase as described in paragraph (a) of this section and the lower increase does not meet or exceed the applicable threshold under §154.200, such lower increase is not subject to this part. If the lower increase meets or exceeds the applicable threshold, the health insurance issuer must submit a new Rate Filing Justification under this part.

(c) If a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, within the later of 10 business days after the implementation of such increase or the health insurance issuer's receipt of CMS's final determination that a rate increase is an unreasonable rate increase, the health insurance issuer must:

(1) Submit to CMS a Final Justification in response to CMS's or the State's final determination, as applicable. The information in the Final Justification must be consistent with the information submitted in the Rate Filing Justification supporting the rate increase; and

(2) Prominently post on its Web site the following information on a form and in the manner prescribed by the Secretary:

(i) The information made available to the public by CMS and described in §154.215(h).

(ii) CMS's or the State's final determination and brief explanation described in §§154.225(a) and 154.210(b)(2), as applicable; and

(iii) The health insurance issuer's Final Justification for implementing an increase that has been determined to be unreasonable by CMS or the State, as applicable.

(3) The health insurance issuer must continue to make this information available to the public on its Web site for at least three years.

(d) CMS will post all Final Justifications on the CMS Web site. This information will remain available to the public on the CMS Web site for three years.

[76 FR 29985, May 23, 2011, as amended at 78 FR 13441, Feb. 27, 2013; 81 FR 12336, Mar. 8, 2016]

Subpart C—Effective Rate Review Programs

§154.301 CMS's determinations of Effective Rate Review Programs.

(a) *Effective Rate Review Program.* In evaluating whether a State has an Effective Rate Review Program, CMS will apply the following criteria for the review of rates for the small group market and the individual market, and also, as applicable depending on State law, the review of rates for different types of products within those markets:

(1) The State receives from issuers data and documentation in connection with rate increases that are sufficient to conduct the examination described in paragraph (a)(3) of this section.

(2) The State conducts an effective and timely review of the data and documentation submitted by a health insurance issuer in support of a proposed rate increase.

(3) The State's rate review process includes an examination of:

(i) The reasonableness of the assumptions used by the health insurance issuer to develop the proposed rate increase and the validity of the historical data underlying the assumptions.

(ii) The health insurance issuer's data related to past projections and actual experience.

(iii) The reasonableness of assumptions used by the health insurance issuer to estimate the rate impact of the reinsurance and risk adjustment programs under sections 1341 and 1343 of the Affordable Care Act.

(iv) The health insurance issuer's data related to implementation and ongoing utilization of a market-wide single risk pool, essential health benefits, actuarial values and other market reform rules as required by the Affordable Care Act.

(4) The examination must take into consideration the following factors to the extent applicable to the filing under review:

(i) The impact of medical trend changes by major service categories.

(ii) The impact of utilization changes by major service categories.

(iii) The impact of cost-sharing changes by major service categories, including actuarial values.

(iv) The impact of benefit changes, including essential health benefits and non-essential health benefits.

(v) The impact of changes in enrollee risk profile and pricing, including rating limitations for age and tobacco use under section 2701 of the Public Health Service Act.

(vi) The impact of any overestimate or underestimate of medical trend for prior year periods related to the rate increase.

(vii) The impact of changes in reserve needs;

(viii) The impact of changes in administrative costs related to programs that improve health care quality;

(ix) The impact of changes in other administrative costs;

(x) The impact of changes in applicable taxes, licensing or regulatory fees.

(xi) Medical loss ratio.

(xii) The health insurance issuer's capital and surplus.

(xiii) The impacts of geographic factors and variations.

(xiv) The impact of changes within a single risk pool to all products or plans within the risk pool.

(xv) The impact of reinsurance and risk adjustment payments and charges under sections 1341 and 1343 of the Affordable Care Act.

(5) The State's determination of whether a rate increase is unreasonable is made under a standard that is set forth in State statute or regulation.

(b) *Public disclosure and input.* (1) In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide:

(i) For proposed rate increases subject to review, access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification that CMS makes available on its Web site (or provide CMS's Web address for such information), and have a mechanism for receiving public comments on those proposed rate increases, no later than the date specified in guidance by the Secretary.

(ii) Beginning with rates filed for coverage effective on or after January 1, 2016, for all final rate increases (including those not subject to review), access from its Web site to at least the information contained in Parts I, II, and III of the Rate Filing Justification (as applicable) that CMS makes available on its Web site (or provide CMS's Web address for such information), no later than the first day of the annual open enrollment period in the individual market for the applicable calendar year.

(2) If a State intends to make the information in paragraph (b)(1)(i) of this section available to the public prior to the date specified by the Secretary, or if it intends to make the information in paragraph (b)(1)(ii) of this section available to the public prior to the first day of the annual open enrollment period in the individual market for the applicable calendar year, the State must notify CMS in writing, no later than five (5) business days prior to the date it intends to make the information public, of its intent to do so and the date it intends to make the information public.

(3) A State with an Effective Rate Review Program must ensure the information in paragraphs (b)(1)(i) and (ii) of this section is made available to the public at a uniform time for all proposed and final rate increases, as applicable, in the relevant market segment and without regard to whether coverage is offered through or outside an Exchange.

(c) CMS will determine whether a State has an Effective Rate Review Program for each market based on information available to CMS that a rate review program meets the criteria described in paragraphs (a) and (b) of this section.

(d) CMS reserves the right to evaluate from time to time whether, and to what extent, a State's circumstances have changed such that it has begun to or has ceased to satisfy the criteria set forth in paragraphs (a) and (b) of this section.

[76 FR 29985, May 23, 2011, as amended at 78 FR 13441, Feb. 27, 2013; 80 FR 10864, Feb. 27, 2015; 83 FR 17060, Apr. 17, 2018]

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

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AUTHORITY: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

SOURCE: 77 FR 11718, Feb. 27, 2012, unless otherwise noted.

Subpart A—General Provisions.

SOURCE: 77 FR 18444, Mar. 27, 2012, unless otherwise noted.

§ 155.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care Act:

(1) 1301. Qualified health plan defined

(2) 1302. Essential health benefits requirements

(3) 1303. Special rules

(4) 1304. Related definitions

(5) 1311. Affordable choices of health benefit plans.

(6) 1312. Consumer choice

(7) 1313. Financial integrity.

(8) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(9) 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

(10) 1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.

(11) 1334. Multi-State plans.

(12) 1402. Reduced cost-sharing for individuals enrolling in QHPs.

(13) 1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.

(14) 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

(15) 1413. Streamlining of procedures for enrollment through an exchange and State Medicaid, CHIP, and health subsidy programs.

(b) *Scope.* This part establishes minimum standards for the establishment of an Exchange, minimum Exchange functions, eligibility determinations, enrollment periods, minimum SHOP functions, certification of QHPs, and health plan quality improvement.

§ 155.20 Definitions.

The following definitions apply to this part:

Advance payments of the premium tax credit means payment of the tax credit authorized by 26 U.S.C. 36B and its implementing regulations, which are provided on an advance basis to an eligible individual enrolled in a QHP through an Exchange in accordance with section 1412 of the Affordable Care Act.

Affordable Care Act means the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152).

Agent or broker means a person or entity licensed by the State as an agent, broker or insurance producer.

Agent or broker direct enrollment technology provider means a type of web-broker business entity that is not a licensed agent or broker under State law and has been engaged or created by, or is owned by an agent or broker, to provide technology services to facilitate participation in direct enrollment under §§ 155.220(c)(3) and 155.221.

Annual open enrollment period means the period each year during which a qualified individual may enroll or change coverage in a QHP through the Exchange.

Applicant means:

(1) An individual who is seeking eligibility for him or herself through an application submitted to the Exchange, excluding those individuals seeking eligibility for an exemption from the individual shared responsibility payment pursuant to subpart G of this part, or transmitted to the Exchange by an agency administering an insurance affordability program for at least one of the following:

(i) Enrollment in a QHP through the Exchange; or

(ii) Medicaid, CHIP, and the BHP, if applicable.

(2) For SHOP:

(i) An employer seeking eligibility to purchase coverage through the SHOP; or

(ii) An employer, employee, or a former employee seeking eligibility for enrollment in a QHP through the

SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, seeking eligibility to enroll his or her dependents in a QHP through the SHOP.

Application filer means an applicant, an adult who is in the applicant's household, as defined in 42 CFR 435.603(f), or family, as defined in 26 CFR 1.36B–1(d), an authorized representative of an applicant, or if the applicant is a minor or incapacitated, someone acting responsibly for an applicant, excluding those individuals seeking eligibility for an exemption from the individual shared responsibility payment pursuant to subpart G of this part.

Benefit year means a calendar year for which a health plan provides coverage for health benefits.

Catastrophic plan means a health plan described in section 1302(e) of the Affordable Care Act.

Code means the Internal Revenue Code of 1986.

Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

Cost-sharing reductions means reductions in cost sharing for an eligible individual enrolled in a silver level plan in the Exchange or for an individual who is an Indian enrolled in a QHP in the Exchange.

Direct enrollment entity means an entity that an Exchange permits to assist consumers with direct enrollment in qualified health plans offered through the Exchange in a manner considered to be through the Exchange as authorized by §155.220(c)(3), §155.221, or §156.1230 of this subchapter.

Direct enrollment entity application assister means an employee, contractor, or agent of a direct enrollment entity who is not licensed as an agent, broker, or producer under State law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs.

Educated health care consumer has the meaning given the term in section 1304(e) of the Affordable Care Act.

Eligible employer-sponsored plan has the meaning given the term in section 5000A(f)(2) of the Code.

Employee has the meaning given to the term in section 2791 of the PHS Act.

Employer has the meaning given to the term in section 2791 of the PHS Act, except that such term includes employers with one or more employees. All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Code are treated as one employer.

Employer contributions means any financial contributions towards an employer sponsored health plan, or other eligible employer-sponsored benefit made by the employer including those made by salary reduction agreement that is excluded from gross income.

Enrollee means a qualified individual or qualified employee enrolled in a QHP. Enrollee also means the dependent of a qualified employee enrolled in a QHP through the SHOP, and any other person who is enrolled in a QHP through the SHOP, consistent with applicable law and the terms of the group health plan. Provided that at least one employee enrolls in a QHP through the SHOP, enrollee also means a business owner enrolled in a QHP through the SHOP, or the dependent of a business owner enrolled in a QHP through the SHOP.

Exchange means a governmental agency or non-profit entity that meets the applicable standards of this part and makes QHPs available to qualified individuals and/or qualified employers. Unless otherwise identified, this term includes an Exchange serving the individual market for qualified individuals and a SHOP serving the small group market for qualified employers, regardless of whether the Exchange is established and operated by a State (including a regional Exchange or subsidiary Exchange) or by HHS.

Exchange Blueprint means information submitted by a State, an Exchange, or a regional Exchange that sets forth how an Exchange established by a State or a regional Exchange meets the Exchange approval standards

established in §155.105(b) and demonstrates operational readiness of an Exchange as described in §155.105(c)(2).

Exchange service area means the area in which the Exchange is certified to operate, in accordance with the standards specified in subpart B of this part.

Federal platform agreement means an agreement between a State Exchange and HHS under which a State Exchange agrees to rely on the Federal platform to carry out select Exchange functions.

Federally-facilitated Exchange means an Exchange established and operated within a State by the Secretary under section 1321(c)(1) of the Affordable Care Act.

Federally-facilitated SHOP means a Small Business Health Options Program established and operated within a State by the Secretary under section 1321(c)(1) of the Affordable Care Act.

Full-time employee has the meaning given in section 4980H (c)(4) of the Code effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which it is effective for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013.

Grandfathered health plan has the meaning given the term in §147.140.

Group health plan has the meaning given to the term in §144.103.

Health insurance issuer or *issuer* has the meaning given to the term in §144.103.

Health insurance coverage has the meaning given to the term in §144.103.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given the term in section 1304(a)(2) of the Affordable Care Act.

Initial open enrollment period means the period during which a qualified individual may enroll in coverage through the Exchange for coverage during the 2014 benefit year.

Issuer application assister means an employee, contractor, or agent of a QHP issuer who is not licensed as an agent, broker, or producer under State law and who assists individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange or for insurance affordability programs.

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a large employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define large employer by substituting ''101 employees'' for ''51 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

Lawfully present has the meaning given the term in §152.2.

Minimum essential coverage has the meaning given in section 5000A(f) of the Code.

Navigator means a private or public entity or individual that is qualified, and licensed, if appropriate, to engage in the activities and meet the standards described in §155.210.

Plan year means a consecutive 12 month period during which a health plan provides coverage for health benefits. A plan year may be a calendar year or otherwise.

Plain language has the meaning given to the term in section 1311(e)(3)(B) of the Affordable Care Act.

Qualified employee means any employee or former employee of a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP for himself or herself and, if the qualified employer offers dependent coverage through the SHOP, for his or her dependents.

Qualified employer means a small employer that elects to make, at a minimum, all full-time employees of such employer eligible for one or more QHPs in the small group market offered through a SHOP. Beginning in 2017, if a

State allows large employers to purchase coverage through the SHOP, the term ''qualified employer'' shall include a large employer that elects to make all full-time employees of such employer eligible for one or more QHPs in the large group market offered through the SHOP.

Qualified health plan or *QHP* means a health plan that has in effect a certification that it meets the standards described in subpart C of part 156 issued or recognized by each Exchange through which such plan is offered in accordance with the process described in subpart K of part 155.

Qualified health plan issuer or *QHP issuer* means a health insurance issuer that offers a QHP in accordance with a certification from an Exchange.

Qualified health plan issuer direct enrollment technology provider means a business entity that provides technology services or provides access to an information technology platform to QHP issuers to facilitate participation in direct enrollment under §155.221 or §156.1230, including a web-broker that provides services as a direct enrollment technology provider to QHP issuers. A QHP issuer direct enrollment technology provider that provides technology services or provides access to an information technology platform to a QHP issuer will be a downstream or delegated entity of the QHP issuer that participates or applies to participate as a direct enrollment entity.

Qualified individual means, with respect to an Exchange, an individual who has been determined eligible to enroll through the Exchange in a QHP in the individual market.

SHOP means a Small Business Health Options Program operated by an Exchange through which a qualified employer can provide its employees and their dependents with access to one or more QHPs.

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least one but not more than 50 employees on business days during the preceding calendar year and who employs at least one employee on the first day of the plan year. In the case of an employer that was not in existence throughout the preceding calendar year, the determination of whether the employer is a small employer is based on the average number of employees that it is reasonably expected the employer will employ on business days in the current calendar year. A State may elect to define small employer by substituting ''100 employees'' for ''50 employees.'' The number of employees must be determined using the method set forth in section 4980H(c)(2) of the Code.

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

Special enrollment period means a period during which a qualified individual or enrollee who experiences certain qualifying events may enroll in, or change enrollment in, a QHP through the Exchange outside of the initial and annual open enrollment periods.

Standardized option means a QHP offered for sale through an individual market Exchange that either—

(1) Has a standardized cost-sharing structure specified by HHS in rulemaking; or

(2) Has a standardized cost-sharing structure specified by HHS in rulemaking that is modified only to the extent necessary to align with high deductible health plan requirements under section 223 of the Internal Revenue Code of 1986, as amended, or the applicable annual limitation on cost sharing and HHS actuarial value requirements.

State means each of the 50 States and the District of Columbia.

Web-broker means an individual agent or broker, group of agents or brokers, or business entity registered with an Exchange under §155.220(d)(1) that develops and hosts a non-Exchange website that interfaces with an Exchange to assist consumers with direct enrollment in QHPs offered through the Exchange as described in §155.220(c)(3) or §155.221. The term also

includes an agent or broker direct enrollment technology provider.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 15532, Mar. 11, 2013; 78 FR 39523, July 1, 2013; 78 FR 42313, July 15, 2013; 78 FR 54134, Aug. 30, 2013; 80 FR 10864, Feb. 27, 2015; 81 FR 12336, Mar. 8, 2016; 81 FR 94175, Dec. 22, 2016; 84 FR 17562, Apr. 25, 2019; 86 FR 24288, May 5, 2021]

EFFECTIVE DATE NOTE: At 89 FR 39436, May 8, 2024, §155.20 was amended by revising the definition of ''Lawfully present'', effective Nov. 1, 2024. For the convenience of the user, the revised text is set forth as follows:

§155.20 Definitions.

* * * * *

Lawfully present means a noncitizen who—

(1) Is a qualified noncitizen as defined at 42 CFR 435.4;

(2) Is in a valid nonimmigrant status, as defined in 8 U.S.C. 1101(a)(15) or otherwise under the immigration laws (as defined in 8 U.S.C. 1101(a)(17));

(3) Is paroled into the United States in accordance with 8 U.S.C. 1182(d)(5) for less than 1 year, except for a noncitizen paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) Is granted temporary resident status in accordance with 8 U.S.C. 1160 or 1255a;

(5) Is granted Temporary Protected Status (TPS) in accordance with 8 U.S.C. 1254a;

(6) Is granted employment authorization under 8 CFR 274a.12(c);

(7) Is a Family Unity beneficiary in accordance with section 301 of Pub. L. 101–649 as amended; or section 1504 of the LIFE Act Amendments of 2000, title XV of H.R. 5666, enacted by reference in Pub. L. 106–554 (see section 1504 of App. D to Pub. L. 106–554);

(8) Is covered by Deferred Enforced Departure (DED) in accordance with a decision made by the President;

(9) Is granted deferred action, including but not limited to individuals granted deferred action under 8 CFR 236.22;

(10) Has a pending application for adjustment of status;

(11)(i) Has a pending application for asylum under 8 U.S.C. 1158, for withholding of removal under 8 U.S.C. 1231(b)(3)(A), or for protection under the regulations implementing the Convention Against Torture; and

(ii) Is under the age of 14;

(12) Has been granted withholding of removal under the regulations implementing the Convention Against Torture; or

(13) Has a pending or approved petition for Special Immigrant Juvenile classification as described in 8 U.S.C. 1101(a)(27)(J).

* * * * *

§155.30 Severability.

(a) Any part of the definition of ''lawfully present'' in §155.20 held to be invalid or unenforceable, including as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision as permitted by law, along with other provisions not found invalid or unenforceable, including as applied to persons not similarly situated or to dissimilar circumstances, unless such holding is that the provision of this subpart is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this subpart and shall not affect the remainder thereof.

(b) The provisions in §155.20 with respect to the definition of ''lawfully present'' are intended to be severable from one another.

[89 FR 39436, May 8, 2024]

EFFECTIVE DATE NOTE: At 89 FR 39436, May 8, 2024, §155.30 was added, effective Nov. 1, 2024.

Subpart B—General Standards Related to the Establishment of an Exchange

§155.100 Establishment of a State Exchange.

(a) *General requirements.* Each State may elect to establish:

(1) An Exchange that facilitates the purchase of health insurance coverage in QHPs in the individual market and that provides for the establishment of a SHOP; or

(2) An Exchange that provides only for the establishment of a SHOP.

(b) *Timing.* For plan years beginning before January 1, 2015, only States that provide reasonable assurances to CMS that they will be in a position to establish and operate only a SHOP for 2014 may elect to establish an Exchange

that provides only for the establishment of a SHOP, pursuant to the process in §155.105(c), (d), and/or (e), whichever is applicable. For plan years beginning on or after January 1, 2015, any State may elect to establish an Exchange that provides only for the establishment of a SHOP, pursuant to the process in §155.106(a).

(c) *Eligible Exchange entities.* The Exchange must be a governmental agency or non-profit entity established by a State, consistent with §155.110.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 54134, Aug. 30, 2013]

§155.105 Approval of a State Exchange.

(a) *State Exchange approval requirement.* Each State Exchange must be approved by HHS by no later than January 1, 2013 to offer QHPs on January 1, 2014, and thereafter required in accordance with §155.106. HHS may consult with other Federal Government agencies in determining whether to approve an Exchange.

(b) *State Exchange approval standards.* HHS will approve the operation of an Exchange established by a State provided that it meets the following standards:

(1) The Exchange is able to carry out the required functions of an Exchange consistent with subparts C, D, E, F, G, H, and K of this part unless the State is approved to operate only a SHOP by HHS pursuant to §155.100(a)(2), in which case the Exchange must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein;

(2) The Exchange is capable of carrying out the information reporting requirements in accordance with section 36B of the Code, unless the State is approved to operate only a SHOP by HHS pursuant to §155.100(a)(2);

(3) The entire geographic area of the State is in the service area of an Exchange, or multiple Exchanges consistent with §155.140(b); and

(4) The Exchange first operates a State Exchange on the Federal platform under §155.106(c), meeting all requirements established under §155.200(f), for at least one plan year, including its first open enrollment period.

(c) *State Exchange approval process.* In order to have its Exchange approved, a State must:

(1) Elect to establish an Exchange by submitting, in a form and manner specified by HHS, an Exchange Blueprint that sets forth how the Exchange meets the standards outlined in paragraph (b) of this section; and

(2) Demonstrate operational readiness to execute its Exchange Blueprint through a readiness assessment conducted by HHS.

(d) *State Exchange approval.* Each Exchange must receive written approval or conditional approval of its Exchange Blueprint and its performance under the operational readiness assessment consistent with paragraph (c) of this section in order to be considered an approved Exchange.

(e) *Significant changes to Exchange Blueprint.* The State must notify HHS in writing before making a significant change to its Exchange Blueprint; no significant change to an Exchange Blueprint may be effective until it is approved by HHS in writing or 60 days after HHS receipt of a completed request. For good cause, HHS may extend the review period by an additional 30 days to a total of 90 days. HHS may deny a request for a significant change to an Exchange Blueprint within the review period.

(f) *HHS operation of an Exchange.* (1) If a State does not elect to operate an Exchange under §155.100(a)(1) or an electing State does not have an approved or conditionally approved Exchange pursuant to §155.100(a)(1) by January 1, 2013, HHS must (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State. In this case, the requirements in §§155.120(c), 155.130 and subparts C, D, E, F, G, H, and K of this part will apply.

(2) If an electing State has an approved or conditionally approved Exchange pursuant to §155.100(a)(2) by January 1, 2013, HHS must (directly or through agreement with a not-for-profit entity) establish and operate an Exchange that facilitates the purchase of health insurance coverage in QHPs in the individual market and operate such Exchange within the State. In this case, the requirements in §§155.120(c),

155.130 and subparts C, D, E, F, G, and K of this part will apply to the Exchange operated by HHS.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42313, July 15, 2013; 78 FR 54134, Aug. 30, 2013; 89 FR 26419, Apr. 15, 2024]

§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange.* Except as provided in paragraph (c) of this section, a State electing to seek approval of its Exchange must:

(1) Comply with the State Exchange approval requirements and process set forth in § 155.105;

(2) Submit an Exchange Blueprint application for HHS approval at least 15 months prior to the date on which the Exchange proposes to begin open enrollment as a State Exchange. HHS requires that a State submitting a Blueprint Application to operate a State Exchange provide, upon request, supplemental information to HHS detailing the State's implementation of its State Exchange functionality, including information on the ability to implement and comply with Federal requirements for operating an Exchange.

(i) *Public notice.* Upon submission of an Exchange Blueprint application to operate a State Exchange, the State shall issue a public notice of its Exchange Blueprint application submission through its website and include a copy of the Exchange Blueprint application, a description of the Plan Year for which the State seeks to transition to a State Exchange, language indicating that the State is seeking approval from HHS to transition to a State Exchange, and information about when and where the State will conduct public engagements regarding the State's Exchange Blueprint application, as described in paragraph (a)(2)(ii) of this section.

(ii) *Public engagements.* After a State issues its public notice as described in paragraph (a)(2)(i) of this section and until HHS approves, or conditionally approves, the State's Exchange Blueprint application, a State must conduct at least one public engagement (such as a townhall meeting or public hearing) either in-person or virtually, regarding the State's Exchange Blueprint application progress, in a timeline and manner considered effective by the State and with HHS' concurrence. A State shall provide public notice of the public engagement. Such public engagement shall also provide interested parties the opportunity to learn about the State's progress in transitioning to a State Exchange and offer input on that transition. Following the initial public engagement described in this paragraph and until HHS approves or conditionally approves the State Exchange Blueprint application, a State shall conduct periodic public engagements, either in-person or virtually, in a timeframe and manner considered effective by the State.

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment prior to the date on which the Exchange would begin open enrollment as a State Exchange;

(4) Develop a plan jointly with HHS to facilitate the transition to a State Exchange; and

(5) If the open enrollment period for the year the State intends to begin operating an SBE has not been established, this deadline must be calculated based on the date open enrollment began or will begin in the year in which the State is submitting the Blueprint application.

(b) *Transition process for State Exchanges that cease operations.* If a State intends to cease operation of its Exchange, HHS will operate the Exchange on behalf of the State. Therefore, a State that intends to cease operations of its Exchange must:

(1) Notify HHS that it will no longer operate an Exchange at least 12 months prior to ceasing operations; and

(2) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

(c) *Process for State Exchanges that seek to utilize the Federal platform for select functions.* States may seek approval to operate a State Exchange utilizing the Federal platform for only the individual market. A State seeking approval to operate a State Exchange utilizing the Federal platform for the individual market to support select functions through a Federal platform agreement under § 155.200(f) must:

(1) If the State Exchange does not have a conditionally approved Exchange Blueprint application, submit one for HHS approval at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(2) If the State Exchange has a conditionally approved Exchange Blueprint application, submit any significant changes to that application for HHS approval, in accordance with §155.105(e), at least 3 months prior to the date on which the Exchange proposes to begin open enrollment as an SBE–FP;

(3) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment prior to the date on which the Exchange proposes to begin open enrollment as a State-based Exchanges on the Federal platform (SBE–FP), in accordance with HHS rules in this chapter, as a State Exchange utilizing the Federal platform;

(4) Prior to approval, or conditional approval, of the Exchange Blueprint, execute a Federal platform agreement for utilizing the Federal platform for select functions; and

(5) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

[77 FR 18444, Mar. 27, 2012, as amended at 79 FR 13837, Mar. 11, 2014; 81 FR 12336, Mar. 8, 2016; 83 FR 17060, Apr. 17, 2018; 88 FR 25917, Apr. 27, 2023; 89 FR 26419, Apr. 15, 2024]

§155.110 Entities eligible to carry out Exchange functions.

(a) *Eligible contracting entities.* The State may elect to authorize an Exchange established by the State to enter into an agreement with an eligible entity to carry out one or more responsibilities of the Exchange. Eligible entities are:

(1) An entity:

(i) Incorporated under, and subject to the laws of, one or more States;

(ii) That has demonstrated experience on a State or regional basis in the individual and small group health insurance markets and in benefits coverage; and

(iii) Is not a health insurance issuer or treated as a health insurance issuer under subsection (a) or (b) of section 52 of the Code of 1986 as a member of the same controlled group of corporations (or under common control with) as a health insurance issuer; or

(2) The State Medicaid agency, or any other State agency that meets the qualifications of paragraph (a)(1) of this section.

(b) *Responsibility.* To the extent that an Exchange establishes such agreements, the Exchange remains responsible for ensuring that all Federal requirements related to contracted functions are met.

(c) *Governing board structure.* If the Exchange is an independent State agency or a non-profit entity established by the State, the State must ensure that the Exchange has in place a clearly-defined governing board that:

(1) Is administered under a formal, publicly-adopted operating charter or by-laws;

(2) Holds regular public governing board meetings that are announced in advance;

(3) Represents consumer interests by ensuring that overall governing board membership:

(i) Includes at least one voting member who is a consumer representative;

(ii) Is not made up of a majority of voting representatives with a conflict of interest, including representatives of health insurance issuers or agents or brokers, or any other individual licensed to sell health insurance; and

(4) Ensures that a majority of the voting members on its governing board have relevant experience in health benefits administration, health care finance, health plan purchasing, health care delivery system administration, public health, or health policy issues related to the small group and individual markets and the uninsured.

(d) *Governance principles.* (1) The Exchange must have in place and make publicly available a set of guiding governance principles that include ethics, conflict of interest standards, accountability and transparency standards, and disclosure of financial interest.

(2) The Exchange must implement procedures for disclosure of financial interests by members of the Exchange board or governance structure.

(e) *SHOP independent governance.* (1) A State may elect to create an independent governance and administrative structure for the SHOP, consistent with this section, if the State ensures that the SHOP coordinates and shares relevant information with the Exchange operating in the same service area.

(2) If a State chooses to operate its Exchange and SHOP under a single governance or administrative structure, it must ensure that the Exchange has adequate resources to assist individuals and small employers in the Exchange.

(f) *HHS review.* HHS may periodically review the accountability structure and governance principles of a State Exchange.

§ 155.120 Non-interference with Federal law and non-discrimination standards.

(a) *Non-interference with Federal law.* An Exchange must not establish rules that conflict with or prevent the application of regulations promulgated by HHS under subtitle D of title I of the Affordable Care Act.

(b) *Non-interference with State law.* Nothing in parts 155, 156, or 157 of this subchapter shall be construed to preempt any State law that does not prevent the application of the provisions of title I of the Affordable Care Act.

(c) *Non-discrimination.* (1) In carrying out the requirements of this part, the State and the Exchange must:

(i) Comply with applicable non-discrimination statutes; and

(ii) Not discriminate based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

(2) Notwithstanding the provisions of paragraph (c)(1)(ii) of this section, an organization that receives Federal funds to provide services to a defined population under the terms of Federal legal authorities that participates in the certified application counselor program under §155.225 may limit its provision of certified application counselor services to the same defined population, but must comply with paragraph (c)(1)(ii) of this section with respect to the provision of certified application counselor services to that defined population. If the organization limits its provision of certified application counselor services pursuant to this exception, but is approached for certified application counselor services by an individual who is not included in the defined population that the organization serves, the organization must refer the individual to other Exchange-approved resources that can provide assistance. If the organization does not limit its provision of certified application counselor services pursuant to this exception, the organization must comply with paragraph (c)(1)(ii) of this section.

[77 FR 18444, Mar. 27, 2012, as amended at 79 FR 30342, May 27, 2014; 85 FR 37247, June 19, 2020; 89 FR 37703, May 6, 2024]

§ 155.130 Stakeholder consultation.

The Exchange must regularly consult on an ongoing basis with the following stakeholders:

(a) Educated health care consumers who are enrollees in QHPs;

(b) Individuals and entities with experience in facilitating enrollment in health coverage;

(c) Advocates for enrolling hard to reach populations, which include individuals with mental health or substance abuse disorders;

(d) Small businesses and self-employed individuals;

(e) State Medicaid and CHIP agencies;

(f) Federally-recognized Tribes, as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a, that are located within such Exchange's geographic area;

(g) Public health experts;

(h) Health care providers;

(i) Large employers;

(j) Health insurance issuers; and

(k) Agents and brokers.

§ 155.140 Establishment of a regional Exchange or subsidiary Exchange.

(a) *Regional Exchange.* A State may participate in a regional Exchange if:

(1) The Exchange spans two or more States, regardless of whether the States are contiguous; and

(2) The regional Exchange submits a single Exchange Blueprint and is approved to operate consistent with § 155.105(c).

(b) *Subsidiary Exchange.* A State may establish one or more subsidiary Exchanges within the State if:

(1) Each such Exchange serves a geographically distinct area; and

(2) The area served by each subsidiary Exchange is at least as large as a rating area described in section 2701(a) of the PHS Act.

(c) *Exchange standards.* Each regional or subsidiary Exchange must:

(1) Otherwise meet the requirements of an Exchange consistent with this part; and

(2) Meet the following standards for SHOP:

(i) Perform the functions of a SHOP for its service area in accordance with subpart H of this part; and

(ii) Encompass the same geographic area for its regional or subsidiary SHOP and its regional or subsidiary Exchange except:

(A) In the case of a regional Exchange established pursuant to § 155.100(a)(2), the regional SHOP must encompass a geographic area that matches the combined geographic areas of the individual market Exchanges established to serve the same set of States establishing the regional SHOP; and

(B) In the case of a subsidiary Exchange established pursuant to § 155.100(a)(2), the combined geographic area of all subsidiary SHOPs established in the State must encompass the geographic area of the individual market Exchange established to serve the State.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 54134, Aug. 30, 2013]

§ 155.150 Transition process for existing State health insurance exchanges.

(a) *Presumption.* Unless an exchange is determined to be non-compliant through the process in paragraph (b) of this section, HHS will otherwise presume that an existing State exchange meets the standards under this part if:

(1) The exchange was in operation prior to January 1, 2010; and

(2) The State has insured a percentage of its population not less than the percentage of the population projected to be covered nationally after the implementation of the Affordable Care Act, according to the Congressional Budget Office estimates for projected coverage in 2016 that were published on March 30, 2011.

(b) *Process for determining non-compliance.* Any State described in paragraph (a) of this section must work with HHS to identify areas of non-compliance with the standards under this part.

§ 155.160 Financial support for continued operations.

(a) *Definition.* For purposes of this section, participating issuers has the meaning provided in § 156.50.

(b) *Funding for ongoing operations.* A State must ensure that its Exchange has sufficient funding in order to support its ongoing operations beginning January 1, 2015, as follows:

(1) States may generate funding, such as through user fees on participating issuers, for Exchange operations; and

(2) No Federal grants under section 1311 of the Affordable Care Act will be awarded for State Exchange establishment after January 1, 2015.

§ 155.170 Additional required benefits.

(a) *Additional required benefits.* (1) A State may require a QHP to offer benefits in addition to the essential health benefits.

(2) A benefit required by State action taking place on or before December 31, 2011, a benefit required by State action for purposes of compliance with Federal requirements, or a benefit covered in the State's EHB-benchmark plan is considered an EHB. A benefit required by State action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, that is not a benefit covered in the State's EHB-benchmark plan is considered in addition to the essential health benefits.

(3) The State will identify which State-required benefits are in addition to the EHB.

(b) *Payments.* The State must make payments to defray the cost of additional required benefits specified in

paragraph (a) of this section to one of the following:

(1) To an enrollee, as defined in §155.20 of this subchapter; or

(2) Directly to the QHP issuer on behalf of the individual described in paragraph (b)(1) of this section.

(c) *Cost of additional required benefits.* (1) Each QHP issuer in the State shall quantify cost attributable to each additional required benefit specified in paragraph (a) of this section.

(2) A QHP issuer's calculation shall be:

(i) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(ii) Conducted by a member of the American Academy of Actuaries; and

(iii) Reported to the State.

[78 FR 12865, Feb. 25, 2013, as amended at 81 FR 12337, Mar. 8, 2016; 89 FR 26419, Apr. 15, 2024]

Subpart C—General Functions of an Exchange

§155.200 Functions of an Exchange.

(a) *General requirements.* An Exchange must perform the functions described in this subpart and in subparts D, E, F, G, H, K, M, and O of this part unless the State is approved to operate only a SHOP by HHS under §155.100(a)(2), in which case the Exchange operated by the State must perform the functions described in subpart H of this part and all applicable provisions of other subparts referenced in that subpart. In a State that is approved to operate only a SHOP, the individual market Exchange operated by HHS in that State will perform the functions described in this subpart and in subparts D, E, F, G, K, M, and O of this part.

(b) *Certificates of exemption.* The Exchange must issue certificates of exemption consistent with sections 1311(d)(4)(H) and 1411 of the Affordable Care Act.

(c) *Oversight and financial integrity.* The Exchange must perform required functions and cooperate with activities related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act and as required under this part, including overseeing its Exchange programs and non-Exchange entities as defined in §155.260(b)(1).

(d) *Quality activities.* The Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting in accordance with sections 1311(c)(1), 1311(c)(3), and 1311(c)(4) of the Affordable Care Act.

(e) *Clarification.* In carrying out its responsibilities under this subpart, an Exchange is not operating on behalf of a QHP.

(f) *Requirements for State Exchanges on the Federal platform.* (1) A State that receives approval or conditional approval to operate a State Exchange on the Federal platform under §155.106(c) may meet its obligations under paragraph (a) of this section by relying on Federal services that the Federal government agrees to provide under a Federal platform agreement.

(2) A State Exchange on the Federal platform must establish and oversee requirements for its issuers that are no less strict than the following requirements that are applied to Federally-facilitated Exchange issuers:

(i) Data submission requirements under §156.122(d)(2) of this subchapter;

(ii)—(iv) [Reserved]

(v) Changes of ownership of issuers requirements under §156.330 of this subchapter;

(vi) QHP issuer compliance and compliance of delegated or downstream entities requirements under §156.340(a)(4) of this subchapter; and

(vii) Casework requirements under §156.1010 of this subchapter.

(3) If a State is not substantially enforcing any requirement listed under §155.200(f)(2) with respect to a QHP issuer or plan in a State-based Exchange on the Federal platform, HHS may enforce that requirement directly against the issuer or plan by means of plan suppression under §156.815 of this subchapter.

(4) A State Exchange on the Federal platform that utilizes the Federal platform for SHOP functions, for plan years beginning on or after January 1, 2018, must require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a

Federally-facilitated SHOP under §155.706(b)(6)(i)(A). A State Exchange on the Federal platform that utilizes the Federal platform for SHOP functions, as set forth in paragraphs (f)(4)(i) through (vii) of this section, for plan years beginning prior to January 1, 2018, must—

(i) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish standard processes for premium calculation, premium payment, and premium collection that are consistent with the requirements applicable in a Federally-facilitated SHOP under §155.705(b)(4);

(ii) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, require its QHP issuers to make any changes to rates in accordance with the timeline applicable in a Federally-facilitated SHOP under §155.705(b)(6)(i)(A);

(iii) If utilizing the Federal platform for SHOP enrollment functions, establish minimum participation rate requirements and calculation methodologies that are consistent with those applicable in a Federally-facilitated SHOP under §155.705(b)(10);

(iv) If utilizing the Federal platform for SHOP enrollment or premium aggregation functions, establish employer contribution methodologies that are consistent with the methodologies applicable in a Federally-facilitated SHOP under §155.705(b)(11)(ii);

(v) If utilizing the Federal platform for SHOP enrollment functions, establish annual employee open enrollment period requirements that are consistent with §155.725(e)(2);

(vi) If utilizing the Federal platform for SHOP enrollment functions, establish effective dates of coverage for an initial group enrollment or a group renewal that are consistent with the effective dates of coverage applicable in a Federally-facilitated SHOP under §155.725(h)(2); and

(vii) If utilizing the Federal platform for SHOP eligibility, enrollment, or premium aggregation functions, establish policies for the termination of SHOP coverage or enrollment that are consistent with the requirements applicable in a Federally-facilitated SHOP under §155.735.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 39523, July 1, 2013; 78 FR 54134, Aug. 30, 2013; 81 FR 12337, Mar. 8, 2016; 81 FR 94175, Dec. 22, 2016; 83 FR 17060, Apr. 17, 2018; 84 FR 71710, Dec. 27, 2019]

§155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* If the Exchange is not an Exchange described in paragraph (a)(1) or (2) of this section, the Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section and at §155.405(c)(2)(ii). At a minimum, the Exchange call center must provide consumers with access to a live call center representative during an Exchange's published hours of operation and a live call center representative who must be able to assist consumers with filing their Exchange application, including providing consumers with information on their eligibility for advance premium tax credits and cost-sharing reductions, facilitating a consumer's comparison of QHPs, and helping consumers complete their Exchange applications for submission to the Exchange. If the Exchange is an Exchange described in paragraph (a)(1) or (2) of this section, the Exchange must provide at a minimum a toll-free telephone hotline that includes the capability to provide information to consumers about eligibility and enrollment processes, and to appropriately direct consumers to the applicable Exchange website and other applicable resources.

(b) *Internet Web site.* The Exchange must maintain an up-to-date Internet Web site that meets the requirements outlined in paragraph (c) of this section and:

(1) Provides standardized comparative information on each available QHP, which may include differential display of standardized options on consumer-facing plan comparison and shopping tools, and at a minimum includes:

(i) Premium and cost-sharing information;

(ii) The summary of benefits and coverage established under section 2715 of the PHS Act;

(iii) Identification of whether the QHP is a bronze, silver, gold, or platinum level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(iv) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(v) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act;

(vi) Medical loss ratio information as reported to HHS in accordance with 45 CFR part 158;

(vii) Transparency of coverage measures reported to the Exchange during certification in accordance with §155.1040; and

(viii) The provider directory made available to the Exchange in accordance with §156.230.

(2) Publishes the following financial information:

(i) The average costs of licensing required by the Exchange;

(ii) Any regulatory fees required by the Exchange;

(iii) Any payments required by the Exchange in addition to fees under paragraphs (b)(2)(i) and (ii) of this section;

(iv) Administrative costs of such Exchange; and

(v) Monies lost to waste, fraud, and abuse.

(3) Provides applicants with information about Navigators as described in §155.210 and other consumer assistance services, including the toll-free telephone number of the Exchange call center required in paragraph (a) of this section.

(4) Allows for an individual to submit a single streamlined eligibility application to the Exchange in accordance with §155.405 and for the Exchange to make all determinations of eligibility for enrollment in a QHP and insurance affordability programs, in accordance with subpart D of this part, through the operation of a centralized eligibility and enrollment platform on the Exchange's website; or, if the Exchange is a State-based Exchange on the Federal platform, through the Federal eligibility and enrollment platform.

(5) Allows a qualified individual to select a QHP and allows the Exchange to maintain records of all QHP enrollments, in accordance with subpart E of this part, through the operation of a centralized eligibility and enrollment platform on the Exchange's website; or, if the Exchange is a State-based Exchange on the Federal platform, through the Federal eligibility and enrollment platform.

(6) Makes available by electronic means a calculator to facilitate the comparison of available QHPs after the application of any advance payments of the premium tax credit and any cost-sharing reductions.

(7) A State-based Exchange on the Federal platform must at a minimum maintain an informational Internet Web site that includes the capability to direct consumers to Federal platform services to apply for, and enroll in, Exchange coverage.

(c) *Accessibility*. Information must be provided to applicants and enrollees in plain language and in a manner that is accessible and timely to—

(1) Individuals living with disabilities including accessible Web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

(2) Individuals who are limited English proficient through the provision of language services at no cost to the individual, including

(i) For all entities subject to this standard, oral interpretation.

(A) For Exchanges and QHP issuers, this standard also includes telephonic interpreter services in at least 150 languages.

(B) For a web-broker, beginning November 1, 2015, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, this standard also includes telephonic interpreter services in at least 150 languages.

(ii) Written translations; and

(iii) For all entities subject to this standard, taglines in non-English languages indicating the availability of language services.

(A) For Exchanges and QHP issuers, this standard also includes taglines on Web site content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. A document is deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if it is required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. If an Exchange is operated by an entity that operates multiple Exchanges, or if an Exchange relies on an entity to conduct its eligibility or enrollment functions and that entity conducts such functions for multiple Exchanges, the Exchange may aggregate the limited English proficient populations across all the States served by the entity that operates the Exchange or conducts its eligibility or enrollment functions to determine the top 15 languages required for taglines. A QHP issuer may aggregate the limited English proficient populations across all States served by the health insurance issuers within the issuer's controlled group (defined for purposes of this section as a group of two or more persons that is treated as a single employer under sections 52(a), 52(b), 414(m), or 414(o) of the Internal Revenue Code of 1986, as amended), whether or not those health insurance issuers offer plans through the Exchange in each of those States, to determine the top 15 languages required for taglines. Exchanges and QHP issuers may satisfy tagline requirements with respect to Web site content if they post a Web link prominently on their home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if they also include taglines on any critical stand-alone document linked to or embedded in the Web site. Exchanges, and QHP issuers that are also subject to §92.8 of this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with §92.8 of this subtitle.

(B) For a web-broker, beginning when such entity has been registered with the Exchange for at least 1 year, this standard also includes taglines on website content and any document that is critical for obtaining health insurance coverage or access to health care services through a QHP for qualified individuals, applicants, qualified employers, qualified employees, or enrollees. Website content or documents are deemed to be critical for obtaining health insurance coverage or access to health care services through a QHP if they are required to be provided by law or regulation to a qualified individual, applicant, qualified employer, qualified employee, or enrollee. Such taglines must indicate the availability of language services in at least the top 15 languages spoken by the limited English proficient population of the relevant State or States, as determined in guidance published by the Secretary. A web-broker that is licensed in and serving multiple States may aggregate the limited English populations in the States it serves to determine the top 15 languages required for taglines. A web-broker may satisfy tagline requirements with respect to website content if it posts a Web link prominently on its home page that directs individuals to the full text of the taglines indicating how individuals may obtain language assistance services, and if it also includes taglines on any critical stand-alone document linked to or embedded in the website.

(iv) For Exchanges, QHP issuers, and web-brokers, website translations.

(A) For an Exchange, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a Web site that is maintained by the Exchange must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the

population of the relevant State, as determined in guidance published by the Secretary.

(B) For a QHP issuer, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, if the content of a Web site maintained by the QHP issuer is critical for obtaining health insurance coverage or access to health care services through a QHP, within the meaning of §156.250 of this subchapter, it must be translated into any non-English language that is spoken by a limited English proficient population that reaches 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(C) For a web-broker, beginning on the first day of the individual market open enrollment period for the 2017 benefit year, or when such entity has been registered with the Exchange for at least 1 year, whichever is later, content that is intended for qualified individuals, applicants, qualified employers, qualified employees, or enrollees on a website that is maintained by the web-broker must be translated into any non-English language that is spoken by a limited English proficient population that comprises 10 percent or more of the population of the relevant State, as determined in guidance published by the Secretary.

(3) Inform individuals of the availability of the services described in paragraphs (c)(1) and (2) of this section and how to access such services.

(d) *Consumer assistance.* (1) The Exchange must have a consumer assistance function that meets the standards in paragraph (c) of this section, including the Navigator program described in §155.210. Any individual providing such consumer assistance must be trained regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the State, as implemented in the State, prior to providing such assistance or the outreach and education activities specified in paragraph (e) of this section.

(2) The Exchange must provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the Public Health Service Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage.

(e) *Outreach and education.* The Exchange must conduct outreach and education activities that meet the standards in paragraph (c) of this section to educate consumers about the Exchange and insurance affordability programs to encourage participation.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42859, July 17, 2013; 80 FR 10864, Feb. 27, 2015; 81 FR 12337, Mar. 8, 2016; 81 FR 94175, Dec. 22, 2016; 84 FR 17563, Apr. 25, 2019; 86 FR 24288, May 5, 2021; 89 FR 26419, Apr. 15, 2024]

§155.206 Civil money penalties for violations of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges.

(a) *Enforcement actions.* If an individual or entity specified in paragraph (b) of this section engages in activity specified in paragraph (c) of this section, the Department of Health and Human Services (HHS) may impose the following sanctions:

(1) Civil money penalties (CMPs), subject to the provisions of this section.

(2) Corrective action plans. In the notice of assessment of CMPs specified in paragraph (l) of this section, HHS may provide an individual or entity specified in paragraph (b) of this section the opportunity to enter into a corrective action plan to correct the violation instead of paying the CMP, based on evaluation of the factors set forth in paragraph (h) of this section. In the event that the individual or entity does not follow such a corrective action plan, HHS could require payment of the CMP.

(b) *Consumer assistance entities.* CMPs may be assessed under this section against the following consumer assistance entities:

(1) Individual Navigators and Navigator entities in a Federally-facilitated Exchange, including grantees, subgrantees, and all personnel carrying out Navigator duties on behalf of a grantee or sub-grantee;

(2) Non-Navigator assistance personnel authorized under § 155.205(d) and (e) and non-Navigator assistance personnel entities in a Federally-facilitated Exchange, including but not limited to individuals and entities under contract with HHS to facilitate consumer enrollment in QHPs in a Federally-facilitated Exchange; and

(3) Organizations that a Federally-facilitated Exchange has designated as certified application counselor organizations and individual certified application counselors carrying out certified application counselor duties in a Federally-facilitated Exchange.

(c) *Grounds for assessing CMPs.* HHS may assess CMPs against a consumer assistance entity if, based on the outcome of the investigative process outlined in paragraphs (d) through (i) of this section, HHS has reasonably determined that the consumer assistance entity has failed to comply with the Federal regulatory requirements applicable to the consumer assistance entity that have been implemented pursuant to section 1321(a)(1) of the Affordable Care Act, including provisions of any agreements, contracts, and grant terms and conditions between HHS and the consumer assistance entity that interpret those Federal regulatory requirements or establish procedures for compliance with them, unless a CMP has been assessed for the same conduct under 45 CFR 155.285.

(d) *Basis for initiating an investigation of a potential violation*—(1) *Information.* Any information received or learned by HHS that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section may warrant an investigation. Information that might trigger an investigation includes, but is not limited to, the following:

(i) Complaints from the general public;

(ii) Reports from State regulatory agencies, and other Federal and State agencies; or

(iii) Any other information that indicates that a consumer assistance entity may have engaged or may be engaging in activity specified in paragraph (c) of this section.

(2) *Who may file a complaint.* Any entity or individual, or the legally authorized representative of an entity or individual, may file a complaint with HHS alleging that a consumer assistance entity has engaged or is engaging in an activity specified in paragraph (c) of this section.

(e) *Notice of investigation.* When HHS performs an investigation under this section, it must provide a written notice to the consumer assistance entity of its investigation. This notice must include the following:

(1) Description of the activity that is being investigated.

(2) Explanation that the consumer assistance entity has 30 days from the date of the notice to respond with additional information or documentation, including information or documentation to refute an alleged violation.

(3) State that a CMP might be assessed if the allegations are not, as determined by HHS, refuted within 30 days from the date of the notice.

(f) *Request for extension.* In circumstances in which a consumer assistance entity cannot prepare a response to HHS within the 30 days provided in the notice of investigation described in paragraph (e) of this section, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the consumer assistance entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or, if applicable, within an extended time frame, may result in HHS's imposition of a CMP depending upon the outcome of HHS's investigation of the alleged violation.

(g) *Responses to allegations of noncompliance.* In determining whether to impose a CMP, HHS may review and consider documents or information received or collected in accordance with paragraph (d)(1) of this section, as well as additional documents or information provided by the consumer assistance entity in response to receiving a notice of investigation in accordance with paragraph (e)(2) of this section. HHS may also conduct an independent

investigation into the alleged violation, which may include site visits and interviews, if applicable, and may consider the results of this investigation in its determination.

(h) *Factors in determining noncompliance and amount of CMPs, if any.* In determining whether there has been noncompliance by the consumer assistance entity, and whether CMPs are appropriate:

(1) HHS must take into account the following:

(i) The consumer assistance entity's previous or ongoing record of compliance, including but not limited to compliance or noncompliance with any corrective action plan.

(ii) The gravity of the violation, which may be determined in part by—

(A) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(B) Whether the violation caused, or could reasonably be expected to cause, financial or other adverse impacts on consumer(s), and the magnitude of those impacts;

(2) HHS may take into account the following:

(i) The degree of culpability of the consumer assistance entity, including but not limited to—

(A) Whether the violation was beyond the direct control of the consumer assistance entity; and

(B) The extent to which the consumer assistance entity received compensation—legal or otherwise—for the services associated with the violation;

(ii) Aggravating or mitigating circumstances;

(iii) Whether other remedies or penalties have been assessed and/or imposed for the same conduct or occurrence; or

(iv) Other such factors as justice may require.

(i) *Maximum per-day penalty.* The maximum amount of penalty imposed for each violation is $100 for each day, as adjusted annually under 45 CFR part 102, for each consumer assistance entity for each individual directly affected by the consumer assistance entity's noncompliance; and where the number of individuals cannot be determined, HHS may reasonably estimate the number of individuals directly affected by the violation.

(j) *Settlement authority.* Nothing in §155.206 limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with paragraph (e) of this section or to compromise on any penalty provided for in this section.

(k) *Limitations on penalties*—(1) *Circumstances under which a CMP is not imposed.* HHS will not impose any CMP on:

(i) Any violation for the period of time during which none of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the violation; or

(ii) The period of time after any of the consumer assistance entities knew, or exercising reasonable diligence would have known, of the failure, if the violation was due to reasonable cause and not due to willful neglect and the violation was corrected within 30 days of the first day that any of the consumer assistance entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the violation existed.

(2) *Burden of establishing knowledge.* The burden is on the consumer assistance entity or entities to establish to HHS's satisfaction that the consumer assistance entity did not know, or exercising reasonable diligence would have known, that the violation existed, as well as the period of time during which that limitation applies; or that the violation was due to reasonable cause and not due to willful neglect and was corrected pursuant to the elements in paragraph (k)(1)(ii) of this section.

(3) *Time limit for commencing action.* No action under this section will be entertained unless commenced, in accordance with §155.206(l), within six years from the date on which the violation occurred.

(l) *Notice of assessment of CMP.* If HHS proposes to assess a CMP in accordance with this section, HHS will send a written notice of this decision to the consumer assistance entity against whom the sanction is being imposed, which notice must include the following:

(1) A description of the basis for the determination;

(2) The basis for the CMP;

(3) The amount of the CMP, if applicable;

(4) The date the CMP, if applicable, is due;

(5) Whether HHS would permit the consumer assistance entity to enter into a corrective action plan in place of paying the CMP, and the terms of any such corrective action plan;

(6) An explanation of the consumer assistance entity's right to a hearing under paragraph (m) of this section; and

(7) Information about the process for filing a request for a hearing.

(m) *Appeal of proposed sanction.* Any consumer assistance entity against which HHS has assessed a sanction may appeal that penalty in accordance with the procedures set forth at 45 CFR part 150, subpart D.

(n) *Failure to request a hearing.* (1) If the consumer assistance entity does not request a hearing within 30 days of the issuance of the notice of assessment of CMP described in paragraph (l) of this section, HHS may require payment of the proposed CMP.

(2) HHS will notify the consumer assistance entity in writing of any CMP that has been assessed and of the means by which the consumer assistance entity may pay the CMP.

(3) The consumer assistance entity has no right to appeal a CMP with respect to which it has not requested a hearing in accordance with paragraph (m) of this section unless the consumer assistance entity can show good cause in accordance with §150.405(b) of this subchapter for failing to timely exercise its right to a hearing.

[79 FR 30342, May 27, 2014, as amended at 87 FR 27388, May 6, 2022]

§ 155.210 Navigator program standards.

(a) *General requirements.* The Exchange must establish a Navigator program consistent with this section through which it awards grants to eligible public or private entities or individuals described in paragraph (c) of this section.

(b) *Standards.* The Exchange must develop and publicly disseminate—

(1) A set of standards, to be met by all entities and individuals to be awarded Navigator grants, designed to prevent, minimize and mitigate any conflicts of interest, financial or otherwise, that may exist for an entity or individuals to be awarded a Navigator grant and to ensure that all entities and individuals carrying out Navigator functions have appropriate integrity; and

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure the entities and individuals are qualified to engage in Navigator activities, including training standards on the following topics:

(i) The needs of underserved and vulnerable populations;

(ii) Eligibility and enrollment rules and procedures;

(iii) The range of QHP options and insurance affordability programs; and

(iv) The privacy and security standards applicable under §155.260.

(c) *Entities and individuals eligible to be a Navigator.* (1) To receive a Navigator grant, an entity or individual must—

(i) Be capable of carrying out at least those duties described in paragraph (e) of this section;

(ii) Demonstrate to the Exchange that the entity has existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP;

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(A) Except as otherwise provided under §155.705(d), requirements that Navigators refer consumers to other entities not required to provide fair, accurate, and impartial information.

(B) Except as otherwise provided under §155.705(d), requirements that

would prevent Navigators from providing services to all persons to whom they are required to provide assistance.

(C) Requirements that would prevent Navigators from providing advice regarding substantive benefits or comparative benefits of different health plans.

(D) Requiring that a Navigator hold an agent or broker license or imposing any requirement that, in effect, would require all Navigators in the Exchange to be licensed agents or brokers.

(E) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to Navigator entities or individuals or applicable to the Exchange's implementation of the Navigator program.

(iv) Not have a conflict of interest during the term as Navigator; and,

(v) Comply with the privacy and security standards adopted by the Exchange as required in accordance with §155.260.

(2) The Exchange must include an entity from at least one of the following categories for receipt of a Navigator grant:

(i) Community and consumer-focused nonprofit groups;

(ii) Trade, industry, and professional associations;

(iii) Commercial fishing industry organizations, ranching and farming organizations;

(iv) Chambers of commerce;

(v) Unions;

(vi) Resource partners of the Small Business Administration;

(vii) Licensed agents and brokers; and

(viii) Other public or private entities or individuals that meet the requirements of this section. Other entities may include but are not limited to Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.

(d) *Prohibition on Navigator conduct.* The Exchange must ensure that a Navigator must not—

(1) Be a health insurance issuer or issuer of stop loss insurance;

(2) Be a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(3) Be an association that includes members of, or lobbies on behalf of, the insurance industry;

(4) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or a non-QHP. Notwithstanding the requirements of this paragraph (d)(4), in a Federally-facilitated Exchange, no health care provider shall be ineligible to operate as a Navigator solely because it receives consideration from a health insurance issuer for health care services provided;

(5) Charge any applicant or enrollee, or request or receive any form of remuneration from or on behalf of an individual applicant or enrollee, for application or other assistance related to Navigator duties;

(6) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (d)(6), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses;

(7) Use Exchange funds to purchase gifts or gift cards, or promotional items that market or promote the products or services of a third party, that would be provided to any applicant or potential enrollee; or

(8) [Reserved]

(9) Initiate any telephone call to a consumer using an automatic telephone dialing system or an artificial or prerecorded voice, except in cases where the individual Navigator or Navigator entity has a relationship with the consumer and so long as other applicable State and Federal laws are otherwise complied with.

(e) *Duties of a Navigator.* An entity that serves as a Navigator must carry out at least the following duties:

(1) Maintain expertise in eligibility, enrollment, and program specifications and conduct public education activities to raise awareness about the Exchange;

(2) Provide information and services in a fair, accurate, and impartial manner, which includes: providing information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process. Such information must acknowledge other health programs;

(3) Facilitate selection of a QHP;

(4) Provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage;

(5) Provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with limited English proficiency, and ensure accessibility and usability of Navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act;

(6) Ensure that applicants—

(i) Are informed, prior to receiving assistance, of the functions and responsibilities of Navigators, including that Navigators are not acting as tax advisers or attorneys when providing assistance as Navigators and cannot provide tax or legal advice within their capacity as Navigators;

(ii) Provide authorization in a form and manner as determined by the Exchange prior to a Navigator's obtaining access to an applicant's personally identifiable information, and that the Navigator maintains a record of the authorization provided in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

(iii) May revoke at any time the authorization provided the Navigator pursuant to paragraph (e)(6)(ii) of this section; and

(7) In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a Navigator solely because its principal place of business is outside of the Exchange service area;

(8) Provide targeted assistance to serve underserved or vulnerable populations, as identified by the Exchange, within the Exchange service area.

(i) In a Federally-facilitated Exchange, this paragraph (e)(8) will apply beginning with the Navigator grant application process for Navigator grants awarded in 2018. The Federally-facilitated Exchange will identify populations as vulnerable or underserved that are disproportionately without access to coverage or care, or that are at a greater risk for poor health outcomes, in the funding opportunity announcement for its Navigator grants, and applicants for those grants will have an opportunity to propose additional vulnerable or underserved populations in their applications for the Federally-facilitated Exchange's approval.

(ii) [Reserved]

(9) The Exchange may require or authorize Navigators to provide information and assistance with any of the following topics. In federally-facilitated Exchanges, FY 2021 Navigator grantees will be required to perform these duties beginning with the Navigator grant funding awarded in FY 2022 for the second 12-month budget period of the 36-month period of performance. Beginning with Navigator grants awarded in 2022, including non-competing continuation awards, Navigators are required to provide information and assistance with all of the following topics:

(i) Understanding the process of filing Exchange eligibility appeals;

(ii) Understanding and applying for exemptions from the requirement to

maintain minimum essential coverage granted through the Exchange;

(iii) The Exchange-related components of the premium tax credit reconciliation process, and understanding the availability of IRS resources on this process;

(iv) Understanding basic concepts and rights related to health coverage and how to use it; and

(v) Referrals to licensed tax advisers, tax preparers, or other resources for assistance with tax preparation and tax advice related to consumer questions about the Exchange application and enrollment process, and premium tax credit reconciliations.

(f) *Funding for Navigator grants.* Funding for Navigator grants may not be from Federal funds received by the State to establish the Exchange.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42859, July 17, 2013; 79 FR 30344, May 27, 2014; 79 FR 42986, July 24, 2014; 81 FR 12337, Mar. 8, 2016; 83 FR 17061, Apr. 17, 2018; 84 FR 17563, Apr. 25, 2019; 86 FR 53503, Sept. 27, 2021; 88 FR 25917, Apr. 27, 2023]

§ 155.215 Standards applicable to Navigators and Non-Navigator Assistance Personnel carrying out consumer assistance functions under §§ 155.205(d) and (e) and 155.210 in a Federally-facilitated Exchange and to Non-Navigator Assistance Personnel funded through an Exchange Establishment Grant.

(a) *Conflict-of-interest standards.* The following conflict-of-interest standards apply in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act:

(1) *Conflict-of-interest standards for Navigators.* (i) All Navigator entities, including Navigator grant applicants, must submit to the Exchange a written attestation that the Navigator, including the Navigator's staff:

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(ii) All Navigator entities must submit to the Exchange a written plan to remain free of conflicts of interest during the term as a Navigator.

(iii) All Navigator entities, including the Navigator's staff, must provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(iv) All Navigator entities, including the Navigator's staff, must disclose to the Exchange and, in plain language, to each consumer who receives application assistance from the Navigator:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in §155.210(d), which the Navigator intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last 5 years, with any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(2) *Conflict-of-interest standards for Non-Navigator assistance personnel carrying out consumer assistance functions under §155.205(d) and (e).* All Non-Navigator entities or individuals authorized to carry out consumer assistance functions under §155.205(d) and (e) must—

(i) Comply with the prohibitions on Navigator conduct set forth at §155.210(d) and the duties of a Navigator set forth at §155.210(e)(2).

(ii) Submit to the Exchange a written attestation that the entity or individual—

(A) Is not a health insurance issuer or issuer of stop loss insurance;

(B) Is not a subsidiary of a health insurance issuer or issuer of stop loss insurance;

(C) Is not an association that includes members of, or lobbies on behalf of, the insurance industry; and

(D) Will not receive any consideration directly or indirectly from any health insurance issuer or issuer of stop loss insurance in connection with the enrollment of any individuals or employees in a QHP or non-QHP.

(iii) Submit to the Exchange a written plan to remain free of conflicts of interest while carrying out consumer assistance functions under §155.205(d) and (e).

(iv) Provide information to consumers about the full range of QHP options and insurance affordability programs for which they are eligible.

(v) Submit to the Exchange, and, in plain language, to each consumer who receives application assistance from the entity or individual:

(A) Any lines of insurance business, not covered by the restrictions on participation and prohibitions on conduct in §155.210(d), which the entity or individual intends to sell while carrying out the consumer assistance functions;

(B) Any existing employment relationships, or any former employment relationships within the last five years, with any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance, including any existing employment relationships between a spouse or domestic partner and any health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance; and

(C) Any existing or anticipated financial, business, or contractual relationships with one or more health insurance issuers or issuers of stop loss insurance, or subsidiaries of health insurance issuers or issuers of stop loss insurance.

(b) *Training standards for Navigators and Non-Navigator assistance personnel carrying out consumer assistance functions under §§155.205(d) and (e) and 155.210.* The following training standards apply in an Exchange operated by HHS during the exercise of its authority under §155.105(f), and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act.

(1) *Certification and recertification standards.* All individuals or entities who carry out consumer assistance functions under §§155.205(d) and (e) and 155.210, including Navigators, must meet the following certification and recertification requirements.

(i) Obtain certification by the Exchange prior to carrying out any consumer assistance functions or outreach and education activities under §155.205(d) and (e) or §155.210;

(ii) Register for and complete a HHS-approved training;

(iii) Following completion of the HHS-approved training described in paragraph (b)(1)(ii) of this section, complete and achieve a passing score on all approved certification examinations prior to carrying out any consumer assistance functions under §155.205(d) and (e) or §155.210;

(iv) Obtain continuing education and be certified and/or recertified on at least an annual basis; and

(v) Be prepared to serve both the individual Exchange and SHOP.

(2) *Training module content standards.* All individuals who carry out the consumer assistance functions under §§155.205(d) and (e) and 155.210 must receive training consistent with standards established by the Exchange consistent with §155.210(b)(2).

(c) *Providing Culturally and Linguistically Appropriate Services (CLAS Standards).* The following standards will apply in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. To ensure that information provided as part of any consumer assistance functions under §155.205(d) and (e) or §155.210 is culturally and linguistically appropriate to the needs of the

population being served, including individuals with limited English proficiency as required by §§155.205(c)(2) and 155.210(e)(5), any entity or individual carrying out these functions must:

(1) Develop and maintain general knowledge about the racial, ethnic, and cultural groups in their service area, including each group's diverse cultural health beliefs and practices, preferred languages, health literacy, and other needs;

(2) Collect and maintain updated information to help understand the composition of the communities in the service area, including the primary languages spoken;

(3) Provide consumers with information and assistance in the consumer's preferred language, at no cost to the consumer, including the provision of oral interpretation of non-English languages and the translation of written documents in non-English languages when necessary or when requested by the consumer to ensure effective communication. Use of a consumer's family or friends as oral interpreters can satisfy the requirement to provide linguistically appropriate services only when requested by the consumer as the preferred alternative to an offer of other interpretive services;

(4) Provide oral and written notice to consumers with limited English proficiency, in their preferred language, informing them of their right to receive language assistance services and how to obtain them;

(5) Receive ongoing education and training in culturally and linguistically appropriate service delivery; and

(6) Implement strategies to recruit, support, and promote a staff that is representative of the demographic characteristics, including primary languages spoken, of the communities in their service area.

(d) *Standards ensuring access by persons with disabilities.* The following standards related to ensuring access by people with disabilities will apply in an Exchange operated by HHS during the exercise of its authority under §155.105(f), and to non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act. Any entity or individual carrying out any consumer assistance functions under §155.205(d) and (e) or §155.210, and in accordance with §155.205(c), must—

(1) Ensure that any consumer education materials, Web sites, or other tools utilized for consumer assistance purposes, are accessible to people with disabilities, including those with sensory impairments, such as visual or hearing impairments, and those with mental illness, addiction, and physical, intellectual, and developmental disabilities;

(2) Provide auxiliary aids and services for individuals with disabilities, at no cost, when necessary or when requested by the consumer to ensure effective communication. Use of a consumer's family or friends as interpreters can satisfy the requirement to provide auxiliary aids and services only when requested by the consumer as the preferred alternative to an offer of other auxiliary aids and services;

(3) Provide assistance to consumers in a location and in a manner that is physically and otherwise accessible to individuals with disabilities;

(4) Ensure that authorized representatives are permitted to assist an individual with a disability to make informed decisions;

(5) Acquire sufficient knowledge to refer people with disabilities to local, state, and federal long-term services and supports programs when appropriate; and

(6) Be able to work with all individuals regardless of age, disability, or culture, and seek advice or experts when needed.

(e) *Monitoring.* Any Exchange operated by HHS during the exercise of its authority under §155.105(f) will monitor compliance with the standards in this section and the requirements of §§155.205(d) and (e) and 155.210.

(f) *State or Exchange standards.* All non-Navigator entities or individuals carrying out consumer assistance functions under §155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must

meet any licensing, certification, or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(1) Requirements that non-Navigator entities or individuals refer consumers to other entities not required to provide fair, accurate, and impartial information.

(2) Requirements that would prevent non-Navigator entities or individuals from providing services to all persons to whom they are required to provide assistance.

(3) Requirements that would prevent non-Navigator entities or individuals from providing advice regarding substantive benefits or comparative benefits of different health plans.

(4) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to non-Navigator entities or individuals or applicable to the Exchange's implementation of the non-Navigator assistance personnel program.

(g) *Consumer authorization.* All non-Navigator entities or individuals carrying out consumer assistance functions under §155.205(d) and (e) in an Exchange operated by HHS during the exercise of its authority under §155.105(f) and all non-Navigator assistance personnel funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must establish procedures to ensure that applicants—

(1) Are informed, prior to receiving assistance, of the functions and responsibilities of non-Navigator assistance personnel, including that non-Navigator assistance personnel are not acting as tax advisers or attorneys when providing assistance as non-Navigator assistance personnel and cannot provide tax or legal advice within their capacity as non-Navigator assistance personnel;

(2) Provide authorization in a form and manner as determined by the Exchange prior to a non-Navigator assistance personnel's obtaining access to an applicant's personally identifiable information, and that the non-Navigator assistance personnel maintains a record of the authorization provided in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

(3) May revoke at any time the authorization provided the non-Navigator assistance personnel pursuant to paragraph (g)(2) of this section.

(h) *Physical presence.* In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a non-Navigator entity or as non-Navigator assistance personnel solely because its principal place of business is outside of the Exchange service area.

(i) *Prohibition on compensation per enrollment.* Beginning November 15, 2014, Navigators and Non-Navigator assistance personnel carrying out consumer assistance functions under §§155.205(d) and (e) and 155.210, if operating in an Exchange operated by HHS during the exercise of its authority under §155.105(f), are prohibited from providing compensation to individual Navigators or non-Navigator assistance personnel on a per-application, per-individual-assisted, or per-enrollment basis.

[78 FR 42859, July 17, 2013, as amended at 79 FR 30344, May 27, 2014; 81 FR 12338, Mar. 8, 2016; 83 FR 17061, Apr. 17, 2018; 84 FR 17563, Apr. 25, 2019]

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents, brokers, and web-brokers to—

(1) Enroll individuals, employers or employees in any QHP in the individual or small group market as soon as the QHP is offered through an Exchange in the State;

(2) Subject to paragraphs (c), (d), and (e) of this section, enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange; and

(3) Subject to paragraphs (d) and (e) of this section, assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs.

(b)(1) *Web site disclosure.* The Exchange or SHOP may elect to provide information regarding licensed agents and brokers on its Web site for the convenience of consumers seeking insurance through that Exchange and may elect to limit the information to information regarding licensed agents and brokers who have completed any required Exchange or SHOP registration and training process.

(2) A Federally-facilitated Exchange or SHOP will limit the information provided on its Web site regarding licensed agents and brokers to information regarding licensed agents and brokers who have completed registration and training.

(c) *Enrollment through the Exchange.* A qualified individual may be enrolled in a QHP through the Exchange with the assistance of an agent, broker, or web-broker if—

(1) The agent, broker, or web-broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange internet website as described in §155.405, or ensures that the eligibility application information is submitted for an eligibility determination through the Exchange-approved web service subject to meeting the requirements in paragraphs (c)(3)(ii) and (c)(4)(i)(F) of this section;

(2) The Exchange transmits enrollment information to the QHP issuer as provided in §155.400(a) to allow the issuer to effectuate enrollment of qualified individuals in the QHP.

(3)(i) When an internet website of a web-broker is used to complete the QHP selection, at a minimum the internet website must:

(A) Disclose and display the following QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of §155.205(c), and to the extent that enrollment support for a QHP is not available using the web-broker's website, prominently display a standardized disclaimer provided by HHS stating that enrollment support for the QHP is available on the Exchange website, and provide a Web link to the Exchange website:

(*1*) Premium and cost-sharing information;

(*2*) The summary of benefits and coverage established under section 2715 of the PHS Act;

(*3*) Identification of whether the QHP is a bronze, silver, gold, or platinum level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(*4*) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(*5*) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act; and

(*6*) The provider directory made available to the Exchange in accordance with §156.230 of this subchapter.

(B) Provide consumers the ability to view all QHPs offered through the Exchange;

(C) Not provide financial incentives, such as rebates or giveaways;

(D) Display all QHP data provided by the Exchange;

(E) Maintain audit trails and records in an electronic format for a minimum of ten years and cooperate with any audit under this section;

(F) Provide consumers with the ability to withdraw from the process and use the Exchange Web site described in §155.205(b) instead at any time;

(G) For the Federally-facilitated Exchange, prominently display a standardized disclaimer provided by HHS, and provide a Web link to the Exchange Web site; and

(H) Differentially display all standardized options prominently and in accordance with the requirements under §155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site and with standards defined by HHS, unless HHS approves a deviation;

(I) Prominently display information provided by HHS pertaining to a consumer's eligibility for advance payments of the premium tax credit or cost-sharing reductions;

(J) Allow the consumer to select an amount for advance payments of the premium tax credit, if applicable, and make related attestations in accordance with §155.310(d)(2);

(K) Comply with the applicable requirements in §155.221; and

(L) Not display QHP advertisements or recommendations, or otherwise provide favored or preferred placement in the display of QHPs, based on compensation the agent, broker, or web-broker receives from QHP issuers; and

(M) Prominently display a clear explanation of the rationale for QHP recommendations and the methodology for its default display of QHPs.

(ii) When an internet website of a web-broker is used to complete the Exchange eligibility application, at a minimum the internet website must:

(A) Comply with the requirements in paragraph (c)(3)(i) of this section;

(B) Use exactly the same eligibility application language as appears in the FFE Single Streamlined Application required in §155.405, unless HHS approves a deviation;

(C) Ensure that all necessary information for the consumer's applicable eligibility circumstances are submitted through the Exchange-approved web service; and

(D) Ensure that the process used for consumers to complete the eligibility application complies with all applicable Exchange standards, including §§155.230 and 155.260(b).

(4) When an agent or broker, through a contract or other arrangement, uses the internet website of a web-broker to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application in the Federally-facilitated Exchange:

(i) The web-broker who makes the website available must:

(A) Provide HHS with a list of agents and brokers who enter into such a contract or other arrangement to use the web-broker's website, in a form and manner to be specified by HHS;

(B) Verify that any agent or broker accessing or using the Web site pursuant to the arrangement is licensed in the State in which the consumer is selecting the QHP; and has completed training and registration and has signed all required agreements with the Federally-facilitated Exchange pursuant to paragraph (d) of this section and §155.260(b);

(C) Ensure that its name and any identifier required by HHS prominently appears on the Internet Web site and on written materials containing QHP information that can be printed from the Web site, even if the agent or broker that is accessing the Internet Web site is able to customize the appearance of the Web site;

(D) Terminate the agent or broker's access to its Web site if HHS determines that the agent or broker is in violation of the provisions of this section and/or HHS terminates any required agreement with the agent or broker;

(E) Report to HHS and applicable State departments of insurance any potential material breach of the standards in paragraphs (c) and (d) of this section, or the agreement entered into under §155.260(b), by the agent or broker accessing the internet website, should it become aware of any such potential breach. A web-broker that provides access to its website to complete the QHP selection or the Exchange eligibility application or ability to transact information with HHS to another web-broker website is responsible for ensuring compliance with applicable requirements in paragraph (c)(3) of this section for any web pages of the other web-broker's website that assist consumers, applicants, qualified individuals, and enrollees in applying for APTC and CSRs for QHPs, or in completing enrollment in QHPs, offered in the Exchanges.

(F) When an internet website of a web-broker is used to complete the Exchange eligibility application, obtain HHS approval verifying that all requirements in this section are met.

(ii) HHS retains the right to temporarily suspend the ability of a web-broker making its website available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in which

HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction.

(iii) Web-brokers operating in State Exchanges that do not use the Federal platform that permit other agents and brokers, through a contract or other arrangement, to use their internet website to help an applicant or enrollee complete a QHP selection or complete the Exchange eligibility application must comply with the standards in paragraphs (c)(4)(i)(A), (B), (D) and (F) of this section, except that all references to ''Federally-facilitated Exchange'' or ''HHS'' in paragraphs (c)(4)(i)(A), (B), (D), and (F) will be understood to mean ''the applicable State Exchange.''

(5) HHS or its designee may periodically monitor and audit an agent, broker, or web-broker under this subpart to assess its compliance with the applicable requirements of this section.

(6) In addition to applicable requirements under §155.221(b)(4), a web-broker must demonstrate operational readiness and compliance with applicable requirements prior to the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Operational data including licensure information, points of contact, and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) Website reviews performed by HHS;

(iv) Security and privacy assessment documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and HHS.

(d) *Agreement.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with the terms of an agreement between the agent, broker, or web-broker and the Exchange under which the agent, broker, or web-broker at least:

(1) Registers with the Exchange in advance of assisting qualified individuals enrolling in QHPs through the Exchange;

(2) Receives training in the range of QHP options and insurance affordability programs, except that a licensed agent or broker entity that registers with the Federally-facilitated Exchange in its capacity as a business organized under the laws of a State, and not as an individual person, and direct enrollment technology providers are exempt from this requirement; and

(3) Complies with the Exchange's privacy and security standards adopted consistent with §155.260.

(e) *Compliance with State law.* An agent, broker, or web-broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with applicable State law related to agents, brokers, or web-brokers including applicable State law related to confidentiality and conflicts of interest.

(f) *Termination notice to HHS.* (1) An agent, broker, or web-broker may terminate its agreement with HHS by sending to HHS a written notice at least 30 days in advance of the date of intended termination.

(2) The notice must include the intended date of termination, but if it does not specify a date of termination, or the date provided is not acceptable to HHS, HHS may set a different termination date that will be no less than 30 days from the date on the agent's, broker's, or web-broker's notice of termination.

(3) Prior to the date of termination, an agent, broker, or web-broker should—

(i) Notify applicants, qualified individuals, or enrollees that the agent, broker, or web-broker is assisting, of

the agent's, broker's, or web-broker's intended date of termination;

(ii) Continue to assist such individuals with Exchange-related eligibility and enrollment services up until the date of termination; and

(iii) Provide such individuals with information about alternatives available for obtaining additional assistance, including but not limited to the Federally-facilitated Exchange Web site.

(4) When the agreement between the agent, broker, or web-broker and the Exchange under paragraph (d) of this section is terminated under paragraph (f) of this section, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under §155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(g) *Standards for termination for cause from the Federally-facilitated Exchange.* (1) If, in HHS' determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's, broker's, or web-broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent, broker, or web-broker may be determined noncompliant if HHS finds that the agent, broker, or web-broker violated—

(i) Any standard specified under this section;

(ii) Any term or condition of the agreement with the Federally-facilitated Exchanges required under paragraph (d) of this section, or any term or condition of the agreement with the Federally-facilitated Exchange required under §155.260(b);

(iii) Any State law applicable to agents, brokers, or web-brokers, as required under paragraph (e) of this section, including but not limited to State laws related to confidentiality and conflicts of interest; or

(iv) Any Federal law applicable to agents, brokers, or web-brokers.

(3)(i) Except as provided in paragraph (g)(3)(ii) of this section, HHS will notify the agent, broker, or web-broker of the specific finding of noncompliance or pattern of noncompliance made under paragraph (g)(1) of this section, and after 30 days from the date of the notice, may terminate the agreement for cause if the matter is not resolved to the satisfaction of HHS.

(ii) HHS may immediately terminate the agreement for cause upon notice to the agent or broker without any further opportunity to resolve the matter if an agent or broker fails to maintain the appropriate license under State law as an agent, broker, or insurance producer in every State in which the agent or broker actively assists consumers with applying for advance payments of the premium tax credit or cost-sharing reductions or with enrolling in QHPs through the Federally-facilitated Exchanges.

(4) After the applicable period in paragraph (g)(3) of this section has elapsed and the agreement under paragraph (d) of this section is terminated, the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent's, broker's, or web-broker's agreement with the Exchange under §155.260(b)(2) will also be terminated through the process set forth in that agreement. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of

either of these agreements with the Federally-facilitated Exchanges.

(5) Fraud or abusive conduct—

(i)(A) If HHS reasonably suspects that an agent, broker, or web-broker may have may have engaged in fraud, or in abusive conduct that may cause imminent or ongoing consumer harm using personally identifiable information of an Exchange enrollee or applicant or in connection with an Exchange enrollment or application, HHS may temporarily suspend the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under §155.260(b) for up to 90 calendar days. Suspension will be effective on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the suspension of the agreements.

(B) The agent, broker, or web-broker may submit evidence in a form and manner to be specified by HHS, to rebut the allegation during this 90-day period. If the agent, broker, or web-broker submits such evidence during the suspension period, HHS will review the evidence and make a determination whether to lift the suspension within 45 calendar days of receipt of such evidence. If the rebuttal evidence does not persuade HHS to lift the suspension, or if the agent, broker, or web-broker fails to submit rebuttal evidence during the suspension period, HHS may terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under §155.260(b) for cause under paragraph (g)(5)(ii) of this section.

(ii) If there is a finding or determination by a Federal or State entity that an agent, broker, or web-broker engaged in fraud, or abusive conduct that may result in imminent or ongoing consumer harm, using personally identifiable information of Exchange enrollees or applicants or in connection with an Exchange enrollment or application, HHS will terminate the agent's, broker's, or web-broker's agreements required under paragraph (d) of this section and under §155.260(b) for cause. The termination will be effective starting on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the termination of the agreements.

(iii) During the suspension period under paragraph (g)(5)(i) of this section and following termination of the agreements under paragraph (g)(5)(i)(B) or (g)(5)(ii) of this section, the agent, broker, or web-broker will not be registered with the Federally-facilitated Exchanges, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges.

(6) The State department of insurance or equivalent State agent or broker licensing authority will be notified by HHS in cases of suspensions or terminations effectuated under this paragraph (g).

(h) *Request for reconsideration of termination for cause from the Federally-facilitated Exchange*—(1) *Request for reconsideration.* An agent, broker, or web-broker whose agreement with the Federally-facilitated Exchange has been terminated may request reconsideration of such action in the manner and form established by HHS.

(2) *Timeframe for request.* The agent, broker, or web-broker must submit a request for reconsideration to the CMS Administrator within 30 calendar days of the written notice from HHS.

(3) *Notice of reconsideration decision.* The CMS Administrator will provide the agent, broker, or web-broker with a written notice of the reconsideration decision within 60 calendar days of the date the CMS Administrator receives the request for reconsideration. This decision will constitute HHS' final determination.

(i) *Use of agents' and brokers' and web-brokers' internet websites for SHOP.* For plan years beginning on or after January 1, 2015, in States that permit this activity under State law, a SHOP may

permit agents, brokers, and web-brokers to use an internet website to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

(j) *Federally-facilitated Exchange standards of conduct.* (1) An agent, broker, or web-broker that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs sold through a Federally-facilitated Exchange, must—

(i) Have executed the required agreement under paragraph §155.260(b);

(ii) Be registered with the Federally-facilitated Exchanges under paragraph (d)(1) of this section; and

(iii) Comply with the standards of conduct in paragraph (j)(2) of this section.

(2) *Standards of conduct.* An individual or entity described in paragraph (j)(1) of this section must—

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes);

(ii) Provide the Federally-facilitated Exchanges with correct information, and document that eligibility application information has been reviewed by and confirmed to be accurate by the consumer, or the consumer's authorized representative designated in compliance with §155.227, prior to the submission of information, under section 1411(b) of the Affordable Care Act, including but not limited to:

(A) Documenting that eligibility application information has been reviewed by and confirmed to be accurate by the consumer or the consumer's authorized representative must require the consumer or their authorized representative to take an action that produces a record that can be maintained by the individual or entity described in paragraph (j)(1) of this section and produced to confirm the consumer or their authorized representative has reviewed and confirmed the accuracy of the eligibility application information. Non-exhaustive examples of acceptable documentation include obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, a written response (electronic or otherwise) from the consumer or their authorized representative to a communication sent by the agent, broker, or web-broker, or other similar means or methods specified by HHS in guidance.

(*1*) The documentation required under paragraph (j)(2)(ii)(A) of this section must include the date the information was reviewed, the name of the consumer or their authorized representative, an explanation of the attestations at the end of the eligibility application, and the name of the assisting agent, broker, or web-broker.

(*2*) An individual or entity described in paragraph (j)(1) of this section must maintain the documentation described in paragraph (j)(2)(ii)(A) of this section for a minimum of ten years, and produce the documentation upon request in response to monitoring, audit, and enforcement activities conducted consistent with paragraphs (c)(5), (g), (h), and (k) of this section.

(B) Entering only an email address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to the consumer or the consumer's authorized representative designated in compliance with §155.227. A consumer's email address may only

be entered with the consent of the consumer or the consumer's authorized representative. Properly entered email addresses must adhere to the following guidelines:

(*1*) The email address must be accessible by the consumer, or the consumer's authorized representative designated in compliance with §155.227, and may not be accessible by the agent, broker, or web-broker assisting the consumer; and

(*2*) The email address may not have domains that belong to the agent, broker, or web-broker or their business or agency.

(C) Entering only a telephone number on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to the consumer or their authorized representative designated in compliance with §155.227. Telephone numbers may not be the personal number or business number of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the telephone number is actually that of the consumer or their authorized representative.

(D) Entering only a mailing address on an application for Exchange coverage or an application for advance payments of the premium tax credit and cost-sharing reductions for QHPs that belongs to, or is primarily accessible by, the consumer or their authorized representative designated in compliance with §155.227, is not for the exclusive or convenient use of the agent, broker, or web-broker, and is an actual residence or a secure location where the consumer or their authorized representative may receive correspondence, such as a P.O. Box or homeless shelter. Mailing addresses may not be that of the agent, broker, or web-broker assisting the consumer, or their business or agency, unless the address is the actual residence of the consumer or their authorized representative.

(E) When submitting household income projections used by the Exchange to determine a tax filer's eligibility for advance payments of the premium tax credit in accordance with §155.305(f) or cost-sharing reductions in accordance with §155.305(g), entering only a consumer's household income projection that the consumer or the consumer's authorized representative designated in compliance with §155.227 has knowingly authorized and confirmed as accurate. Household income projections must be calculated and attested to by the consumer. The agent, broker, or web-broker assisting the consumer may answer questions posed by the consumer related to household income projection, such as helping the consumer determine what qualifies as income.

(iii) Obtain and document the receipt of consent of the consumer or their authorized representative designated in compliance with §155.227, employer, or employee prior to assisting with or facilitating enrollment through a Federally-facilitated Exchange or assisting the individual in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs;

(A) Obtaining and documenting the receipt of consent must require the consumer, or the consumer's authorized representative designated in compliance with §155.227, to take an action that produces a record that can be maintained and produced by an individual or entity described in paragraph (j)(1) of this section to confirm the consumer's or their authorized representative's consent has been provided. Nonexhaustive examples of acceptable documentation of consent include obtaining the signature of the consumer or their authorized representative (electronically or otherwise), verbal confirmation by the consumer or their authorized representative that is captured in an audio recording, a response from the consumer or their authorized representative to an electronic or other communication sent by the agent, broker, or web-broker, or other similar means or methods specified by HHS in guidance.

(B) The documentation required under paragraph (j)(2)(iii)(A) of this section must include a description of the scope, purpose, and duration of the consent provided by the consumer or their authorized representative designated in compliance with §155.227, the date consent was given, name of the consumer or their authorized representative, and the name of the agent,

broker, web-broker, or agency being granted consent, as well as a process through which the consumer or their authorized representative may rescind the consent.

(C) An individual or entity described in paragraph (j)(1) of this section must maintain the documentation described in paragraph (j)(2)(iii)(A) of this section for a minimum of 10 years, and produce the documentation upon request in response to monitoring, audit, and enforcement activities conducted consistent with paragraphs (c)(5), (g), (h), and (k) of this section.

(iv) Protect consumer personally identifiable information according to §155.260(b)(3) and the agreement described in §155.260(b)(2);

(v) Comply with all applicable Federal and State laws and regulations.

(vi) Not engage in scripting and other automation of interactions with CMS Systems or the Direct Enrollment Pathways, unless approved in advance in writing by CMS.

(vii) Only use an identity that belongs to the consumer when identity proofing the consumer's account on *HealthCare.gov*.

(viii) When providing information to Federally-facilitated Exchanges that may result in a determination of eligibility for a special enrollment period in accordance with §155.420, obtain authorization from the consumer to submit the request for a determination of eligibility for a special enrollment period and make the consumer aware of the specific triggering event and special enrollment period for which the agent, broker, or web-broker will be submitting an eligibility determination request on the consumer's behalf.

(3) If an agent, broker, or web-broker fails to provide correct information, he, she, or it will nonetheless be deemed in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent, broker, or web-broker acted in good faith.

(k) *Penalties other than termination of the agreement with the Federally-facilitated Exchanges.* (1) If HHS determines that an agent, broker, or web-broker has failed to comply with the requirements of this section, in addition to any other available remedies, that agent, broker, or web-broker—

(i) May be denied the right to enter into agreements with the Federally-facilitated Exchanges in future years; and

(ii) May be subject to civil money penalties as described in §155.285.

(2) HHS will notify the agent, broker, or web-broker of the proposed imposition of penalties under paragraph (k)(1)(i) of this section as part of the termination notice issued under paragraph (g) of this section and, after 30 calendar days from the date of the notice, may impose the penalty if the agent, broker, or web-broker has not requested a reconsideration under paragraph (h) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under §155.285.

(3) HHS may immediately suspend the agent's or broker's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to Exchange operations or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(l) *Application to State Exchanges using a Federal platform.* An agent, broker, or web-broker who enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using the Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

(m) *Web-broker agreement suspension, termination, and denial and information collection.* (1) A web-broker's agreement executed under paragraph (d) of this section, may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges

under paragraph (k)(1)(i) of this section, based on the actions of its officers, employees, contractors, or agents, whether or not the officer, employee, contractor, or agent is registered with the Exchange as an agent or broker.

(2) A web-broker's agreement executed under paragraph (d) of this section may be suspended or terminated under paragraph (g) of this section, and a web-broker may be denied the right to enter into agreements with the Federally-facilitated Exchanges under paragraph (k)(1)(i) of this section, if it is under the common ownership or control or is an affiliated business of another web-broker that had its agreement suspended or terminated under paragraph (g) of this section.

(3) The Exchange may collect information from a web-broker during its registration with the Exchange under paragraph (d)(1) of this section, or at another time on an annual basis, in a form and manner to be specified by HHS, sufficient to establish the identities of the individuals who comprise its corporate ownership and leadership and to ascertain any corporate or business relationships it has with other entities that may seek to register with the Federally-facilitated Exchange as web-brokers.

(n) *Application to State Exchanges that do not use the Federal platform.* A web-broker that assists or enrolls qualified individuals, qualified employers or qualified employees in coverage in a manner that constitutes enrollment through the State Exchange, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through the State Exchange, must comply with the Federally-facilitated Exchange standards in paragraphs (c)(3)(i)(A), (G), (I), and (j)(2)(i) of this section, including any additional State-specific standards under paragraph (n)(1) of this section, and the State Exchange's operational readiness standards under paragraph (n)(2) of this section. For the purposes of paragraph (j)(2)(i) of this section, references to ''HHS'' and ''the federally facilitated Exchanges'' will be understood to mean ''the applicable State Exchange, applied for web-brokers'', and the reference to ''*HealthCare.gov*'' will be understood to mean ''the State Exchange website, applied for web-brokers.''

(1) State Exchanges may add State-specific information to the standardized disclaimers and information under paragraphs (c)(3)(i)(A), (G), and (I) of this section that does not conflict with the HHS-provided language.

(2) State Exchanges must establish the form and manner for their web-brokers to demonstrate operational readiness and compliance with applicable requirements in order for the web-broker's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion of the following items to the State Exchange, in the form and manner specified by the Exchange:

(i) Operational data including licensure information, points of contact and third-party relationships;

(ii) Enrollment testing, prior to approval or renewal;

(iii) website reviews performed by the State Exchange;

(iv) Security and privacy documentation, including:

(A) Penetration testing results;

(B) Security and privacy assessment reports;

(C) Vulnerability scan results;

(D) Plans of action and milestones; and

(E) System security and privacy plans.

(v) Agreements between the web-broker and the State Exchange.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 15533, Mar. 11, 2013; 78 FR 54134, Aug. 30, 2013; 79 FR 13837, Mar. 11, 2014; 81 FR 12338, Mar. 8, 2016; 81 FR 94176, Dec. 22, 2016; 84 FR 17563, Apr. 25, 2019; 85 FR 37248, June 19, 2020; 86 FR 24288, May 5, 2021; 87 FR 27388, May 6, 2022; 88 FR 25917, Apr. 27, 2023; 89 FR 26420, Apr. 15, 2024; 89 FR 37703, May 6, 2024]

§ 155.221 Standards for direct enrollment entities and for third-parties to perform audits of direct enrollment entities.

(a) *Direct enrollment entities.* All Exchanges may permit the following entities to assist consumers with direct enrollment in QHPs offered through the Exchange in a manner that is considered to be through the Exchange, to

the extent permitted by applicable State law:

(1) QHP issuers that meet the applicable requirements in this section and §156.1230 of this subchapter; and

(i) For purposes of applying the requirements of §156.1230(b) of this subchapter to State Exchanges, all references to ''Federally-facilitated Exchange'' and ''HHS'', and ''HealthCare.gov'' will be understood to mean ''the applicable State Exchange'', ''the applicable State Exchange'', and ''the applicable State Exchange website'', respectively.

(ii) [Reserved]

(2) Web-brokers that meet the applicable requirements in this section and §155.220.

(b) *Direct enrollment entity requirements.* For the Federally-facilitated Exchanges, a direct enrollment entity must:

(1) Display and market QHPs offered through the Exchange, individual health insurance coverage as defined in §144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and any other products, such as excepted benefits, on at least three separate website pages on its non-Exchange website, except as permitted under paragraph (c) of this section;

(2) Prominently display a standardized disclaimer in the form and manner provided by HHS;

(3) Limit marketing of non-QHPs during the Exchange eligibility application and QHP selection process in a manner that minimizes the likelihood that consumers will be confused as to which products and plans are available through the Exchange and which products and plans are not, except as permitted under paragraph (c)(1) of this section;

(4) Demonstrate operational readiness and compliance with applicable requirements prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion, in the form and manner specified by HHS, of the following:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

(C) Business audit reports including testing results.

(ii) Security and privacy audit documentation including:

(A) Interconnection security agreements;

(B) Security and privacy controls assessment test plans;

(C) Security and privacy assessment reports;

(D) Plans of action and milestones;

(E) Privacy impact assessments;

(F) System security and privacy plans;

(G) Incident response plans; and

(H) Vulnerability scan results.

(iii) Eligibility application audits performed by HHS;

(iv) Online training modules offered by HHS; and

(v) Agreements between the direct enrollment entity and HHS.

(5) Comply with applicable Federal and State requirements.

(6) Implement and prominently display website changes in a manner that is consistent with display changes made to the Federally-facilitated Exchange website by meeting standards communicated and defined by HHS within a time period set by HHS, unless HHS approves a deviation from those standards. Direct enrollment entities may request a deviation by submitting a proposed alternative *display and* accompanying rationale to HHS for review.

(c) *Exceptions to direct enrollment entity display and marketing requirement.* For the Federally-facilitated Exchanges, a direct enrollment entity may:

(1) Display and market QHPs offered through the Exchange and individual health insurance coverage as defined in §144.103 of this subchapter offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits) on the same website pages when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement as described in §146.123(c)

of this subchapter, as a standalone benefit, or in addition to an offer of an arrangement under which the individual may pay the portion of the premium for individual health insurance coverage that is not covered by an individual coverage health reimbursement arrangement using a salary reduction arrangement pursuant to a cafeteria plan under section 125 of the Internal Revenue Code, but must clearly distinguish between the QHPs offered through the Exchange and individual health insurance coverage offered outside the Exchange (including QHPs and non-QHPs other than excepted benefits), and prominently communicate that advance payments of the premium tax credit and cost-sharing reductions are available only for QHPs purchased through the Exchange, that advance payments of the premium tax credit are not available to individuals who accept an offer of an individual coverage health reimbursement arrangement or who opt out of an individual coverage health reimbursement arrangement that is considered affordable, and that a salary reduction arrangement under a cafeteria plan may only be used toward the cost of premiums for plans purchased outside the Exchange; and

(2) Display and market Exchange-certified stand-alone dental plans offered outside the Exchange and non-certified stand-alone dental plans on the same website pages.

(d) *Direct enrollment entity application assister requirements.* For the Federally-facilitated Exchanges, to the extent permitted under state law, a direct enrollment entity may permit its direct enrollment entity application assisters, as defined at §155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such direct enrollment entity ensures that each of its direct enrollment entity application assisters meets the requirements in §155.415(b).

(e) *Federally-facilitated Exchange direct enrollment entity suspension.* HHS may immediately suspend the direct enrollment entity's ability to transact information with the Exchange if HHS discovers circumstances that pose unacceptable risk to the accuracy of the Exchange's eligibility determinations, Exchange operations, or Exchange information technology systems until the incident or breach is remedied or sufficiently mitigated to HHS' satisfaction.

(f) *Third parties to perform audits of direct enrollment entities.* A direct enrollment entity must engage an independent, third-party entity to conduct an initial and annual review to demonstrate the direct enrollment entity's operational readiness and compliance with applicable direct enrollment entity requirements in accordance with paragraph (b)(4) of this section prior to the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection. The third-party entity will be a downstream or delegated entity of the direct enrollment entity that participates or wishes to participate in direct enrollment.

(g) *Third-party auditor standards.* A direct enrollment entity must satisfy the requirement to demonstrate operational readiness under paragraph (f) of this section by engaging a third-party entity that executes a written agreement with the direct enrollment entity under which the third-party entity agrees to comply with each of the following standards:

(1) Has experience conducting audits or similar services, including experience with relevant privacy and security standards;

(2) Adheres to HHS specifications for content, format, privacy, and security in the conduct of an operational readiness review, which includes ensuring that direct enrollment entities are in compliance with the applicable privacy and security standards and other applicable requirements;

(3) Collects, stores, and shares with HHS all data related to the third-party entity's audit of direct enrollment entities in a manner, format, and frequency specified by HHS until 10 years from the date of creation, and complies with the privacy and security standards HHS adopts for direct enrollment entities as required in accordance with §155.260;

(4) Discloses to HHS any financial relationships between the entity and individuals who own or are employed by a direct enrollment entity for which it is conducting an operational readiness review;

(5) Complies with all applicable Federal and State requirements;

(6) Ensures, on an annual basis, that appropriate staff successfully complete operational readiness review training as established by HHS prior to conducting audits under paragraph (f) of this section;

(7) Permits access by the Secretary and the Office of the Inspector General or their designees in connection with their right to evaluate through audit, inspection, or other means, to the third-party entity's books, contracts, computers, or other electronic systems, relating to the third-party entity's audits of a direct enrollment entity's obligations in accordance with standards under paragraph (f) of this section until 10 years from the date of creation of a specific audit; and

(8) Complies with other minimum business criteria as specified in guidance by HHS.

(h) *Multiple auditors.* A direct enrollment entity may engage multiple third-party entities to conduct the audit under paragraph (f) of this section.

(i) *Application to State Exchanges using a Federal platform.* A direct enrollment entity that enrolls qualified individuals in coverage in a manner that constitutes enrollment through a State Exchange using the Federal platform, or assists individual market consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through a State Exchange using a Federal platform must comply with all applicable Federally-facilitated Exchange standards in this section.

(j) *Application to State* Exchanges *that do not use the Federal platform.* A direct enrollment entity that enrolls qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through the State Exchange, or assists consumers with submission of applications for advance payments of the premium tax credit and cost-sharing reductions through the State Exchange, must comply with the Federally-facilitated Exchange standards in paragraphs (b)(1) through (3) and (d) of this section, including the exceptions in paragraph (c) of this section, where applicable; any additional State-specific standards under paragraph (j)(1) of this section; the State Exchange's operational readiness standards under paragraph (j)(2) of this section; and the State Exchange's website display change standards under paragraph (j)(3) of this section. References to §§155.415(b), and 155.415(b)(1) in paragraph (d) of this section will be understood to also apply to State Exchanges.

(1) State Exchanges may add State-specific information to the standardized disclaimer under paragraph (b)(2) of this section that does not conflict with the HHS-provided language.

(2) State Exchanges must establish the form and manner for their direct enrollment entities to demonstrate operational readiness and compliance with applicable requirements in order for the direct enrollment entity's internet website being used to complete an Exchange eligibility application or a QHP selection, which may include submission or completion of the following documentation to the State Exchange, in the form and manner specified by the Exchange:

(i) Business audit documentation including:

(A) Notices of intent to participate including auditor information;

(B) Documentation packages including privacy questionnaires, privacy policy statements, and terms of service; and

(C) Business audit reports including testing results.

(ii) Security and privacy audit documentation including:

(A) Interconnection security agreements;

(B) Security and privacy controls assessment test plans;

(C) Security and privacy assessment reports;

(D) Plans of action and milestones;

(E) Privacy impact assessments;

(F) System security and privacy plans;

(G) Incident response plans; and

(H) Vulnerability scan results.

(3) State Exchanges must require their direct enrollment entities to implement and prominently display website changes in a manner that is consistent with the display changes made by State Exchanges to the State Exchanges' websites, consistent with the process of defining and communicating standards and setting advance notice periods in paragraph (b)(6) of this section, except that all references in paragraph (b)(6) of this section to ''Federally-Facilitated Exchange website'' would be understood to mean ''State Exchange website,'' references to ''HHS'' would be understood to mean ''State Exchange,'' and the reference to ''unless HHS approves a deviation from those standards'' would be understood to mean ''unless the State Exchange approves a deviation from those standards under the deviation request process it is required to establish should the State Exchange elect to permit deviation requests.''

[83 FR 17061, Apr. 17, 2018, as amended at 84 FR 17566, Apr. 25, 2019; 86 FR 6176, Jan. 19, 2021; 86 FR 24289, May 5, 2021; 86 FR 53503, Sept. 27, 2021; 89 FR 26420, Apr. 15, 2024]

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated Exchange training for agents and brokers.

(a) *Application for approval.* (1) A vendor must be approved by HHS, in a form and manner to be determined by HHS, to have its training program recognized for agents and brokers assisting with or facilitating enrollment in individual market or SHOP coverage through the Federally-facilitated Exchanges consistent with § 155.220.

(2) As part of the training program, the vendor must require agents and brokers to provide identifying information and successfully complete the required curriculum.

(3) HHS will approve vendors on an annual basis for a given plan year, and each vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS and maintain its status as an approved vendor for plan year 2016 and future plan years, a vendor must meet each of the following standards:

(1) Submit a complete and accurate application by the deadline established by HHS, which includes demonstration of prior experience with successfully conducting online training, as well as providing technical support to a large customer base.

(2) Adhere to HHS specifications for content, format, and delivery of training, which includes offering continuing education units (CEUs) for at least five States in which a Federally-facilitated Exchange or State-Based Exchange using a Federal platform is operating.

(3) Collect, store, and share with HHS training completion data from agent and broker users of the vendor's training in a manner, format, and frequency specified by HHS, and protect all data from agent and broker users of the vendor's training in accordance with applicable privacy and security requirements.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with applicable HHS guidelines for implementing the training and interfacing with HHS data systems, and the use of all data collected.

(5) Permit any individual who holds a valid State license or equivalent State authority to sell health insurance products to access the vendor's training.

(6) Provide technical support to agent and broker users of the vendor's training as specified by HHS.

(c) *Approved list.* A list of approved vendors will be published on an HHS Web site.

(d) *Monitoring.* HHS may periodically monitor and audit vendors approved under this subpart, and their records related to the training functions described in this section, to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved vendor is not in compliance with the standards required in paragraph (b) of this section, the vendor may be removed from the approved list described in paragraph (c) of this section and may be required by HHS to cease performing the training functions described under this subpart.

(e) *Appeals.* A vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section, or an approved vendor whose agreement is revoked under paragraph (d) of this section, may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section and (if applicable) the terms of its agreement with HHS. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

[80 FR 10865, Feb. 27, 2015, as amended at 81 FR 12340, Mar. 8, 2016]

§ 155.225 Certified application counselors.

(a) *General rule.* The Exchange must have a certified application counselor program that complies with the requirements of this section.

(b) *Exchange designation of organizations.* (1) The Exchange may designate an organization, including an organization designated as a Medicaid certified application counselor organization by a state Medicaid or CHIP agency, to certify its staff members or volunteers to act as certified application counselors who perform the duties and meet the standards and requirements for certified application counselors in this section if the organization—

(i) Enters into an agreement with the Exchange to comply with the standards and requirements of this section including the standards specified in paragraphs (d)(3) through (d)(5) of this section; and

(ii) Maintains a registration process and method to track the performance of certified application counselors.

(iii) Provides data and information to the Exchange regarding the number and performance of its certified application counselors and regarding the consumer assistance provided by its certified application counselors, upon request, in the form and manner specified by the Exchange. Beginning for the third quarter of calendar year 2017, in a Federally-facilitated Exchange, organizations designated by the Exchange must submit quarterly reports that include, at a minimum, data regarding the number of individuals who have been certified by the organization; the total number of consumers who received application and enrollment assistance from the organization; and of that number, the number of consumers who received assistance in applying for and selecting a QHP, enrolling in a QHP, or applying for Medicaid or CHIP.

(2) An Exchange may comply with paragraph (a) of this section either by—

(i) Designating organizations to certify application counselors in compliance with paragraph (b)(1) of this section;

(ii) Directly certifying individual staff members or volunteers of Exchange designated organizations to provide the duties specified in paragraph (c) of this section if the staff member or volunteer enters into an agreement with the Exchange to comply with the standards and requirements for certified application counselors in this section; or

(iii) A combination of paragraphs (b)(2)(i) and (b)(2)(ii) of this section.

(3) In a Federally-facilitated Exchange, no individual or entity shall be ineligible to operate as a certified application counselor or organization designated by the Exchange under paragraph (b) of this section solely because its principal place of business is outside of the Exchange service area.

(c) *Duties.* Certified application counselors are certified to—

(1) Provide information to individuals and employees about the full range of QHP options and insurance affordability programs for which they are eligible, which includes: providing fair, impartial, and accurate information that assists consumers with submitting the eligibility application; clarifying the distinctions among health coverage options, including QHPs; and helping consumers make informed decisions during the health coverage selection process;

(2) Assist individuals and employees to apply for coverage in a QHP through the Exchange and for insurance affordability programs; and

(3) Help to facilitate enrollment of eligible individuals in QHPs and insurance affordability programs.

(d) *Standards of certification.* An organization designated by the Exchange to provide certified application counselor services, or an Exchange that chooses to certify individual staff members or volunteers directly under paragraph (b)(2)(ii) of this section, may certify a staff member or volunteer to perform the duties specified in paragraph (c) of this section only if the staff member or volunteer—

(1) Completes Exchange approved training regarding QHP options, insurance affordability programs, eligibility, and benefits rules and regulations governing all insurance affordability programs operated in the state, as implemented in the state, and completes and achieves a passing score on all Exchange approved certification examinations, prior to functioning as a certified application counselor;

(2) Discloses to the organization, or to the Exchange if directly certified by an Exchange, and potential applicants any relationships the certified application counselor or sponsoring agency has with QHPs or insurance affordability programs, or other potential conflicts of interest;

(3) Complies with the Exchange's privacy and security standards adopted consistent with §155.260, and applicable authentication and data security standards;

(4) Agrees to act in the best interest of the applicants assisted;

(5) Either directly or through an appropriate referral to a Navigator or non-Navigator assistance personnel authorized under §155.205(d) and (e) or §155.210, or to the Exchange call center authorized under §155.205(a), provides information in a manner that is accessible to individuals with disabilities, as defined by the Americans with Disabilities Act, as amended, 42 U.S.C. 12101 et seq. and section 504 of the Rehabilitation Act, as amended, 29 U.S.C. 794;

(6) Enters into an agreement with the organization regarding compliance with the standards specified in paragraphs (d), (f), and (g) of this section;

(7) Is recertified on at least an annual basis after successfully completing recertification training as required by the Exchange; and

(8) Meets any licensing, certification, or other standards prescribed by the State or Exchange, if applicable, so long as such standards do not prevent the application of the provisions of title I of the Affordable Care Act. Standards that would prevent the application of the provisions of title I of the Affordable Care Act include but are not limited to the following:

(i) Requirements that certified application counselors refer consumers to other entities not required to provide fair, accurate, and impartial information.

(ii) Requirements that would prevent certified application counselors from providing services to all persons to whom they are required to provide assistance.

(iii) Requirements that would prevent certified application counselors from providing advice regarding substantive benefits or comparative benefits of different health plans.

(iv) Imposing standards that would, as applied or as implemented in a State, prevent the application of Federal requirements applicable to certified application counselors, to an organization designated by the Exchange under paragraph (b) of this section, or to the Exchange's implementation of the certified application counselor program.

(e) *Withdrawal of designation and certification.* (1) The Exchange must establish procedures to withdraw designation from a particular organization it has designated under paragraph (b) of this section, when it finds noncompliance with the terms and conditions of the organization's agreement required by paragraph (b) of this section.

(2) If an Exchange directly certifies organizations' individual certified application counselors, it must establish procedures to withdraw certification from individual certified application counselors when it finds noncompliance with the requirements of this section.

(3) An organization designated by the Exchange under paragraph (b) of this section must establish procedures to withdraw certification from individual certified application counselors when

it finds noncompliance with the requirements of this section.

(f) *Availability of information; authorization.* An organization designated by the Exchange under paragraph (b) of this section, or, if applicable, an Exchange that certifies staff members or volunteers of organizations directly must establish procedures to ensure that applicants—

(1) Are informed, prior to receiving assistance, of the functions and responsibilities of certified application counselors, including that certified application counselors are not acting as tax advisers or attorneys when providing assistance as certified application counselors and cannot provide tax or legal advice within their capacity as certified application counselors;

(2) Provide authorization in a form and manner as determined by the Exchange prior to a certified application counselor obtaining access to an applicant's personally identifiable information, and that the organization or certified application counselor maintains a record of the authorization in a form and manner as determined by the Exchange. The Exchange must establish a reasonable retention period for maintaining these records. In Federally-facilitated Exchanges, this period is no less than six years, unless a different and longer retention period has already been provided under other applicable Federal law; and

(3) May revoke at any time the authorization provided the certified application counselor, pursuant to paragraph (f)(2) of this section.

(g) *Fees, consideration, solicitation, and marketing.* Organizations designated by the Exchange under paragraph (b) of this section and certified application counselors must not—

(1) Impose any charge on applicants or enrollees for application or other assistance related to the Exchange;

(2) Receive any consideration directly or indirectly from any health insurance issuer or issuer of stop-loss insurance in connection with the enrollment of any individuals in a QHP or a non-QHP. In a Federally-facilitated Exchange, no health care provider shall be ineligible to operate as a certified application counselor or organization designated by the Exchange under paragraph (b) of this section solely because it receives consideration from a health insurance issuer for health care services provided;

(3) Beginning November 15, 2014, if operating in a Federally-facilitated Exchange, provide compensation to individual certified application counselors on a per-application, per-individual-assisted, or per-enrollment basis;

(4) Provide to an applicant or potential enrollee gifts of any value as an inducement for enrollment. The value of gifts provided to applicants and potential enrollees for purposes other than as an inducement for enrollment must not exceed nominal value, either individually or in the aggregate, when provided to that individual during a single encounter. For purposes of this paragraph (g)(4), the term gifts includes gift items, gift cards, cash cards, cash, and promotional items that market or promote the products or services of a third party, but does not include the reimbursement of legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as travel or postage expenses; or

(5) [Reserved]

(6) Initiate any telephone call to a consumer using an automatic telephone dialing system or an artificial or prerecorded voice, except in cases where the individual certified application counselor or designated organization has a relationship with the consumer and so long as other applicable State and Federal laws are otherwise complied with.

[78 FR 42861, July 17, 2013, as amended at 79 FR 30345, May 27, 2014; 79 FR 42986, July 24, 2014; 81 FR 12341, Mar. 8, 2016; 88 FR 25918, Apr. 27, 2023]

§ 155.227 Authorized representatives.

(a) *General rule.* (1) The Exchange must permit an applicant or enrollee in the individual or small group market, subject to applicable privacy and security requirements, to designate an individual person or organization to act on his or her behalf in applying for an eligibility determination or redetermination, under subpart D, G, or H of this part, and in carrying out other ongoing communications with the Exchange.

(2) Designation of an authorized representative must be in a written document signed by the applicant or enrollee, or through another legally binding format subject to applicable authentication and data security standards. If submitted, legal documentation of authority to act on behalf of an applicant or enrollee under State law, such as a court order establishing legal guardianship or a power of attorney, shall serve in the place of the applicant's or enrollee's signature.

(3) The Exchange must ensure that the authorized representative agrees to maintain, or be legally bound to maintain, the confidentiality of any information regarding the applicant or enrollee provided by the Exchange.

(4) The Exchange must ensure that the authorized representative is responsible for fulfilling all responsibilities encompassed within the scope of the authorized representation, as described in this section, to the same extent as the applicant or enrollee he or she represents.

(5) The Exchange must provide information both to the applicant or enrollee, and to the authorized representative, regarding the powers and duties of authorized representatives.

(b) *Timing of designation.* The Exchange must permit an applicant or enrollee to designate an authorized representative:

(1) At the time of application; and

(2) At other times and through methods as described in §155.405(c)(2).

(c) *Duties.* (1) The Exchange must permit an applicant or enrollee to authorize his or her representative to:

(i) Sign an application on the applicant or enrollee's behalf;

(ii) Submit an update or respond to a redetermination for the applicant or enrollee in accordance with §155.330 or §155.335;

(iii) Receive copies of the applicant's or enrollee's notices and other communications from the Exchange; and

(iv) Act on behalf of the applicant or enrollee in all other matters with the Exchange.

(2) The Exchange may permit an applicant or enrollee to authorize a representative to perform fewer than all of the activities described in paragraph (c)(1) of this section, provided that the Exchange tracks the specific permissions for each authorized representative.

(d) *Duration.* The Exchange must consider the designation of an authorized representative valid until:

(1) The applicant or enrollee notifies the Exchange that the representative is no longer authorized to act on his or her behalf using one of the methods available for the submission of an application, as described in §155.405(c). The Exchange must notify the authorized representative of such change; or

(2) The authorized representative informs the Exchange and the applicant or enrollee that he or she no longer is acting in such capacity. An authorized representative must notify the Exchange and the applicant or enrollee on whose behalf he or she is acting when the authorized representative no longer has legal authority to act on behalf of the applicant or enrollee.

(e) *Compliance with State and Federal law.* The Exchange must require an authorized representative to comply with applicable state and federal laws concerning conflicts of interest and confidentiality of information.

(f) *Signature.* For purposes of this section, designation of an authorized representative must be through a written document signed by the applicant or enrollee, or through another legally binding format, as described in §155.227(a)(2), and must be accepted through all of the modalities described in §155.405(c).

[78 FR 42313, July 15, 2013]

§155.230 General standards for Exchange notices.

(a) *General requirement.* Any notice required to be sent by the Exchange to individuals or employers must be written and include:

(1) An explanation of the action reflected in the notice, including the effective date of the action.

(2) Any factual findings relevant to the action.

(3) Citations to, or identification of, the relevant regulations supporting the action.

(4) Contact information for available customer service resources.

(5) An explanation of appeal rights, if applicable.

(b) *Accessibility and readability requirements.* All applications, forms, and notices, including the single, streamlined application described in §155.405 and notice of annual redetermination described in §155.335(c), must conform to the standards outlined in §155.205(c).

(c) *Re-evaluation of appropriateness and usability.* The Exchange must re-evaluate the appropriateness and usability of applications, forms, and notices.

(d) *Electronic notices.* (1) The individual market Exchange must provide required notices either through standard mail, or if an individual or employer elects, electronically, provided that the requirements for electronic notices in 42 CFR 435.918 are met, except that the individual market Exchange is not required to implement the process specified in 42 CFR 435.918(b)(1) for eligibility determinations for enrollment in a QHP through the Exchange and insurance affordability programs that are effective before January 1, 2015.

(2) Unless otherwise required by Federal or State law, the SHOP must provide required notices electronically or, if an employer or employee elects, through standard mail. If notices are provided electronically, the SHOP must comply with the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) for the employer or employee.

(3) In the event that an individual market Exchange or SHOP is unable to send select required notices electronically due to technical limitations, it may instead send these notices through standard mail, even if an election has been made to receive such notices electronically.

[77 FR 11718, Feb. 27, 2012, as amended at 78 FR 42314, July 15, 2013; 81 FR 94177, Dec. 22, 2016]

§155.240 Payment of premiums.

(a) *Payment by individuals.* The Exchange must allow a qualified individual to pay any applicable premium owed by such individual directly to the QHP issuer.

(b) *Payment by tribes, tribal organizations, and urban Indian organizations.* The Exchange may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, including aggregated payment, subject to terms and conditions determined by the Exchange.

(c) *Payment facilitation.* The Exchange may establish a process to facilitate through electronic means the collection and payment of premiums to QHP issuers.

(d) *Required standards.* In conducting an electronic transaction with a QHP issuer that involves the payment of premiums or an electronic funds transfer, the Exchange must comply with the privacy and security standards adopted in accordance with §155.260 and use the standards and operating rules referenced in §155.270.

(e) *Premium calculation.* The Exchange may establish one or more standard processes for premium calculation.

(1) For a Federally-facilitated Exchange, the premium for coverage lasting less than one month must equal the product of—

(i) The premium for one month of coverage divided by the number of days in the month; and

(ii) The number of days for which coverage is being provided in the month described in paragraph (e)(1)(i) of this section.

(2) [Reserved]

[77 FR 18444, Mar. 27, 2012, as amended at 79 FR 30346, May 27, 2014]

§155.260 Privacy and security of personally identifiable information.

(a) *Creation, collection, use and disclosure.* (1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in §155.300; or determining eligibility for exemptions from the individual shared responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary:

(i) For the Exchange to carry out the functions described in §155.200;

(ii) For the Exchange to carry out other functions not described in paragraph (a)(1)(i) of this section, which the

Secretary determines to be in compliance with section 1411(g)(2)(A) of the Affordable Care Act and for which an individual provides consent for his or her information to be used or disclosed; or

(iii) For the Exchange to carry out other functions not described in paragraphs (a)(1)(i) and (ii) of this section, for which an individual provides consent for his or her information to be used or disclosed, and which the Secretary determines are in compliance with section 1411(g)(2)(A) of the Affordable Care Act under the following substantive and procedural requirements:

(A) *Substantive requirements.* The Secretary may approve other uses and disclosures of personally identifiable information created or collected as described in paragraph (a)(1) of this section that are not described in paragraphs (a)(1)(i) or (ii) of this section, provided that HHS determines that the information will be used only for the purposes of and to the extent necessary in ensuring the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act, and that the uses and disclosures are also permissible under relevant law and policy.

(B) *Procedural requirements for approval of a use or disclosure of personally identifiable information.* To seek approval for a use or disclosure of personally identifiable information created or collected as described in paragraph (a)(1) of this section that is not described in paragraphs (a)(1)(i) or (ii) of this section, the Exchange must submit the following information to HHS:

(*1*) Identity of the Exchange and appropriate contact persons;

(*2*) Detailed description of the proposed use or disclosure, which must include, but not necessarily be limited to, a listing or description of the specific information to be used or disclosed and an identification of the persons or entities that may access or receive the information;

(*3*) Description of how the use or disclosure will ensure the efficient operation of the Exchange consistent with section 1411(g)(2)(A) of the Affordable Care Act; and

(*4*) Description of how the information to be used or disclosed will be protected in compliance with privacy and security standards that meet the requirements of this section or other relevant law, as applicable.

(2) The Exchange may not create, collect, use, or disclose personally identifiable information unless the creation, collection, use, or disclosure is consistent with this section.

(3) The Exchange must establish and implement privacy and security standards that are consistent with the following principles:

(i) *Individual access.* Individuals should be provided with a simple and timely means to access and obtain their personally identifiable information in a readable form and format;

(ii) *Correction.* Individuals should be provided with a timely means to dispute the accuracy or integrity of their personally identifiable information and to have erroneous information corrected or to have a dispute documented if their requests are denied;

(iii) *Openness and transparency.* There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their personally identifiable information;

(iv) *Individual choice.* Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their personally identifiable information;

(v) *Collection, use, and disclosure limitations.* Personally identifiable information should be created, collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately;

(vi) *Data quality and integrity.* Persons and entities should take reasonable steps to ensure that personally identifiable information is complete, accurate, and up-to-date to the extent necessary for the person's or entity's intended purposes and has not been altered or destroyed in an unauthorized manner;

(vii) *Safeguards.* Personally identifiable information should be protected with reasonable operational, administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent

unauthorized or inappropriate access, use, or disclosure; and,

(viii) *Accountability*. These principles should be implemented, and adherence assured, through appropriate monitoring and other means and methods should be in place to report and mitigate non-adherence and breaches.

(4) For the purposes of implementing the principle described in paragraph (a)(3)(vii) of this section, the Exchange must establish and implement operational, technical, administrative and physical safeguards that are consistent with any applicable laws (including this section) to ensure—

(i) The confidentiality, integrity, and availability of personally identifiable information created, collected, used, and/or disclosed by the Exchange;

(ii) Personally identifiable information is only used by or disclosed to those authorized to receive or view it;

(iii) Return information, as such term is defined by section 6103(b)(2) of the Code, is kept confidential under section 6103 of the Code;

(iv) Personally identifiable information is protected against any reasonably anticipated threats or hazards to the confidentiality, integrity, and availability of such information;

(v) Personally identifiable information is protected against any reasonably anticipated uses or disclosures of such information that are not permitted or required by law; and

(vi) Personally identifiable information is securely destroyed or disposed of in an appropriate and reasonable manner and in accordance with retention schedules;

(5) The Exchange must monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of those controls.

(6) The Exchange must develop and utilize secure electronic interfaces when sharing personally identifiable information electronically.

(b) *Application to non-Exchange entities*—(1) *Non-Exchange entities.* A non-Exchange entity is any individual or entity that:

(i) Gains access to personally identifiable information submitted to an Exchange; or

(ii) Collects, uses, or discloses personally identifiable information gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing functions agreed to with the Exchange.

(2) Prior to any person or entity becoming a non-Exchange entity, Exchanges must execute with the person or entity a contract or agreement that includes:

(i) A description of the functions to be performed by the non-Exchange entity;

(ii) A provision(s) binding the non-Exchange entity to comply with the privacy and security standards and obligations adopted in accordance with paragraph (b)(3) of this section, and specifically listing or incorporating those privacy and security standards and obligations;

(iii) A provision requiring the non-Exchange entity to monitor, periodically assess, and update its security controls and related system risks to ensure the continued effectiveness of those controls in accordance with paragraph (a)(5) of this section;

(iv) A provision requiring the non-Exchange entity to inform the Exchange of any change in its administrative, technical, or operational environments defined as material within the contract; and

(v) A provision that requires the non-Exchange entity to bind any downstream entities to the same privacy and security standards and obligations to which the non-Exchange entity has agreed in its contract or agreement with the Exchange.

(3) When collection, use or disclosure is not otherwise required by law, the privacy and security standards to which an Exchange binds non-Exchange entities must:

(i) Be consistent with the principles and requirements listed in paragraphs (a)(1) through (6) of this section, including being at least as protective as the standards the Exchange has established and implemented for itself in compliance with paragraph (a)(3) of this section;

(ii) Comply with the requirements of paragraphs (c), (d), (f), and (g) of this section; and

(iii) Take into specific consideration:

(A) The environment in which the non-Exchange entity is operating;

(B) Whether the standards are relevant and applicable to the non-Exchange entity's duties and activities in connection with the Exchange; and

(C) Any existing legal requirements to which the non-Exchange entity is bound in relation to its administrative, technical, and operational controls and practices, including but not limited to, its existing data handling and information technology processes and protocols.

(c) *Workforce compliance.* The Exchange must ensure its workforce complies with the policies and procedures developed and implemented by the Exchange to comply with this section.

(d) *Written policies and procedures.* Policies and procedures regarding the creation collection, use, and disclosure of personally identifiable information must, at minimum:

(1) Be in writing, and available to the Secretary of HHS upon request; and

(2) Identify applicable law governing collection, use, and disclosure of personally identifiable information.

(e) *Data sharing.* Data matching and sharing arrangements that facilitate the sharing of personally identifiable information between the Exchange and agencies administering Medicaid, CHIP or the BHP for the exchange of eligibility information must:

(1) Meet any applicable requirements described in this section;

(2) Meet any applicable requirements described in section 1413(c)(1) and (c)(2) of the Affordable Care Act;

(3) Be equal to or more stringent than the requirements for Medicaid programs under section 1942 of the Act; and

(4) For those matching agreements that meet the definition of ''matching program'' under 5 U.S.C. 552a(a)(8), comply with 5 U.S.C. 552a(o).

(f) *Compliance with the Code.* Return information, as defined in section 6103(b)(2) of the Code, must be kept confidential and disclosed, used, and maintained only in accordance with section 6103 of the Code.

(g) *Improper use and disclosure of information.* Any person who knowingly and willfully uses or discloses information in violation of section 1411(g) of the Affordable Care Act will be subject to a CMP of not more than $25,000 as adjusted annually under 45 CFR part 102 per person or entity, per use or disclosure, consistent with the bases and process for imposing civil penalties specified at §155.285, in addition to other penalties that may be prescribed by law.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 79 FR 13837, Mar. 11, 2014; 79 FR 30346, May 27, 2014; 81 FR 12341, Mar. 8, 2016; 81 FR 61581, Sept. 6, 2016]

§ 155.270 Use of standards and protocols for electronic transactions.

(a) *HIPAA administrative simplification.* To the extent that the Exchange performs electronic transactions with a covered entity, the Exchange must use standards, implementation specifications, operating rules, and code sets that are adopted by the Secretary in 45 CFR parts 160 and 162 or that are otherwise approved by HHS.

(b) *HIT enrollment standards and protocols.* The Exchange must incorporate interoperable and secure standards and protocols developed by the Secretary in accordance with section 3021 of the PHS Act. Such standards and protocols must be incorporated within Exchange information technology systems.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 54135, Aug. 30, 2013]

§ 155.280 Oversight and monitoring of privacy and security requirements.

(a) *General.* HHS will oversee and monitor the Federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and non-Exchange entities required to comply with the privacy and security standards established and implemented by a Federally-facilitated Exchange pursuant to §155.260 for compliance with those standards. HHS will oversee and monitor State Exchanges for compliance with the standards State Exchanges establish and implement pursuant to §155.260. State Exchanges will oversee and monitor non-Exchange entities required to comply with the privacy and security standards established and implemented by a State Exchange in accordance to §155.260.

(b) *Audits and investigations.* HHS may conduct oversight activities that

include but are not limited to the following: audits, investigations, inspections, and any reasonable activities necessary for appropriate oversight of compliance with the Exchange privacy and security standards. HHS may also pursue civil, criminal or administrative proceedings or actions as determined necessary.

[78 FR 54135, Aug. 30, 2013, as amended at 81 FR 12341, Mar. 8, 2016]

§ 155.285 Bases and process for imposing civil penalties for provision of false or fraudulent information to an Exchange or improper use or disclosure of information.

(a) *Grounds for imposing civil money penalties.* (1) HHS may impose civil money penalties on any person, as defined in paragraph (a)(2) of this section, if, based on credible evidence, HHS reasonably determines that a person has engaged in one or more of the following actions:

(i) Failure to provide correct information under section 1411(b) of the Affordable Care Act where such failure is attributable to negligence or disregard of any rules or regulations of the Secretary with negligence and disregard defined as they are in section 6662 of the Internal Revenue Code of 1986:

(A) ''Negligence'' includes any failure to make a reasonable attempt to provide accurate, complete, and comprehensive information; and

(B) ''Disregard'' includes any careless, reckless, or intentional disregard for any rules or regulations of the Secretary.

(ii) Knowing and willful provision of false or fraudulent information required under section 1411(b) of the Affordable Care Act, where knowing and willful means the intentional provision of information that the person knows to be false or fraudulent; or

(iii) Knowing and willful use or disclosure of information in violation of section 1411(g) of the Affordable Care Act, where knowing and willful means the intentional use or disclosure of information in violation of section 1411(g). Such violations would include, but not be limited to, the following:

(A) Any use or disclosure performed which violates relevant privacy and security standards established by the Exchange pursuant to § 155.260;

(B) Any other use or disclosure which has not been determined by the Secretary to be in compliance with section 1411(g)(2)(A) of the Affordable Care Act pursuant to § 155.260(a); and

(C) Any other use or disclosure which is not necessary to carry out a function described in a contract with a non-Exchange entity executed pursuant to § 155.260(b)(2).

(2) For purposes of this section, the term ''person'' is defined to include, but is not limited to, all individuals; corporations; Exchanges; Medicaid and CHIP agencies; other entities gaining access to personally identifiable information submitted to an Exchange to carry out additional functions which the Secretary has determined ensure the efficient operation of the Exchange pursuant to § 155.260(a)(1); and non-Exchange entities as defined in § 155.260(b) which includes agents, brokers, Web-brokers, QHP issuers, Navigators, non-Navigator assistance personnel, certified application counselors, in-person assistors, and other third party contractors.

(b) *Factors in determining the amount of civil money penalties imposed.* In determining the amount of civil money penalties, HHS may take into account factors which include, but are not limited to, the following:

(1) The nature and circumstances of the conduct including, but not limited to:

(i) The number of violations;

(ii) The severity of the violations;

(iii) The person's history with the Exchange including any prior violations that would indicate whether the violation is an isolated occurrence or represents a pattern of behavior;

(iv) The length of time of the violation;

(v) The number of individuals affected or potentially affected;

(vi) The extent to which the person received compensation or other consideration associated with the violation;

(vii) Any documentation provided in any complaint or other information, as well as any additional information provided by the individual to refute performing the violation; and

(viii) Whether other remedies or penalties have been imposed for the same conduct or occurrence.

(2) The nature of the harm resulting from, or reasonably expected to result from, the violation, including but not limited to:

(i) Whether the violation resulted in actual or potential financial harm;

(ii) Whether there was actual or potential harm to an individual's reputation;

(iii) Whether the violation hindered or could have hindered an individual's ability to obtain health insurance coverage;

(iv) [Reserved]

(v) The actual or potential impact of the provision of false or fraudulent information or of the improper use or disclosure of the information; and

(vi) Whether any person received a more favorable eligibility determination for enrollment in a QHP or insurance affordability program, such as greater advance payment of the premium tax credits or cost-sharing reductions than he or she would be eligible for if the correct information had been provided.

(3) No penalty will be imposed under paragraph (a)(1)(i) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information required under section 1411(b) of the Affordable Care Act and that the person acted in good faith.

(c) *Maximum penalty.* The amount of a civil money penalty will be determined by HHS in accordance with paragraph (b) of this section.

(1) The following provisions provide maximum penalties for a single ''plan year,'' where ''plan year'' has the same meaning as at §155.20:

(i) Any person who fails to provide correct information as specified in paragraph (a)(1)(i) of this section may be subject to a maximum civil money penalty of $25,000 as adjusted annually under 45 CFR part 102 for each application, as defined at paragraph (c)(1)(iii) of this section, pursuant to which a person fails to provide correct information.

(ii) Any person who knowingly and willfully provides false information as specified in paragraph (a)(1)(ii) of this section may be subject to a maximum civil money penalty of $250,000 as adjusted annually under 45 CFR part 102 for each application, as defined at paragraph (c)(1)(iii) of this section, on which a person knowingly and willfully provides false information.

(iii) For the purposes of this subsection, ''application'' is defined as a submission of information, whether through an online portal, over the telephone through a call center, or through a paper submission process, in which the information is provided in relation to an eligibility determination; an eligibility redetermination based on a change in an individual's circumstances; or an annual eligibility redetermination for any of the following:

(A) Enrollment in a qualified health plan;

(B) Premium tax credits or cost sharing reductions; or

(C) An exemption from the individual shared responsibility payment.

(2) Any person who knowingly or willfully uses or discloses information as specified in paragraph (a)(1)(iii) of this section may be subject to the following civil money penalty:

(i) A civil money penalty for each use or disclosure described in paragraph (a)(1)(iii) of this section of not more than $25,000 as adjusted annually under 45 CFR part 102 per use or disclosure.

(ii) For purposes of paragraph (c) of this section, a use or disclosure includes one separate use or disclosure of a single individual's personally identifiable information where the person against whom a civil money penalty may be imposed has made the use or disclosure.

(3) These penalties may be imposed in addition to any other penalties that may be prescribed by law.

(d) *Notice of intent to issue civil money penalty.* If HHS intends to impose a civil money penalty in accordance with this part, HHS will send a written notice of such intent to the person against whom it intends to impose a civil money penalty.

(1) This written notice will be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required. The written notice must include the following elements:

(i) A description of the findings of fact regarding the violations with respect to which the civil money penalty is proposed;

(ii) The basis and reasons why the findings of fact subject the person to a penalty;

(iii) Any circumstances described in paragraph (b) of this section that were considered in determining the amount of the proposed penalty;

(iv) The amount of the proposed penalty;

(v) An explanation of the person's right to a hearing under any applicable administrative hearing process;

(vi) A statement that failure to request a hearing within 60 calendar days after the date of issuance printed on the notice permits the assessment of the proposed penalty; and

(vii) Information explaining how to file a request for a hearing and the address to which the hearing request must be sent.

(2) The person may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with the procedure to file an appeal specified in paragraph (f) of this section.

(e) *Failure to request a hearing.* If the person does not request a hearing within 60 calendar days of the date of issuance printed on the notice described in paragraph (d) of this section, HHS may impose the proposed civil money penalty.

(1) HHS will notify the person in writing of any penalty that has been imposed, the means by which the person may satisfy the penalty, and the date on which the penalty is due.

(2) A person has no right to appeal a penalty with respect to which the person has not timely requested a hearing in accordance with paragraph (d) of this section.

(f) *Appeal of proposed penalty.* Subject to paragraph (e)(2) of this section, any person against whom HHS proposed to impose a civil money penalty may appeal that penalty in accordance with the rules and procedures outlined at 45 CFR part 150, subpart D, excluding §§ 150.461, 150.463, and 150.465.

(g) *Enforcement authority*—(1) *HHS.* HHS may impose civil money penalties up to the maximum amounts specified in paragraph (d) of this section for any of the violations described in paragraph (a) of this section.

(2) *OIG.* In accordance with the rules and procedures of 42 CFR part 1003, and in place of imposition of penalties by CMS, the OIG may impose civil money penalties for violations described in paragraph (a)(1)(ii) of this section.

(h) *Settlement authority.* Nothing in this section limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 155.285(d) or to compromise on any penalty provided for in this section.

(i) *Limitations.* No action under this section will be entertained unless commenced, in accordance with § 155.285(d), within 6 years from the date on which the violation occurred.

[79 FR 30346, May 27, 2014, as amended at 81 FR 61581, Sept. 6, 2016]

Subpart D—Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

§ 155.300 Definitions and general standards for eligibility determinations.

(a) *Definitions.* In addition to those definitions in § 155.20, for purposes of this subpart, the following terms have the following meaning:

Applicable Children's Health Insurance Program (CHIP) MAGI-based income standard means the applicable income standard as defined at 42 CFR 457.310(b)(1), as applied under the State plan adopted in accordance with title XXI of the Act, or waiver of such plan and as certified by the State CHIP Agency in accordance with 42 CFR 457.348(d), for determining eligibility for child health assistance and enrollment in a separate child health program.

Applicable Medicaid modified adjusted gross income (MAGI)-based income standard has the same meaning as ''applicable modified adjusted gross income standard,'' as defined at 42 CFR 435.911(b), as applied under the State plan adopted in accordance with title XIX of the Act, or waiver of such plan,

and as certified by the State Medicaid agency in accordance with 42 CFR 435.1200(b)(2) for determining eligibility for Medicaid.

Federal poverty level or *FPL* means the most recently published Federal poverty level, updated periodically in the FEDERAL REGISTER by the Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2), as of the first day of the annual open enrollment period for coverage in a QHP through the Exchange, as specified in §155.410.

Indian means any individual as defined in section 4(d) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

Insurance affordability program has the same meaning as ''insurance affordability program,'' as specified in 42 CFR 435.4.

MAGI-based income has the same meaning as it does in 42 CFR 435.603(e).

Minimum value when used to describe coverage in an eligible employer-sponsored plan, means that the employer-sponsored plan meets the standards for coverage of the total allowed costs of benefits set forth in §156.145.

Modified Adjusted Gross Income (MAGI) has the same meaning as it does in 26 CFR 1.36B–1(e)(2).

Non-citizen means an individual who is not a citizen or national of the United States, in accordance with section 101(a)(3) of the Immigration and Nationality Act.

Qualifying coverage in an eligible employer-sponsored plan means coverage in an eligible employer-sponsored plan that meets the affordability and minimum value standards specified in 26 CFR 1.36B–2(c)(3).

State CHIP Agency means the agency that administers a separate child health program established by the State under title XXI of the Act in accordance with implementing regulations at 42 CFR 457.

State Medicaid Agency means the agency established or designated by the State under title XIX of the Act that administers the Medicaid program in accordance with implementing regulations at 42 CFR parts 430 through 456.

Tax dependent has the same meaning as the term dependent under section 152 of the Code.

Tax filer means an individual, or a married couple, who indicates that he, she or they expects—

(1) To file an income tax return for the benefit year, in accordance with 26 U.S.C. 6011, 6012, and implementing regulations;

(2) If married (within the meaning of 26 CFR 1.7703–1), to file a joint tax return for the benefit year;

(3) That no other taxpayer will be able to claim him, her or them as a tax dependent for the benefit year; and

(4) That he, she, or they expects to claim a personal exemption deduction under section 151 of the Code on his or her tax return for one or more applicants, who may or may not include himself or herself and his or her spouse.

(b) *Medicaid and CHIP.* In general, references to Medicaid and CHIP regulations in this subpart refer to those regulations as implemented in accordance with rules and procedures which are the same as those applied by the State Medicaid or State CHIP agency or approved by such agency in the agreement described in §155.345(a).

(c) *Attestation.* (1) Except as specified in paragraph (c)(2) of this section, for the purposes of this subpart, an attestation may be made by the application filer.

(2) The attestations specified in §§155.310(d)(2)(ii) and 155.315(f)(4)(ii) must be provided by the tax filer.

(d) *Reasonably compatible.* For purposes of this subpart, the Exchange must consider information obtained through electronic data sources, other information provided by the applicant, or other information in the records of the Exchange to be reasonably compatible with an applicant's attestation if the difference or discrepancy does not impact the eligibility of the applicant, including the amount of advance payments of the premium tax credit or category of cost-sharing reductions.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42314, July 15, 2013]

§155.302 Options for conducting eligibility determinations.

(a) *Options for conducting eligibility determinations.* The Exchange may satisfy the requirements of this subpart—

(1) Directly, through contracting arrangements in accordance with §155.110(a) under which the Exchange carries out all eligibility determinations for QHP coverage and related insurance affordability programs; or, as a State-based Exchange on the Federal platform, through a Federal platform agreement under which HHS carries out eligibility determinations and other requirements contained within this subpart; or

(2) Through a combination of the approach described in paragraph (a)(1) of this section and one or both of the options described in paragraph (b) or (c) of this section, subject to the standards in paragraph (d) of this section.

(b) *Medicaid and CHIP.* Notwithstanding the requirements of this subpart, the Exchange may conduct an assessment of eligibility for Medicaid and CHIP, rather than an eligibility determination for Medicaid and CHIP, provided that—

(1) The Exchange makes such an assessment based on the applicable Medicaid and CHIP MAGI-based income standards and citizenship and immigration status, using verification rules and procedures consistent with 42 CFR parts 435 and 457, without regard to how such standards are implemented by the State Medicaid and CHIP agencies.

(2) Notices and other activities required in connection with an eligibility determination for Medicaid or CHIP are performed by the Exchange consistent with the standards identified in this subpart or the State Medicaid or CHIP agency consistent with applicable law.

(3) *Applicants found potentially eligible for Medicaid or CHIP.* When the Exchange assesses an applicant as potentially eligible for Medicaid or CHIP consistent with the standards in paragraph (b)(1) of this section, the Exchange transmits all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency or CHIP agency via secure electronic interface, promptly and without undue delay.

(4) *Applicants not found potentially eligible for Medicaid and CHIP.* (i) If the Exchange conducts an assessment in accordance with paragraph (b) of this section and finds that an applicant is not potentially eligible for Medicaid or CHIP based on the applicable Medicaid and CHIP MAGI-based income standards, the Exchange must consider the applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions and must notify such applicant, and provide him or her with the opportunity to—

(A) Withdraw his or her application for Medicaid and CHIP, unless the Exchange has assessed the applicant as potentially eligible for Medicaid based on factors not otherwise considered in this subpart, in accordance with §155.345(b), and provided that the application will not be considered withdrawn if he or she appeals his or her eligibility determination for advance payments of the premium tax credit or cost-sharing reductions and the appeals entity described in §155.500(a) finds that the individual is potentially eligible for Medicaid or CHIP; or

(B) Request a full determination of eligibility for Medicaid and CHIP by the applicable State Medicaid and CHIP agencies.

(ii) To the extent that an applicant described in paragraph (b)(4)(i) of this section requests a full determination of eligibility for Medicaid and CHIP, the Exchange must—

(A) Transmit all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency and CHIP agency via secure electronic interface, promptly and without undue delay; and

(B) Consider such an applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions until the State Medicaid or CHIP agency notifies the Exchange that the applicant is eligible for Medicaid or CHIP.

(5) The Exchange and the Exchange appeals entity adheres to the eligibility determination or appeals decision for Medicaid or CHIP made by the

State Medicaid or CHIP agency, or the appeals entity for such agency.

(6) The Exchange and the State Medicaid and CHIP agencies enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for Medicaid and CHIP, and provide a copy of such agreement to HHS upon request.

(c) *Advance payments of the premium tax credit and cost-sharing reductions.* Notwithstanding the requirements of this subpart, the Exchange may implement a determination of eligibility for advance payments of the premium tax credit and cost-sharing reductions made by HHS, provided that—

(1) Verifications, notices, and other activities required in connection with an eligibility determination for advance payments of the premium tax credit and cost-sharing reductions are performed by the Exchange in accordance with the standards identified in this subpart or by HHS in accordance with the agreement described in paragraph (c)(4) of this section;

(2) The Exchange transmits all information provided as a part of the application, update, or renewal that initiated the eligibility determination, and any information obtained or verified by the Exchange, to HHS via secure electronic interface, promptly and without undue delay;

(3) The Exchange adheres to the eligibility determination for advance payments of the premium tax credit and cost-sharing reductions made by HHS; and

(4) The Exchange and HHS enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions.

(d) *Standards.* To the extent that assessments of eligibility for Medicaid and CHIP based on MAGI or eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions are made in accordance with paragraphs (b) or (c) of this section, the Exchange must ensure that—

(1) Eligibility processes for all insurance affordability programs are streamlined and coordinated across HHS, the Exchange, the State Medicaid agency, and the State CHIP agency, as applicable;

(2) Such arrangement does not increase administrative costs and burdens on applicants, enrollees, beneficiaries, or application filers, or increase delay; and

(3) Applicable requirements under 45 CFR 155.260, 155.270, and 155.315(i), and section 6103 of the Code for the confidentiality, disclosure, maintenance, and use of information are met.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42314, July 15, 2013; 81 FR 12341, Mar. 8, 2016; 89 FR 26421, Apr. 15, 2024]

§ 155.305 Eligibility standards.

(a) *Eligibility for enrollment in a QHP through the Exchange.* The Exchange must determine an applicant eligible for enrollment in a QHP through the Exchange if he or she meets the following requirements:

(1) *Citizenship, status as a national, or lawful presence.* Is a citizen or national of the United States, or is a non-citizen who is lawfully present in the United States, and is reasonably expected to be a citizen, national, or a non-citizen who is lawfully present for the entire period for which enrollment is sought;

(2) *Incarceration.* Is not incarcerated, other than incarceration pending the disposition of charges; and

(3) *Residency.* Meets the applicable residency standard identified in this paragraph (a)(3).

(i) For an individual who is age 21 and over, is not living in an institution as defined in 42 CFR 435.403(b), is capable of indicating intent, and is not receiving an optional State supplementary payment as addressed in 42 CFR 435.403(f), the service area of the Exchange of the individual is the service areas of the Exchange in which he or she is living and—

(A) Intends to reside, including without a fixed address; or

(B) Has entered with a job commitment or is seeking employment (whether or not currently employed).

(ii) For an individual who is under the age of 21, is not living in an institution as defined in 42 CFR 435.403(b), is not eligible for Medicaid based on receipt of assistance under title IV–E of the Social Security Act as addressed in 42 CFR 435.403(g), is not emancipated,

is not receiving an optional State supplementary payment as addressed in 42 CFR 435.403(f), the Exchange service area of the individual—

(A) Is the service area of the Exchange in which he or she resides, including without a fixed address; or

(B) Is the service area of the Exchange of a parent or caretaker, established in accordance with paragraph (a)(3)(i) of this section, with whom the individual resides.

(iii) *Other special circumstances.* In the case of an individual who is not described in paragraphs (a)(3)(i) or (ii) of this section, the Exchange must apply the residency requirements described in 42 CFR 435.403 with respect to the service area of the Exchange.

(iv) *Special rule for tax households with members in multiple Exchange service areas.* (A) Except as specified in paragraph (a)(3)(iv)(B) of this section if all of the members of a tax household are not within the same Exchange service area, in accordance with the applicable standards in paragraphs (a)(3)(i), (ii), and (iii) of this section, any member of the tax household may enroll in a QHP through any of the Exchanges for which one of the tax filers meets the residency standard.

(B) If both spouses in a tax household enroll in a QHP through the same Exchange, a tax dependent may only enroll in a QHP through that Exchange, or through the Exchange that services the area in which the dependent meets a residency standard described in paragraphs (a)(3)(i), (ii), or (iii) of this section.

(v) *Temporary absence.* The Exchange may not deny or terminate an individual's eligibility for enrollment in a QHP through the Exchange if the individual meets the standards in paragraph (a)(3) of this section but for a temporary absence from the service area of the Exchange and intends to return when the purpose of the absence has been accomplished.

(b) *Eligibility for QHP enrollment periods.* The Exchange must determine an applicant eligible for an enrollment period if he or she meets the criteria for an enrollment period, as specified in §§ 155.410 and 155.420.

(c) *Eligibility for Medicaid.* The Exchange must determine an applicant eligible for Medicaid if he or she meets the non-financial eligibility criteria for Medicaid for populations whose eligibility is based on MAGI-based income, as certified by the Medicaid agency in accordance with 42 CFR 435.1200(b)(2), has a household income, as defined in 42 CFR 435.603(d), that is at or below the applicable Medicaid MAGI-based income standard as defined in 42 CFR 435.911(b)(1) and—

(1) Is a pregnant woman, as defined in the Medicaid State Plan in accordance with 42 CFR 435.4;

(2) Is under age 19;

(3) Is a parent or caretaker relative of a dependent child, as defined in the Medicaid State plan in accordance with 42 CFR 435.4; or

(4) Is not described in paragraph (c)(1), (2), or (3) of this section, is under age 65 and is not 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 title XVIII of the Social Security Act.

(d) *Eligibility for CHIP.* The Exchange must determine an applicant eligible for CHIP if he or she meets the requirements of 42 CFR 457.310 through 457.320 and has a household income, as defined in 42 CFR 435.603(d), at or below the applicable CHIP MAGI-based income standard.

(e) *Eligibility for BHP.* If a BHP is operating in the service area of the Exchange, the Exchange must determine an applicant eligible for the BHP if he or she meets the requirements specified in section 1331(e) of the Affordable Care Act and regulations implementing that section.

(f) *Eligibility for advance payments of the premium tax credit*—(1) *In general.* The Exchange must determine a tax filer eligible for advance payments of the premium tax credit if the Exchange determines that—

(i) He or she is expected to have a household income that will qualify the tax filer as an applicable taxpayer according to 26 CFR 1.36B–2(b) for the benefit year for which coverage is requested; and

(ii) One or more applicants for whom the tax filer expects to claim a personal exemption deduction on his or

her tax return for the benefit year, including the tax filer and his or her spouse—

(A) Meets the requirements for eligibility for enrollment in a QHP through the Exchange, as specified in paragraph (a) of this section; and

(B) Is not eligible for minimum essential coverage for the full calendar month for which advance payments of the premium tax credit would be paid, with the exception of coverage in the individual market, in accordance with 26 CFR 1.36B–2(a)(2) and (c).

(2) *Special rule for non-citizens who are lawfully present and who are ineligible for Medicaid by reason of immigration status.* The Exchange must determine a tax filer eligible for advance payments of the premium tax credit if the Exchange determines that—

(i) He or she meets the requirements specified in paragraph (f)(1) of this section, except for paragraph (f)(1)(i);

(ii) He or she is expected to have a household income, as defined in 26 CFR 1.36B–1(e) of less than 100 percent of the FPL for the benefit year for which coverage is requested; and

(iii) One or more applicants for whom the tax filer expects to claim a personal exemption deduction on his or her tax return for the benefit year, including the tax filer and his or her spouse, is a non-citizen who is lawfully present and ineligible for Medicaid by reason of immigration status, in accordance with 26 CFR 1.36B–2(b)(5).

(3) *Enrollment required.* The Exchange may provide advance payments of the premium tax credit on behalf of a tax filer only if one or more applicants for whom the tax filer attests that he or she expects to claim a personal exemption deduction for the benefit year, including the tax filer and his or her spouse, is enrolled in a QHP that is not a catastrophic plan, through the Exchange.

(4) *Compliance with filing requirement.* The Exchange may not determine a tax filer eligible for advance payments of the premium tax credit (APTC) if HHS notifies the Exchange as part of the process described in §155.320(c)(3) that APTC payments were made on behalf of either the tax filer or spouse, if the tax filer is a married couple, for two consecutive years for which tax data would be utilized for verification of household income and family size in accordance with §155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for that year and for the previous year as required by 26 U.S.C. 6011, 6012, and in 26 CFR chapter I, and reconcile APTC for that period.

(i) If HHS notifies the Exchange as part of the process described in §155.320(c)(3) that APTC payments were made on behalf of either the tax filer or spouse, if the tax filer is a married couple, for 1 year for which tax data would be utilized for verification of household income and family size in accordance with §155.320(c)(1)(i), and the tax filer or the tax filer's spouse did not comply with the requirement to file an income tax return for that year as required by 26 U.S.C. 6011, 6012, and their implementing regulations and reconcile APTC for that period (''file and reconcile''), the Exchange must:

(A) Send a notification to the tax filer, consistent with the standards applicable to the protection of Federal Tax Information, that informs the tax filer that the Exchange has determined that the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile, and educate the tax filer of the need to file and reconcile or risk being determined ineligible for APTC if they fail to file and reconcile for a second consecutive tax year; or

(B) Send a notification to either the tax filer or their enrollee, that informs the tax filer or enrollee that they may be at risk of being determined ineligible for APTC in the future. These notices must educate tax filers or their enrollees on the requirement to file and reconcile, while not directly stating that the IRS indicates the tax filer or the tax filer's spouse, if the tax filer is married, has failed to file and reconcile.

(ii) [Reserved]

(5) *Calculation of advance payments of the premium tax credit.* The Exchange must calculate advance payments of the premium tax credit in accordance with 26 CFR 1.36B–3 and §155.340(i) of this subpart.

(6) *Collection of Social Security numbers*. The Exchange must require an application filer to provide the Social Security number of a tax filer who is not an applicant only if an applicant attests that the tax filer has a Social Security number and filed a tax return for the year for which tax data would be utilized for verification of household income and family size.

(g) *Eligibility for cost-sharing reductions*—(1) *Eligibility criteria*. (i) The Exchange must determine an applicant eligible for cost-sharing reductions if he or she—

(A) Meets the requirements for eligibility for enrollment in a QHP through the Exchange, as specified in paragraph (a) of this section;

(B) Meets the requirements for advance payments of the premium tax credit, as specified in paragraph (f) of this section; and

(C) Is expected to have a household income that does not exceed 250 percent of the FPL, for the benefit year for which coverage is requested.

(ii) The Exchange may only provide cost-sharing reductions to an enrollee who is not an Indian if he or she is enrolled through the Exchange in a silver-level QHP, as defined by section 1302(d)(1)(B) of the Affordable Care Act.

(2) *Eligibility categories*. The Exchange must use the following eligibility categories for cost-sharing reductions when making eligibility determinations under this section—

(i) An individual who is expected to have a household income greater than or equal to 100 percent of the FPL and less than or equal to 150 percent of the FPL for the benefit year for which coverage is requested, or for an individual who is eligible for advance payments of the premium tax credit under paragraph (f)(2) of this section, a household income less than 100 percent of the FPL for the benefit year for which coverage is requested;

(ii) An individual is expected to have a household income greater than 150 percent of the FPL and less than or equal to 200 percent of the FPL for the benefit year for which coverage is requested; and

(iii) An individual who is expected to have a household income greater than 200 percent of the FPL and less than or equal to 250 percent of the FPL for the benefit year for which coverage is requested.

(3) *Special rule for family policies*. To the extent that an enrollment in a QHP in the individual market offered through an Exchange under a single policy covers two or more individuals who, if they were to enroll in separate individual policies would be eligible for different cost sharing, the Exchange must deem the individuals under such policy to be collectively eligible only for the category of eligibility last listed below for which all the individuals covered by the policy would be eligible:

(i) Individuals not eligible for changes to cost sharing;

(ii) Individuals described in §155.350(b) (the special cost-sharing rule for Indians regardless of income);

(iii) Individuals described in paragraph (g)(2)(iii) of this section;

(iv) Individuals described in paragraph (g)(2)(ii) of this section;

(v) Individuals described in paragraph (g)(2)(i) of this section; and

(vi) Individuals described in §155.350(a) (the cost-sharing rule for Indians with household incomes under 300 percent of the FPL).

(4) For the purposes of paragraph (g) of this section, ''household income'' means household income as defined in section 36B(d)(2) of the Code.

(h) *Eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan*. The Exchange must determine an applicant eligible for enrollment in a QHP through the Exchange in a QHP that is a catastrophic plan as defined by section 1302(e) of the Affordable Care Act, if he or she has met the requirements for eligibility for enrollment in a QHP through the Exchange, in accordance with §155.305(a), and either—

(1) Has not attained the age of 30 before the beginning of the plan year; or

(2) Has a certification in effect for any plan year that he or she is exempt from the requirement to maintain minimum essential coverage under section 5000A of the Code by reason of—

(i) Section 5000A(e)(1) of the Code (relating to individuals without affordable coverage); or

(ii) Section 5000A(e)(5) of the Code (relating to individuals with hardships).

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§ 155.310 Eligibility process.

(a) *Application*—(1) *Accepting applications*. The Exchange must accept applications from individuals in the form and manner specified in § 155.405.

(2) *Information collection from non-applicants*. The Exchange may not request information regarding citizenship, status as a national, or immigration status for an individual who is not seeking coverage for himself or herself on any application or supplemental form.

(3) *Collection of Social Security numbers*. (i) The Exchange must require an applicant who has a Social Security number to provide such number to the Exchange.

(ii) The Exchange may not require an individual who is not seeking coverage for himself or herself to provide a Social Security number, except as specified in § 155.305(f)(6).

(b) *Applicant choice for Exchange to determine eligibility for insurance affordability programs*. The Exchange must permit an applicant to request only an eligibility determination for enrollment in a QHP through the Exchange; however, the Exchange may not permit an applicant to request an eligibility determination for less than all insurance affordability programs.

(c) *Timing*. The Exchange must accept an application and make an eligibility determination for an applicant seeking an eligibility determination at any point in time during the year.

(d) *Determination of eligibility*. (1) The Exchange must determine an applicant's eligibility, in accordance with the standards specified in § 155.305.

(2) *Special rules relating to advance payments of the premium tax credit*. (i) The Exchange must permit an enrollee to accept less than the full amount of advance payments of the premium tax credit for which he or she is determined eligible.

(ii) The Exchange may authorize advance payments of the premium tax credit on behalf of a tax filer only if the Exchange first obtains necessary attestations from the tax filer regarding advance payments of the premium tax credit, including, but not limited to attestations that—

(A) He or she will file an income tax return for the benefit year, in accordance with 26 U.S.C. 6011, 6012, and implementing regulations;

(B) If married (within the meaning of 26 CFR 1.7703–1), he or she will file a joint tax return for the benefit year;

(C) No other taxpayer will be able to claim him or her as a tax dependent for the benefit year; and

(D) He or she will claim a personal exemption deduction on his or her tax return for the applicants identified as members of his or her family, including the tax filer and his or her spouse, in accordance with § 155.320(c)(3)(i).

(3) *Special rule relating to Medicaid and CHIP*. To the extent that the Exchange determines an applicant eligible for Medicaid or CHIP, the Exchange must notify the State Medicaid or CHIP agency and transmit all information from the records of the Exchange to the State Medicaid or CHIP agency, promptly and without undue delay, that is necessary for such agency to provide the applicant with coverage.

(e) *Timeliness standards*. (1) The Exchange must determine eligibility promptly and without undue delay.

(2) The Exchange must assess the timeliness of eligibility determinations based on the period from the date of application or transfer from an agency administering an insurance affordability program to the date the Exchange notifies the applicant of its decision or the date the Exchange transfers the application to another agency administering an insurance affordability program, when applicable.

(f) *Effective dates for eligibility*. Upon making an eligibility determination, the Exchange must implement the eligibility determination under this section for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, and cost-sharing reductions as follows—

(1) For an initial eligibility determination, in accordance with the dates specified in §§ 155.410(c) and (f) and 155.420(b), as applicable,

(2) For a redetermination, in accordance with the dates specified in §§ 155.330(f) and 155.335(i), as applicable.

(g) *Notification of eligibility determination.* The Exchange must provide timely written notice to an applicant of any eligibility determination made in accordance with this subpart.

(h) *Notice of an employee's receipt of advance payments of the premium tax credit and cost-sharing reductions to an employer.* The Exchange must notify an employer that an employee has been determined eligible for advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange within a reasonable timeframe following a determination that the employee is eligible for advance payments of the premium tax credit and cost-sharing reductions in accordance with § 155.305(g) or § 155.350(a) and enrollment by the employee in a qualified health plan through the Exchange. Such notice must:

(1) Identify the employee;

(2) Indicate that the employee has been determined eligible advance payments of the premium tax credit and cost-sharing reductions and has enrolled in a qualified health plan through the Exchange;

(3) Indicate that, if the employer has 50 or more full-time employees, the employer may be liable for the payment assessed under section 4980H of the Code; and

(4) Notify the employer of the right to appeal the determination.

(i) *Certification program for employers.* As part of its determination of whether an employer has a liability under section 4980H of the Code, the Internal Revenue Service will adopt methods to certify to an employer that one or more employees has enrolled for one or more months during a year in a QHP for which a premium tax credit or cost-sharing reduction is allowed or paid.

(j) *Duration of eligibility determinations without enrollment.* To the extent that an applicant who is determined eligible for enrollment in a QHP through the Exchange does not select a QHP within his or her enrollment period, or is not eligible for an enrollment period, in accordance with subpart E, and seeks a new enrollment period prior to the date on which his or her eligibility is redetermined in accordance with § 155.335, the Exchange must require the applicant to attest as to whether information affecting his or her eligibility has changed since his or her most recent eligibility determination before determining his or her eligibility for a special enrollment period, and must process any changes reported in accordance with the procedures specified in § 155.330.

(k) *Incomplete application.* If an application filer submits an application that does not include sufficient information for the Exchange to conduct an eligibility determination for enrollment in a QHP through the Exchange or for insurance affordability programs, if applicable, the Exchange must—

(1) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; and

(2) Provide the applicant with a period of no less than 10 days and no more than 90 days from the date on which the notice described in paragraph (k)(1) of this section is sent to the applicant to provide the information needed to complete the application to the Exchange.

(3) During the period described in paragraph (k)(2) of this section, the Exchange must not proceed with an applicant's eligibility determination or provide advance payments of the premium tax credit or cost-sharing reductions, unless an application filer has provided sufficient information to determine his or her eligibility for enrollment in a QHP through the Exchange, in which case the Exchange must make such a determination for enrollment in a QHP.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42314, July 15, 2013; 78 FR 54136, Aug. 30, 2013; 81 FR 12341, Mar. 8, 2016]

§ 155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.

(a) *General requirement.* Unless a request for modification is granted in accordance with paragraph (h) of this section, the Exchange must verify or obtain information as provided in this section in order to determine that an applicant is eligible for enrollment in a QHP through the Exchange.

(b) *Validation of Social Security number.* (1) For any individual who provides his or her Social Security number to the Exchange, the Exchange must transmit the Social Security number and other identifying information to HHS, which will submit it to the Social Security Administration.

(2) To the extent that the Exchange is unable to validate an individual's Social Security number through the Social Security Administration, or the Social Security Administration indicates that the individual is deceased, the Exchange must follow the procedures specified in paragraph (f) of this section, except that the Exchange must provide the individual with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration. The date on which the notice is received means 5 days after the date on the notice, unless the individual demonstrates that he or she did not receive the notice within the 5 day period.

(c) *Verification of citizenship, status as a national, or lawful presence*—(1) *Verification with records from the Social Security Administration.* For an applicant who attests to citizenship and has a Social Security number, the Exchange must transmit the applicant's Social Security number and other identifying information to HHS, which will submit it to the Social Security Administration.

(2) *Verification with the records of the Department of Homeland Security.* For an applicant who has documentation that can be verified through the Department of Homeland Security and who attests to lawful presence, or who attests to citizenship and for whom the Exchange cannot substantiate a claim of citizenship through the Social Security Administration, the Exchange must transmit information from the applicant's documentation and other identifying information to HHS, which will submit necessary information to the Department of Homeland Security for verification.

(3) *Inconsistencies and inability to verify information.* For an applicant who attests to citizenship, status as a national, or lawful presence, and for whom the Exchange cannot verify such attestation through the Social Security Administration or the Department of Homeland Security, the Exchange must follow the procedures specified in paragraph (f) of this section, except that the Exchange must provide the applicant with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration or the Department of Homeland Security, as applicable. The date on which the notice is received means 5 days after the date on the notice, unless the applicant demonstrates that he or she did not receive the notice within the 5 day period.

(d) *Verification of residency.* The Exchange must verify an applicant's attestation that he or she meets the standards of § 155.305(a)(3) as follows—

(1) Except as provided in paragraphs (d)(3) and (4) of this section, accept his or her attestation without further verification; or

(2) Examine electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current and accurate, and minimize administrative costs and burdens.

(3) If information provided by an applicant regarding residency is not reasonably compatible with other information provided by the individual or in the records of the Exchange the Exchange must examine information in data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data

sources are sufficiently current and accurate.

(4) If the information in such data sources is not reasonably compatible with the information provided by the applicant, the Exchange must follow the procedures specified in paragraph (f) of this section. Evidence of immigration status may not be used to determine that an applicant is not a resident of the Exchange service area.

(e) *Verification of incarceration status.* The Exchange must verify an applicant's attestation that the applicant meets the requirements of § 155.305(a)(2) by—

(1) Accepting an applicant's attestation that they are not currently incarcerated; or

(2) Verifying an applicant's attestation of incarceration status using any electronic data source that is available to the Exchange and which has been approved by HHS for this purpose. HHS will approve an electronic data source for incarceration verification if it provides data that are current and accurate, and if its use minimizes administrative costs and burdens.

(3) If an Exchange verifies an applicant's attestation of incarceration status using an approved data source under paragraph (e)(2) of this section, to the extent that an applicant's attestation is not reasonably compatible with information from the approved data source or other information provided by the applicant or in the records of the Exchange, the Exchange must follow the procedures specified in § 155.315(f).

(f) *Inconsistencies.* Except as otherwise specified in this subpart, for an applicant for whom the Exchange cannot verify information required to determine eligibility for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, and cost-sharing reductions, including when electronic data is required in accordance with this subpart but data for individuals relevant to the eligibility determination are not included in such data sources or when electronic data from IRS, DHS, or SSA is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source, the Exchange:

(1) Must make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors, by contacting the application filer to confirm the accuracy of the information submitted by the application filer;

(2) If unable to resolve the inconsistency through the process described in paragraph (f)(1) of this section, must—

(i) Provide notice to the applicant regarding the inconsistency; and

(ii) Provide the applicant with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is sent to the applicant to either present satisfactory documentary evidence via the channels available for the submission of an application, as described in § 155.405(c), except for by telephone through a call center, or otherwise resolve the inconsistency.

(3) May extend the period described in paragraph (f)(2)(ii) of this section for an applicant if the applicant demonstrates that a good faith effort has been made to obtain the required documentation during the period.

(4) During the periods described in paragraphs (f)(1) and (f)(2)(ii) of this section, must:

(i) Proceed with all other elements of eligibility determination using the applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified; and

(ii) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant within this period who is otherwise qualified for such payments and reductions, as described in § 155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation.

(5) If, after the period described in paragraph (f)(2)(ii) of this section, the Exchange remains unable to verify the attestation, the Exchange must determine the applicant's eligibility based on the information available from the data sources specified in this subpart, unless such applicant qualifies for the exception provided under paragraph (g)

of this section, and notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), including notice that the Exchange is unable to verify the attestation.

(6) When electronic data to support the verifications specified in §155.315(d) or §155.320(b) is required but it is not reasonably expected that data sources will be available within 1 day of the initial request to the data source, the Exchange must accept the applicant's attestation regarding the factor of eligibility for which the unavailable data source is relevant.

(7) Must extend the period described in paragraph (f)(2)(ii) of this section by a period of 60 days for an applicant if the applicant is required to present satisfactory documentary evidence to verify household income.

(g) *Exception for special circumstances.* For an applicant who does not have documentation with which to resolve the inconsistency through the process described in paragraph (f)(2) of this section because such documentation does not exist or is not reasonably available and for whom the Exchange is unable to otherwise resolve the inconsistency, with the exception of an inconsistency related to citizenship or immigration status, the Exchange must provide an exception, on a case-by-case basis, to accept an applicant's attestation as to the information which cannot otherwise be verified along with an explanation of circumstances as to why the applicant does not have documentation.

(h) *Flexibility in information collection and verification.* HHS may approve an Exchange Blueprint in accordance with §155.105(d) or a significant change to the Exchange Blueprint in accordance with §155.105(e) to modify the methods to be used for collection of information and verification of information as set forth in this subpart, as well as the specific information required to be collected, provided that HHS finds that such modification would reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, that it would not undermine coordination with Medicaid and CHIP, and that applicable requirements under §§155.260, 155.270, paragraph (i) of this section, and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information will be met.

(i) *Applicant information.* The Exchange must not require an applicant to provide information beyond the minimum necessary to support the eligibility and enrollment processes of the Exchange, Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, described in this subpart.

(j) *Verification related to eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan.* The Exchange must verify an applicant's attestation that he or she meets the requirements of §155.305(h) by—

(1) Verifying the applicant's attestation of age as follows—

(i) Except as provided in paragraph (j)(1)(iii) of this section, accepting his or her attestation without further verification; or

(ii) Examining electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current and accurate, and minimize administrative costs and burdens.

(iii) If information regarding age is not reasonably compatible with other information provided by the individual or in the records of the Exchange, the Exchange must examine information in data sources that are available to the Exchange and which have been approved by HHS for this purpose based on evidence showing that such data sources are sufficiently current and accurate.

(2) Verifying that an applicant has a certification of exemption in effect as described in §155.305(h)(2).

(3) To the extent that the Exchange is unable to verify the information required to determine eligibility for enrollment through the Exchange in a QHP that is a catastrophic plan as described in paragraphs (j)(1) and (2) of this section, the Exchange must follow

the procedures specified in §155.315(f), except for §155.315(f)(4).

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 78 FR 42316, July 15, 2013; 88 FR 25918, Apr. 27, 2023; 89 FR 26421, Apr. 15, 2024]

§ 155.320 Verification process related to eligibility for insurance affordability programs.

(a) *General requirements.* (1) The Exchange must verify information in accordance with this section only for an applicant or tax filer who requested an eligibility determination for insurance affordability programs in accordance with §155.310(b).

(2) Unless a request for modification is granted in accordance with §155.315(h), the Exchange must verify or obtain information in accordance with this section before making an eligibility determination for insurance affordability programs, and must use such information in such determination.

(b) *Verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan.* (1)(i) The Exchange must verify whether an applicant is eligible for minimum essential coverage other than through an eligible employer-sponsored plan, Medicaid, CHIP, or the BHP, using information obtained by transmitting identifying information specified by HHS to HHS for verification purposes.

(ii) The Exchange must verify whether an applicant has already been determined eligible for coverage through Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, within the State or States in which the Exchange operates using information obtained from the agencies administering such programs.

(2) Consistent with §164.512(k)(6)(i) of this subchapter, the disclosure to HHS of information regarding eligibility for and enrollment in a health plan, which may be considered protected health information, as that term is defined in §160.103 of this subchapter, is expressly authorized, for the purposes of verification of applicant eligibility for minimum essential coverage as part of the eligibility determination process for advance payments of the premium tax credit or cost-sharing reductions.

(c) *Verification of household income and family/household size*—(1) *Data*—(i) *Data regarding annual household income.* (A) For all individuals whose income is counted in calculating a tax filer's household income, as defined in 26 CFR 1.36B–1(e), or an applicant's household income, calculated in accordance with 42 CFR 435.603(d), and for whom the Exchange has a Social Security number, the Exchange must request tax return data regarding MAGI and family size from the Secretary of the Treasury and data regarding Social security benefits described in 26 CFR 1.36B–1(e)(2)(iii) from the Commissioner of Social Security by transmitting identifying information specified by HHS to HHS.

(B) If the identifying information for one or more individuals does not match a tax record on file with the Secretary of the Treasury that may be disclosed in accordance with section 6103(l)(21) of the Code and its accompanying regulations, the Exchange must proceed in accordance with §155.315(f)(1).

(ii) *Data regarding MAGI-based income.* For all individuals whose income is counted in calculating a tax filer's household income, as defined in 26 CFR 1.36B–1(e), or an applicant's household income, calculated in accordance with 42 CFR 435.603(d), the Exchange must request data regarding MAGI-based income in accordance with 42 CFR 435.948(a).

(iii) *Payment to use income data through the Verify Current Income Hub service.* Beginning July 1, 2024, State Exchanges that elect the option to access the Verify Current Income service through the Federal Data Services Hub (''the Hub'') to verify an individual's income as described in paragraph (c)(3)(vi)(A) of this section, must reimburse HHS for the costs of their access to and use of the income data provided by the Verify Current Income Hub service. HHS will invoice States monthly for the amount the State must pay to HHS based on their actual utilization of CSI income data from the prior month and this invoiced amount will equal the product of the number of purchased transactions returned from the Verify Current Income Hub service

and the price per transaction established under the contract maintained by HHS to provide the VCI Hub service, as well as an administrative fee to account for any direct or indirect costs of making CSI income data accessed through the VCI Hub service available to State Exchanges and State Medicaid and CHIP agencies.

(2) *Verification process for Medicaid and CHIP*—(i) *Household size.* (A) The Exchange must verify household size in accordance with 42 CFR 435.945(a) or through other reasonable verification procedures consistent with the requirements in 42 CFR 435.952.

(B) The Exchange must verify the information in paragraph (c)(2)(i)(A) of this section by accepting an applicant's attestation without further verification, unless the Exchange finds that an applicant's attestation to the individuals that comprise his or her household for Medicaid and CHIP is not reasonably compatible with other information provided by the application filer for the applicant or in the records of the Exchange, in which case the Exchange must utilize data obtained through electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange must request additional documentation to support the attestation within the procedures specified in 42 CFR 435.952.

(ii) *Verification process for MAGI-based household income.* The Exchange must verify MAGI-based income, within the meaning of 42 CFR 435.603(d), for the household described in paragraph (c)(2)(i) in accordance with the procedures specified in Medicaid regulations 42 CFR 435.945, 42 CFR 435.948, and 42 CFR 435.952 and CHIP regulations at 42 CFR 457.380.

(3) *Verification process for advance payments of the premium tax credit and cost-sharing reductions*—(i) *Family size.* (A) The Exchange must require an applicant to attest to the individuals that comprise a tax filer's family for advance payments of the premium tax credit and cost-sharing reductions.

(B) To the extent that the applicant attests that the information described in paragraph (c)(1)(i) of this section represents an accurate projection of a tax filer's family size for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the family size data in paragraph (c)(1)(i) of this section.

(C) To the extent that the data described in paragraph (c)(1)(i) of this section is unavailable, or an applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so it does not represent an accurate projection of a tax filer's family size for the benefit year for which coverage is requested, the Exchange must verify the tax filer's family size for advance payments of the premium tax credit and cost-sharing reductions by accepting an applicant's attestation without further verification, except as specified in paragraph (c)(3)(i)(D) of this section.

(D) If the Exchange finds that an applicant's attestation of a tax filer's family size is not reasonably compatible with other information provided by the application filer for the family or in the records of the Exchange, with the exception of the data described in paragraph (c)(1)(i) of this section, the Exchange must utilize data obtained through other electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange must request additional documentation to support the attestation within the procedures specified in §155.315(f).

(E) The Exchange must verify that neither advance payments of the premium tax credit nor cost-sharing reductions are being provided on behalf of an individual using information obtained by transmitting identifying information specified by HHS to HHS.

(ii) *Basic verification process for annual household income.* (A) The Exchange must compute annual household income for the family described in paragraph (c)(3)(i)(A) of this section based on the data described in paragraph (c)(1)(i) of this section;

(B) The Exchange must require the applicant to attest regarding a tax filer's projected annual household income;

(C) To the extent that the applicant's attestation indicates that the information described in paragraph (c)(3)(ii)(A) of this section represents an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the household income data in paragraph (c)(3)(ii)(A) of this section.

(D) To the extent that the data described in paragraph (c)(1)(i) of this section is unavailable, or an applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so it does not represent an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must require the applicant to attest to the tax filer's projected household income for the benefit year for which coverage is requested.

(iii) *Verification process for changes in household income.* (A) Except as specified in paragraph (c)(3)(iii)(B) and (C) of this section, if an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section for the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation regarding a tax filer's annual household income without further verification.

(B) If data available to the Exchange in accordance with paragraph (c)(1)(ii) of this section indicate that a tax filer's projected annual household income is in excess of his or her attestation by a significant amount, the Exchange must proceed in accordance with §155.315(f)(1) through (4).

(C) If other information provided by the application filer indicates that a tax filer's projected annual household income is in excess of his or her attestation by a significant amount, the Exchange must utilize data available to the Exchange in accordance with paragraph (c)(1)(ii) of this section to verify the attestation. If such data is unavailable or are not reasonably compatible with the applicant's attestation, the Exchange must proceed in accordance with §155.315(f)(1) through (4).

(D) [Reserved]

(E) If, at the conclusion of the period specified in §155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), and implement such determination in accordance with the effective dates specified in §155.330(f).

(F) If, at the conclusion of the period specified in §155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in §155.330(f).

(iv) *Eligibility for alternate verification process for decreases in annual household income and situations in which tax return data is unavailable.* The Exchange must determine a tax filer's annual household income for advance payments of the premium tax credit and cost-sharing reductions based on the alternate verification procedures described in paragraph (c)(3)(v) of this section, if an applicant attests to projected annual household income in accordance with paragraph (c)(3)(ii)(B) of this section,

the tax filer does not meet the criteria specified in paragraph (c)(3)(iii) of this section, the applicants in the tax filer's family have not established MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section that is within the applicable Medicaid or CHIP MAGI-based income standard, and one of the following conditions is met—

(A) The Secretary of the Treasury does not have tax return data that may be disclosed under section 6103(l)(21) of the Code for the tax filer that is at least as recent as the calendar year two years prior to the calendar year for which advance payments of the premium tax credit or cost-sharing reductions would be effective;

(B) The applicant attests that the tax filer's applicable family size has changed or is reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage, or the members of the tax filer's family have changed or are reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage;

(C) The applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so the tax filer's annual household income has decreased or is reasonably expected to decrease from the data described in paragraph (c)(1)(i) of this section for the benefit year for which the applicants in his or her family are requesting coverage;

(D) The applicant attests that the tax filer's filing status has changed or is reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage; or

(E) An applicant in the tax filer's family has filed an application for unemployment benefits.

(v) *Alternate verification process.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is no more than ten percent below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, the Exchange must accept the applicant's attestation without further verification.

(vi) *Alternate verification process for decreases in annual household income estimates and for situations in which tax return data is unavailable.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, or if data described in paragraph (c)(1)(i) of this section is unavailable, the Exchange must attempt to verify the applicant's attestation of the tax filer's projected annual household income by following the procedures specified in paragraph (c)(3)(vi)(A) through (G) of this section. For the purposes of this paragraph (c)(3)(vi), a reasonable threshold is established by the Exchange in guidance and approved by HHS, but must not be less than 10 percent, and can also include a threshold dollar amount. The Exchange's threshold is subject to approval by HHS.

(A) *Data.* The Exchange must annualize data from the MAGI-based income sources specified in paragraph (c)(1)(ii) of this section, and obtain any data available from other electronic data sources that have been approved by HHS, based on evidence showing that such data sources are sufficiently accurate and offer less administrative complexity than paper verification.

(B) *Eligibility.* To the extent that the applicant's attestation indicates that the information described in paragraph (c)(3)(vi)(A) of this section represents an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the household income data in paragraph (c)(3)(vi)(A) of this section.

(C) *Increases in annual household income.* If an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B)

of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(vi)(A) of this section to the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation for the tax filer's family without further verification, unless:

(*1*) The Exchange finds that an applicant's attestation of a tax filer's annual household income is not reasonably compatible with other information provided by the application filer, or

(*2*) [Reserved]

(D) *Decreases in annual household income and situations in which electronic data is unavailable*. If electronic data are unavailable or an applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is more than a reasonable threshold below the annual household income as computed using data sources described in paragraphs (c)(3)(vi)(A) of this section, the Exchange must follow the procedures specified in §155.315(f)(1) through (4). The reasonable threshold used under this paragraph must be equal to the reasonable threshold established in accordance with paragraph (c)(3)(vi) of this section.

(E) If, following the 90-day period described in paragraph (c)(3)(vi)(D) of this section, an applicant has not responded to a request for additional information from the Exchange and the data sources specified in paragraph (c)(1) of this section indicate that an applicant in the tax filer's family is eligible for Medicaid or CHIP, the Exchange must not provide the applicant with eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP or the BHP, if a BHP is operating in the service area of the Exchange.

(F) If, at the conclusion of the period specified in §155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in §155.310(g), and implement such determination in accordance with the effective dates specified in §155.330(f).

(G) If, at the conclusion of the period specified in §155.315(f)(2)(ii), the Exchange remains unable to verify the applicant's attestation for the tax filer and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirement specified in §155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in §155.330(f).

(vii) For the purposes of paragraph (c)(3) of this section, ''household income'' means household income as specified in 26 CFR 1.36B–1(e).

(viii) For the purposes of paragraph (c)(3) of this section, ''family size'' means family size as specified in 26 CFR 1.36B–1(d).

(viii) For purposes of paragraph (c)(3) of this section, ''family size'' means family size as specified in section 36B(d)(1) of the Code.

(4) The Exchange must provide education and assistance to an applicant regarding the process specified in this paragraph.

(5) *Acceptance of attestation*. Notwithstanding any other requirement described in this paragraph (c) to the contrary, when the Exchange requests tax return data and family size from the Secretary of Treasury as described in paragraph (c)(1)(i)(A) of this section but no such data is returned for an applicant, the Exchange will accept that applicant's attestation of income and family size without further verification.

(d) *Verification related to enrollment in an eligible employer-sponsored plan and*

eligibility for qualifying coverage in an eligible employer-sponsored plan—(1) *General requirement.* The Exchange must verify whether an applicant reasonably expects to be enrolled in an eligible employer-sponsored plan or is eligible for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested.

(2) *Data.* The Exchange must—

(i) Obtain data about enrollment in and eligibility for an eligible employer-sponsored plan from any electronic data sources that are available to the Exchange and which have been approved by HHS, based on evidence showing that such data sources are sufficiently current, accurate, and minimize administrative burden.

(ii) Obtain any available data regarding enrollment in employer-sponsored coverage or eligibility for qualifying coverage in an eligible employer-sponsored plan based on federal employment by transmitting identifying information specified by HHS to HHS for HHS to provide the necessary verification using data obtained by HHS.

(iii) Obtain any available data from the SHOP that corresponds to the State in which the Exchange is operating.

(3) *Verification procedures.* (i) If an applicant's attestation is not reasonably compatible with the information obtained by the Exchange as specified in paragraphs (d)(2)(i) through (iii) of this section, other information provided by the application filer, or other information in the records of the Exchange, the Exchange must follow the procedures specified in §155.315(f).

(ii) Except as specified in paragraph (d)(3)(i) or (d)(4)(i) of this section, the Exchange must accept an applicant's attestation regarding the verification specified in paragraph (d) of this section without further verification.

(4) *Alternate procedures.* For any benefit year for which it does not reasonably expect to obtain sufficient verification data as described in paragraphs (d)(2)(i) through (iii) of this section, the Exchange may follow the procedures specified in paragraph (d)(4)(i) of this section. For purposes of this paragraph (d)(4), the Exchange reasonably expects to obtain sufficient verification data for the benefit year when the Exchange is able to obtain data about enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan from at least one electronic data source that is available to the Exchange and that has been approved by HHS, based on evidence showing that the data source is sufficiently current, accurate, and minimizes administrative burden, as described under paragraphs (d)(2)(i) of this section.

(i) Based on the Exchange's assessment of risk for inappropriate payment of advance payments of the premium tax credit or cost-sharing reductions, implement a verification process that is reasonably designed to ensure the accuracy of the data and is based on the activities or methods used by an Exchange such as studies, research, and analysis of an Exchange's own enrollment data, for enrollment in or eligibility for qualifying coverage in an eligible employer sponsored plan, as appropriate.

(A) The Exchange must provide notice to the applicant if, as part of the verification process described under paragraph (d)(4)(i) of this section, the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her family, as defined in 26 CFR 1.36B–1(d), to verify whether the applicant is enrolled in an eligible employer sponsored plan or is eligible for qualifying coverage in an eligible employer sponsored plan for the benefit year for which coverage is requested;

(B) Proceed with all other elements of the eligibility determination using the applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified;

(C) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant who is otherwise qualified for such payments and reductions, as described in §155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation;

(D) If the Exchange receives any information from an employer relevant to the applicant's enrollment in an eligible employer-sponsored plan or eligibility for qualifying coverage in an eligible employer-sponsored plan, the Exchange must determine the applicant's eligibility based on such information and in accordance with the effective dates specified in §155.330(f), and if such information changes his or her eligibility determination, notify the applicant and his or her employer or employers of such determination in accordance with the notice requirements specified in §155.310(g) and (h);

(E) To carry out the process described in paragraph (d)(4)(iii) of this section, the Exchange must only disclose an individual's information to an employer to the extent necessary for the employer to identify the employee.

(ii) [Reserved]

(e) *Additional verification related to immigration status for Medicaid and CHIP.* (1) For purposes of determining eligibility for Medicaid, the Exchange must verify whether an applicant who does not attest to being a citizen or a national has satisfactory immigration status to be eligible for Medicaid, as required by 42 CFR 435.406 and, if applicable under the State Medicaid plan, section 1903(v)(4) of the Act.

(2) For purposes of determining eligibility for CHIP, the Exchange must verify whether an applicant who does not attest to being a citizen or a national has satisfactory immigration status to be eligible for CHIP, in accordance with 42 CFR 457.320(b) and if applicable under the State Child Health Plan, section 2107(e)(1)(J) of the Act.

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§155.330 Eligibility redetermination during a benefit year.

(a) *General requirement.* The Exchange must redetermine the eligibility of an enrollee in a QHP through the Exchange during the benefit year if it receives and verifies new information reported by an enrollee or identifies updated information through the data matching described in paragraph (d) of this section.

(b) *Requirement for individuals to report changes.* (1) Except as specified in paragraphs (b)(2) and (3) of this section, the Exchange must require an enrollee to report any change with respect to the eligibility standards specified in §155.305 within 30 days of such change.

(2) The Exchange must not require an enrollee who did not request an eligibility determination for insurance affordability programs to report changes that affect eligibility for insurance affordability programs.

(3) The Exchange may establish a reasonable threshold for changes in income, such that an enrollee who experiences a change in income that is below the threshold is not required to report such change.

(4) The Exchange must allow an enrollee, or an application filer on behalf of the enrollee, to report changes via the channels available for the submission of an application, as described in §155.405(c)(2), except that the Exchange is permitted but not required to allow an enrollee, or an application filer, on behalf of the enrollee, to report changes via mail.

(c) *Verification of reported changes.* The Exchange must—

(1) Verify any information reported by an enrollee in accordance with the processes specified in §§155.315 and 155.320 prior to using such information in an eligibility redetermination; and

(2) Provide periodic electronic notifications regarding the requirements for reporting changes and an enrollee's opportunity to report any changes as described in paragraph (b)(3) of this section, to an enrollee who has elected to receive electronic notifications, unless he or she has declined to receive notifications under this paragraph (c)(2).

(d) *Periodic examination of data sources*—(1) *General requirement.* Subject to paragraph (d)(3) of this section, the Exchange must periodically examine available data sources described in §§155.315(b)(1) and 155.320(b) to identify the following changes:

(i) Death; and

(ii) For an enrollee on whose behalf advance payments of the premium tax

credit or cost-sharing reductions are being provided, eligibility determinations for or enrollment in Medicare, Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange.

(2) *Flexibility*. The Exchange may make additional efforts to identify and act on changes that may affect an enrollee's eligibility for enrollment in a QHP through the Exchange or for insurance affordability programs, provided that such efforts—

(i) Would reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, that it would not undermine coordination with Medicaid and CHIP, and that applicable requirements under §§155.260, 155.270, 155.315(i), and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information will be met; and

(ii) Comply with the standards specified in paragraph (e)(2) of this section.

(3) *Definition of periodically*. (i) Beginning with the 2021 calendar year, the Exchange must perform the periodic examination of data sources described in paragraphs (d)(1)(ii) of this section at least twice in a calendar year. State Exchanges that have implemented a fully integrated eligibility system with their respective State Medicaid programs, that have a single eligibility rules engine that uses MAGI to determine eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, will be deemed in compliance with the Medicaid/CHIP PDM requirements and, if applicable, BHP PDM requirements, in paragraphs (d)(1)(ii) and (d)(3) of this section.

(ii) Beginning with the 2025 calendar year, the Exchange must perform the periodic examination of data sources described in paragraph (d)(1)(i) of this section at least twice in a calendar year.

(iii) Notwithstanding the requirements of paragraphs (d)(3)(i) and (ii) of this section, the Secretary has authority to temporarily suspend the requirement that Exchanges conduct the PDM processes described at paragraph (d)(3)(i) or (ii) of this section during certain situations or circumstances that leads to the limited availability of data needed to conduct PDM or of documentation needed for an enrollee to notify the Exchange that the result of PDM is inaccurate as described in paragraph (e)(2)(i)(C) of this section.

(e) *Redetermination and notification of eligibility*—(1) *Enrollee-reported data*. If the Exchange verifies updated information reported by an enrollee, the Exchange must—

(i) Redetermine the enrollee's eligibility in accordance with the standards specified in §155.305;

(ii) Notify the enrollee regarding the determination in accordance with the requirements specified in §155.310(g); and

(iii) Notify the enrollee's employer, as applicable, in accordance with the requirements specified in §155.310(h).

(2) *Data matching*. (i) Except as provided in paragraph (e)(2)(iii) of this section, if the Exchange identifies updated information regarding death, in accordance with paragraph (d)(1)(i) of this section, or regarding any factor of eligibility not regarding income, family size, or family composition, or tax filing status, the Exchange must—

(A) Notify the enrollee regarding the updated information, as well as the enrollee's projected eligibility determination after considering such information.

(B) Allow an enrollee 30 days from the date of the notice to notify the Exchange that such information is inaccurate.

(C) If the enrollee responds contesting the updated information, proceed in accordance with §155.315(f) of this part.

(D) If the enrollee does not respond contesting the updated information within the 30-day period specified in paragraph (e)(2)(i)(B) of this section, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section, provided the enrollee has not directed the Exchange to terminate his or her coverage under such circumstances, in

which case the Exchange will terminate the enrollee's coverage in accordance with §155.430(b)(1)(ii), and provided the enrollee has not been determined to be deceased, in which case the Exchange will terminate the enrollee's coverage in accordance with §155.430(d)(7).

(ii) If the Exchange identifies updated information regarding income, family size, or family composition, with the exception of information regarding death, the Exchange must—

(A) Follow procedures described in paragraph (e)(2)(i)(A) and (B) of this section; and

(B) If the enrollee responds confirming the updated information, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(C) If the enrollee does not respond within the 30-day period specified in paragraph (e)(2)(i)(B) of this section, maintain the enrollee's existing eligibility determination without considering the updated information.

(D) If the enrollee provides more up-to-date information, proceed in accordance with paragraph (c)(1) of this section.

(iii) If the Exchange identifies updated information that the tax filer for the enrollee's household or the tax filer's spouse did not comply with the requirements described in §155.305(f)(4), the Exchange when redetermining and providing notification of eligibility for advance payments of the premium tax credit must:

(A) Follow the procedures specified in paragraph (e)(2)(i) of this section;

(B) Follow the procedures in guidance published by the Secretary; or

(C) Follow alternative procedures approved by the Secretary based on a showing by the Exchange that the alternative procedures facilitate continued enrollment in coverage with financial assistance for which the enrollee remains eligible, provide appropriate information about the process to the enrollee (including regarding any action by the enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections and safeguards for Federal tax information under section 6103 of the Internal Revenue Code with respect to the confidentiality, disclosure, maintenance, or use of such information.

(f) *Effective dates.* (1) Except as specified in paragraphs (f)(2) through (f)(5) of this section, the Exchange must implement changes—

(i) Resulting from a redetermination under this section on the first day of the month following the date of the notice described in paragraph (e)(1)(ii) of this section; or

(ii) Resulting from an appeal decision, on the date specified in the appeal decision; or

(iii) Affecting enrollment or premiums only, on the first day of the month following the date on which the Exchange is notified of the change;

(2) Except as specified in paragraphs (f)(3) through (5) of this section, the Exchange may determine a reasonable point in a month after which a change described in paragraph (f)(1) of this section will not be effective until the first day of the month after the month specified in paragraph (f)(1) of this section. Such reasonable point in a month must be no earlier than the 15th of the month.

(3) Except as specified in paragraphs (f)(4) and (5) of this section, the Exchange must implement a change described in paragraph (f)(1) of this section that results in a decreased amount of advance payments of the premium tax credit, or a change in the level of cost-sharing reductions, and for which the date of the notices described in paragraphs (f)(1)(i) and (ii) of this section, or the date on which the Exchange is notified in accordance with paragraph (f)(1)(iii) of this section is after the 15th of the month, on the first day of the month after the month specified in paragraph (f)(1) of this section.

(4) The Exchange must implement a change associated with the events described in §155.420(b)(2)(i) and (ii) on the coverage effective dates described in §155.420(b)(2)(i) and (ii), respectively.

(5) Notwithstanding paragraphs (f)(1) through (f)(4) of this section, the Exchange may provide the effective date of a change associated with the events described in §155.420(d)(4), (d)(5), and (d)(9) based on the specific circumstances of each situation.

(g) *Recalculation of advance payments of the premium tax credit and cost-sharing reductions.* (1) When an eligibility redetermination in accordance with this section results in a change in the amount of advance payments of the premium tax credit for the benefit year, the Exchange must:

(i) Recalculate the amount of advance payments of the premium tax credit in such a manner as to account for any advance payments already made on behalf of the tax filer for the benefit year for which information is available to the Exchange, such that the recalculated advance payment amount is projected to result in total advance payments for the benefit year that correspond to the tax filer's total projected premium tax credit for the benefit year, calculated in accordance with 26 CFR 1.36B–3 (or, if less than zero, be set at zero); or

(ii) Recalculate advance payments of the premium tax credit using an alternate method that has been approved by the Secretary.

(2) When an eligibility redetermination in accordance with this section results in a change in cost-sharing reductions, the Exchange must determine an individual eligible for the category of cost-sharing reductions that corresponds to his or her expected annual household income for the benefit year (subject to the special rule for family policies set forth in §155.305(g)(3)).

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 15533, Mar. 11, 2013; 78 FR 42318, July 15, 2013; 79 FR 30347, May 27, 2014; 79 FR 53005, Sept. 5, 2014; 81 FR 94177, Dec. 22, 2016; 84 FR 71710, Dec. 27, 2019; 85 FR 29259, May 14, 2020; 89 FR 26422, Apr. 15, 2024]

§155.335 Annual eligibility redetermination.

(a) *General requirement.* (1) Except as specified in paragraphs (l) and (m) of this section, the Exchange must redetermine the eligibility of a qualified individual on an annual basis.

(2) The Exchange must conduct annual redeterminations required under paragraph (a)(1) of this section using one of the following:

(i) The procedures described in paragraphs (b) through (m) of this section;

(ii) Alternative procedures specified by the Secretary for the applicable benefit year; or

(iii) Alternative procedures approved by the Secretary based on a showing by the Exchange that the alternative procedures would facilitate continued enrollment in coverage for which the enrollee remains eligible, provide clear information about the process to the qualified individual or enrollee (including regarding any action by the qualified individual or enrollee necessary to obtain the most accurate redetermination of eligibility), and provide adequate program integrity protections.

(b) *Updated income and family size information.* In the case of a qualified individual who requested an eligibility determination for insurance affordability programs in accordance with §155.310(b) of this part, the Exchange must request updated tax return information, if the qualified individual has authorized the request of such tax return information, data regarding Social Security benefits, and data regarding MAGI-based income as described in §155.320(c)(1) of this part for use in the qualified individual's eligibility redetermination.

(c) *Notice to qualified individual.* The Exchange must provide a qualified individual with an annual redetermination notice including the following:

(1)–(2) [Reserved]

(3) The qualified individual's projected eligibility determination for the following year, after considering any updated information described in paragraph (b) of this section, including, if applicable, the amount of any advance payments of the premium tax credit and the level of any cost-sharing reductions or eligibility for Medicaid, CHIP or BHP.

(d) *Timing.* (1) For redeterminations under this section for coverage effective January 1, 2015, the Exchange must satisfy the notice provisions of paragraph (c) of this section and §155.410(d) through a single, coordinated notice.

(2) For redeterminations under this section for coverage effective on or after January 1, 2017, the Exchange may send the notice specified in paragraph (c) of this section separately

from the notice of annual open enrollment specified in §155.410(d), provided that—

(i) The Exchange sends the notice specified in paragraph (c) of this section no earlier than the date of the notice of annual open enrollment specified in §155.410(d); and

(ii) The timing of the notice specified in paragraph (c) of this section allows a reasonable amount of time for the enrollee to review the notice, provide a timely response, and for the Exchange to implement any changes in coverage elected during the annual open enrollment period.

(e) *Changes reported by qualified individuals.* Except as specified in paragraph (e)(1) of this section, the Exchange must require a qualified individual to report any change with respect to the eligibility standards specified in §155.305 within 30 days of such change.

(1) The Exchange must not require a qualified individual who did not request an eligibility determination for insurance affordability programs to report changes that affect eligibility for insurance affordability programs.

(2) The Exchange must allow a qualified individual, or an application filer, on behalf of the qualified individual, to report changes via the channels available for the submission of an application, as described in §155.405(c)(2), except that the Exchange is permitted but not required to allow a qualified individual, or an application filer, on behalf of the qualified individual, to report changes via mail.

(f) *Verification of reported changes.* The Exchange must verify any information reported by a qualified individual under paragraph (e) of this section using the processes specified in §§155.315 and 155.320, including the relevant provisions in those sections regarding inconsistencies, prior to using such information to determine eligibility.

(g) *Response to redetermination notice.* (1) The Exchange must require a qualified individual, or an application filer, on behalf of the qualified individual, to sign and return the notice described in paragraph (c) of this section.

(2) To the extent that a qualified individual does not sign and return the notice described in paragraph (c) of this section within the 30-day period specified in paragraph (e) of this section, the Exchange must proceed in accordance with the procedures specified in paragraph (h)(1) of this section.

(h) *Redetermination and notification of eligibility.* (1) After the 30-day period specified in paragraph (e) of this section has elapsed, the Exchange must—

(i) Redetermine the qualified individual's eligibility in accordance with the standards specified in §155.305 using the information provided to the qualified individual in the notice specified in paragraph (c) of this section, as supplemented with any information reported by the qualified individual and verified by the Exchange in accordance with paragraphs (e) and (f) of this section.

(ii) Notify the qualified individual in accordance with the requirements specified in §155.310(g).

(iii) If applicable, notify the qualified individual employer, in accordance with the requirements specified in §155.310(h).

(2) If a qualified individual reports a change for the information provided in the notice specified in paragraph (c) of this section that the Exchange has not verified as of the end of the 30-day period specified in paragraph (e) of this section, the Exchange must redetermine the qualified individual's eligibility after completing verification, as specified in paragraph (f) of this section.

(i) *Effective date of annual redetermination.* The Exchange must ensure that a redetermination under this section is effective on the first day of the coverage year following the year in which the Exchange provided the notice in paragraph (c) of this section, or in accordance with the rules specified in §155.330(f) regarding effective dates, whichever is later.

(j) *Re-enrollment.* If an enrollee remains eligible for enrollment in a QHP through the Exchange upon annual redetermination and—

(1) The product under which the QHP in which the enrollee is enrolled remains available through the Exchange for renewal, consistent with §147.106 of this subchapter, the Exchange will renew the enrollee in a QHP under that product, unless the enrollee terminates

coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430, or unless otherwise provided in paragraph (j)(1)(iii)(A) or (j)(4) of this section, as follows:

(i) The Exchange will re-enroll the enrollee in the same plan as the enrollee's current QHP, unless the current QHP is not available through the Exchange;

(ii) If the enrollee's current QHP is not available through the Exchange, the Exchange will re-enroll the enrollee in a QHP within the same product at the same coverage level as described in sections 1302(d) or (e) of the ACA as the enrollee's current QHP that has the most similar network compared to the enrollee's current QHP;

(iii) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP at the same coverage level as described in sections 1302(d) or (e) of the ACA as the enrollee's current QHP and—

(A) The enrollee's current QHP is a silver level plan, the Exchange will re-enroll the enrollee in a silver level QHP under a different product offered by the same QHP issuer that is most similar to the enrollee's current product and that has the most similar network compared to the enrollee's current QHP. If no such silver level QHP is available for enrollment through the Exchange, the Exchange will re-enroll the enrollee in a QHP under the same product that is coverage level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP; or

(B) The enrollee's current QHP is not a silver level plan, the Exchange will re-enroll the enrollee in a QHP under the same product that is one coverage level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP;

(iv) If the enrollee's current QHP is not available through the Exchange and the enrollee's product no longer includes a QHP that is at the same coverage level as described in sections 1302(d) or (e) of the ACA as, or one coverage level higher or lower than, the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP; or

(v) Notwithstanding the other provisions in this paragraph (j)(1), to the extent permitted by applicable State law, if the enrollee's current QHP is a catastrophic plan as described in section 1302(e) of the ACA, and the enrollee will no longer meet the criteria for enrollment in a catastrophic plan as described in section 1302(e)(2) of the ACA:

(A) The Exchange will re-enroll the enrollee in a bronze metal level QHP within the same product as the enrollee's current QHP that has the most similar network compared to the enrollee's current QHP; or

(B) If no bronze plan is available through this product, the Exchange will re-enroll the enrollee in the QHP with the lowest coverage level offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP.

(2) No plans under the product under which the QHP in which the enrollee is enrolled are available through the Exchange for renewal, consistent with §147.106 of this subchapter, the Exchange will enroll the enrollee in a QHP under a different product offered by the same QHP issuer, to the extent permitted by applicable State law, unless the enrollee terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430, as follows, except as provided in paragraph (j)(4) of this section.

(i) The Exchange will re-enroll the enrollee in a QHP at the same coverage level as the enrollee's current QHP in the product offered by the same issuer that is the most similar to the enrollee's current product and that has the most similar network compared to the enrollee's current QHP;

(ii) If the issuer does not offer another QHP at the same coverage level

as the enrollee's current QHP, the Exchange will re-enroll the enrollee in a QHP that is one coverage level higher or lower than the enrollee's current QHP and that has the most similar network compared to the enrollee's current QHP in the product offered by the same issuer through the Exchange that is the most similar to the enrollee's current product;

(iii) If the issuer does not offer another QHP through the Exchange at the same coverage level as, or one metal level higher or lower than the enrollee's current QHP, the Exchange will re-enroll the enrollee in any other QHP offered by the same issuer in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP in the product that is most similar to the enrollee's current product; or

(iv) Notwithstanding the other provisions in this paragraph (j)(2), to the extent permitted by applicable State law, if the enrollee's current QHP is a catastrophic plan as described in section 1302(e) of the ACA, and the enrollee will no longer meet the criteria for enrollment in a catastrophic plan as described in section 1302(e)(2) of the ACA:

(A) The Exchange will re-enroll the enrollee in a bronze metal level QHP offered by the same issuer in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP in the product that is most similar to the enrollee's current product; or

(B) If no bronze plan is available through this product, the Exchange will re-enroll the enrollee in the QHP with the lowest coverage level offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll and that has the most similar network compared to the enrollee's current QHP.

(3) No QHPs from the same issuer are available through the Exchange, the Exchange may enroll the enrollee in a QHP issued by a different issuer, to the extent permitted by applicable State law, unless the enrollee terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430, as follows:

(i) As directed by the applicable State regulatory authority; or

(ii) If the applicable State regulatory authority declines to provide direction, in a similar QHP from a different issuer, as determined by the Exchange.

(4) The enrollee is determined upon annual redetermination eligible for cost-sharing reductions, in accordance with §155.305(g), is currently enrolled in a bronze level QHP, and would be re-enrolled in a bronze level QHP under paragraph (j)(1) or (2) of this section, then to the extent permitted by applicable State law, unless the enrollee terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430, at the option of the Exchange, the Exchange may re-enroll such enrollee in a silver level QHP within the same product, with the same provider network, and with a lower or equivalent premium after the application of advance payments of the premium tax credit as the bronze level QHP into which the Exchange would otherwise re-enroll the enrollee under paragraph (j)(1) or (2) of this section.

(5) For purposes of this section, catastrophic coverage is not a coverage level that is considered higher or lower than metal level coverage when re-enrolling an enrollee to a plan that is a metal level higher or lower than their current plan, and an Exchange may not re-enroll an enrollee that has coverage under section 1302(d) into catastrophic coverage.

(k) *Authorization of the release of tax data to support annual redetermination.* (1) The Exchange must have authorization from a qualified individual to obtain updated tax return information described in paragraph (b) of this section for purposes of conducting an annual redetermination.

(2) The Exchange is authorized to obtain the updated tax return information described in paragraph (b) of this section for a period of no more than five years based on a single authorization, provided that—

(i) An individual may decline to authorize the Exchange to obtain updated tax return information; or

(ii) An individual may authorize the Exchange to obtain updated tax return

information for fewer than five years; and

(iii) The Exchange must allow an individual to discontinue, change, or renew his or her authorization at any time.

(l) *Limitation on redetermination.* To the extent that a qualified individual has requested an eligibility determination for insurance affordability programs in accordance with §155.310(b) and the Exchange does not have an active authorization to obtain tax data as a part of the annual redetermination process, the Exchange must redetermine the qualified individual's eligibility only for enrollment in a QHP and notify the enrollee in accordance with the timing described in paragraph (d) of this section. The Exchange may not proceed with a redetermination for insurance affordability programs until such authorization has been obtained or the qualified individual continues his or her request for an eligibility determination for insurance affordability programs in accordance with §155.310(b).

(m) *Special rule.* The Exchange must not redetermine a qualified individual's eligibility in accordance with this section if the qualified individual's eligibility was redetermined under this section during the prior year, and the qualified individual was not enrolled in a QHP through the Exchange at the time of such redetermination, and has not enrolled in a QHP through the Exchange since such redetermination.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42319, July 15, 2013; 79 FR 53005, Sept. 5, 2014; 81 FR 12342, Mar. 8, 2016; 88 FR 25918, Apr. 27, 2023; 89 FR 26422, Apr. 15, 2024]

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

(a) *Requirement to provide information to enable advance payments of the premium tax credit and cost-sharing reductions.* In the event that the Exchange determines that a tax filer is eligible for advance payments of the premium tax credit, an applicant is eligible for cost-sharing reductions, or that such eligibility for such programs has changed, the Exchange must, simultaneously—

(1) Transmit eligibility and enrollment information to HHS necessary to enable HHS to begin, end, or change advance payments of the premium tax credit or cost-sharing reductions; and

(2) Notify and transmit information necessary to enable the issuer of the QHP to implement, discontinue the implementation, or modify the level of advance payments of the premium tax credit or cost-sharing reductions, as applicable, including:

(i) The dollar amount of the advance payment; and

(ii) The cost-sharing reductions eligibility category.

(b) *Requirement to provide information related to employer responsibility.* (1) In the event that the Exchange determines that an individual is eligible for advance payments of the premium tax credit or cost-sharing reductions based in part on a finding that an individual's employer does not provide minimum essential coverage, or provides minimum essential coverage that is unaffordable, within the standard of 26 CFR 1.36B–2(c)(3)(v), or provide minimum essential coverage that does not meet the minimum value standard of §156.145, the Exchange must transmit the individual's name and taxpayer identification number to HHS.

(2) If an enrollee for whom advance payments of the premium tax credit are made or who is receiving cost-sharing reductions notifies the Exchange that he or she has changed employers, the Exchange must transmit the enrollee's name and taxpayer identification number to HHS.

(3) In the event that an individual for whom advance payments of the premium tax credit are made or who is receiving cost-sharing reductions terminates coverage from a QHP through the Exchange during a benefit year, the Exchange must—

(i) Transmit the individual's name and taxpayer identification number, and the effective date of coverage termination, to HHS, which will transmit it to the Secretary of the Treasury; and,

(ii) Transmit the individual's name and the effective date of the termination of coverage to his or her employer.

(c) *Requirement to provide information related to reconciliation of advance payments of the premium tax credit.* The Exchange must comply with the requirements of 26 CFR 1.36B–5 regarding reporting to the IRS and to taxpayers.

(d) *Timeliness standard.* The Exchange must transmit all information required in accordance with paragraphs (a) and (b) of this section promptly and without undue delay.

(e) *Allocation of advance payments of the premium tax credit among policies.* If one or more advance payments of the premium tax credit are to be made on behalf of a tax filer (or two tax filers covered by the same plan(s)), and individuals in the tax filers' tax households are enrolled in more than one QHP or stand-alone dental plan, then the advance payment must be allocated as follows:

(1) That portion of the advance payment of the premium tax credit that is less than or equal to the aggregate adjusted monthly premiums, as defined in 26 CFR 1.36B–3(e), for the QHP policies properly allocated to EHB must be allocated among the QHP policies in a reasonable and consistent manner specified by the Exchange; and

(2) Any remaining advance payment of the premium tax credit must be allocated among the stand-alone dental policies in a reasonable and consistent manner specified by the Exchange.

(f) *Allocation of advance payments of the premium tax credit among policies offered through a Federally-facilitated Exchange.* If one or more advance payments of the premium tax credit are to be made on behalf of a tax filer (or two tax filers covered by the same plan(s)), and individuals in the tax filers' tax households are enrolled in more than one QHP or stand-alone dental plan offered through a Federally-facilitated Exchange, then that portion of the advance payment of the premium tax credit that is less than or equal to the aggregate adjusted monthly premiums, as defined in 26 CFR 1.36B–3(e), properly allocated to EHB for the QHP policies, will be allocated among the QHP policies, as described in §155.340(f)(1); and any remaining advance payment of the premium tax credit will be allocated among the stand-alone dental policies based on the methodology described in §155.340(f)(2).

(1) That portion of the advance payment(s) of the premium tax credit to be allocated among QHP policies will be allocated based on the number of enrollees covered under the QHP, weighted by the age of the enrollees, using the default uniform age rating curve established by the Secretary of HHS under 45 CFR 147.102(e), with the portion allocated to any single QHP policy not to exceed the portion of the QHP's adjusted monthly premium properly allocated to EHB. If the portion of the advance payment(s) of the premium tax credit allocated to a QHP under this subparagraph exceeds the portion of the same QHP's adjusted monthly premium properly allocated to EHB, the remainder will be allocated evenly among all other QHPs in which individuals in the tax filers' tax households are enrolled.

(2) That portion of the advance payment(s) of the premium tax credit to be allocated among stand-alone dental policies will be allocated based on the number of enrollees covered under the stand-alone dental policy, weighted by the age of the enrollees, using the default uniform age rating curve established by the Secretary of HHS under 45 CFR 147.102(e), with the portion allocated to any single stand-alone dental policy not to exceed the portion of the stand-alone dental policy premium properly allocated to EHB. If the portion of the advance payment(s) of the premium tax credit allocated to a stand-alone dental policy under this subparagraph exceeds the portion of the same policy's premium properly allocated to EHB, the remainder will be allocated evenly among all other stand-alone dental policies in which individuals in the tax filers' tax households are enrolled.

(g) *Reduction of enrollee's portion of premium to account for advance payments of the premium tax credit.* If an Exchange is facilitating the collection and payment of premiums to QHP issuers and stand-alone dental plans on behalf of enrollees under §155.240, and if a QHP issuer or stand-alone dental plan has been notified that it will receive an advance payment of the premium tax credit on behalf of an enrollee for

whom the Exchange is facilitating such functions, the Exchange must—

(1) Reduce the portion of the premium for the policy collected from the individual for the applicable month(s) by the amount of the advance payment of the premium tax credit; and

(2) Include with each billing statement, as applicable, to or for the individual the amount of the advance payment of the premium tax credit for the applicable month(s) and the remaining premium owed for the policy.

(h) *Failure to reduce enrollee's premiums to account for advance payments of the premium tax credit.* If the Exchange discovers that it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit, then the Exchange must notify the enrollee of the improper reduction within 45 calendar days of discovery of the improper reduction and refund the enrollee any excess premium paid by or for the enrollee as follows:

(1) Unless a refund is requested by or for the enrollee, the Exchange must, within 45 calendar days of discovery of the error, apply the excess premium paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the Exchange must then apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess premium is fully refunded (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the Exchange must refund any excess premium within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(2) If a refund is requested by or for the enrollee, the refund must be provided within 45 calendar days of the date of the request.

(i) *Calculation of advance payments of the premium tax credit when policy coverage lasts less than the full coverage month.* (1) For plan years beginning with 2024 and beyond, when an Exchange determines that an individual is eligible for advance payments of the premium tax credit and the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month—

(i) In an Exchange using the Federal eligibility and enrollment platform, the amount of the advance payment of the premium tax credit paid to the issuer of the policy must equal the product of—

(A) The advance payments of the premium tax credit applied to the policy for one month of coverage divided by the number of days in the month; and

(B) The number of days for which coverage is being provided in the month under the policy described in paragraph (i)(1)(i) of this section.

(ii) [Reserved]

(2) For plan years beginning with 2024 and beyond, a State Exchange operating its own platform will be required to calculate advance payments of the premium tax credit in accordance with a methodology that does not cause the amount of advance payments of the premium tax credit applied to an enrollee's monthly premium to exceed their expected monthly premium assistance credit amount when the enrollee is enrolled in a policy for less than the full coverage month, including when the enrollee is enrolled in multiple policies within a month, each lasting less than the full coverage month, and to prospectively report the methodology it intends to implement in the subsequent plan year to HHS under §155.1200(b)(2).

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 15533, Mar. 11, 2013; 78 FR 42320, July 15, 2013; 78 FR 65095, Oct. 30, 2013; 87 FR 27389, May 6, 2022]

§ 155.345 Coordination with Medicaid, CHIP, the Basic Health Program, and the Pre-existing Condition Insurance Plan.

(a) *Agreements.* The Exchange must enter into agreements with agencies administering Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, as are necessary to fulfill the requirements of this subpart and provide copies of any such agreements to HHS upon request. Such agreements must include a clear

delineation of the responsibilities of each agency to—

(1) Minimize burden on individuals;

(2) Ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay, based on the date the application is submitted to or redetermination is initiated by the Exchange or the agency administering Medicaid, CHIP, or the BHP;

(3) [Reserved]

(4) Ensure compliance with paragraphs (c), (d), (e), and (g) of this section.

(b) *Responsibilities related to individuals potentially eligible for Medicaid based on other information or through other coverage groups.* For an applicant who is not eligible for Medicaid based on the standards specified in §155.305(c), the Exchange must assess the information provided by the applicant on his or her application to determine whether he or she is potentially eligible for Medicaid based on factors not otherwise considered in this subpart.

(c) *Individuals requesting additional screening.* The Exchange must notify an applicant of the opportunity to request a full determination of eligibility for Medicaid based on eligibility criteria that are not described in §155.305(c), and provide such an opportunity. The Exchange must also make such notification to an enrollee and provide an enrollee such opportunity in any determination made in accordance with §155.330 or §155.335.

(d) *Notification of applicant and State Medicaid agency.* If an Exchange identifies an applicant as potentially eligible for Medicaid under paragraph (b) of this section or an applicant requests a full determination for Medicaid under paragraph (c) of this section, the Exchange must—

(1) Transmit all information provided on the application and any information obtained or verified by, the Exchange to the State Medicaid agency, promptly and without undue delay; and

(2) Notify the applicant of such transmittal.

(e) *Treatment of referrals to Medicaid on eligibility for advance payments of the premium tax credit and cost-sharing reductions.* The Exchange must consider an applicant who is described in paragraph (d) of this section and has not been determined eligible for Medicaid based on the standards specified in §155.305(c) as ineligible for Medicaid for purposes of eligibility for advance payments of the premium tax credit or cost-sharing reductions until the State Medicaid agency notifies the Exchange that the applicant is eligible for Medicaid.

(f) *Special rule.* If the Exchange verifies that a tax filer's household income, as defined in 26 CFR 1.36B–1(e), is less than 100 percent of the FPL for the benefit year for which coverage is requested, determines that the tax filer is not eligible for advance payments of the premium tax credit based on §155.305(f)(2), and one or more applicants in the tax filer's household has been determined ineligible for Medicaid and CHIP based on income, the Exchange must—

(1) Provide the applicant with any information regarding income used in the Medicaid and CHIP eligibility determination; and

(2) Follow the procedures specified in §155.320(c)(3).

(g) *Determination of eligibility for individuals submitting applications directly to an agency administering Medicaid, CHIP, or the BHP.* The Exchange, in consultation with the agency or agencies administering Medicaid, CHIP, and the BHP if a BHP is operating in the service area of the Exchange, must establish procedures to ensure that an eligibility determination for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions is performed when an application is submitted directly to an agency administering Medicaid, CHIP, or the BHP if a BHP is operating in the service area of the Exchange. Under such procedures, the Exchange must—

(1) Accept, via secure electronic interface, all information provided on the application and any information obtained or verified by, the agency administering Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, for the individual, and not require submission of another application;

(2) Notify such agency of the receipt of the information described in paragraph (g)(1) of this section and final eligibility determination for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions.

(3) Not duplicate any eligibility and verification findings already made by the transmitting agency, to the extent such findings are made in accordance with this part.

(4) Not request information or documentation from the individual already provided to another agency administering an insurance affordability program and included in the transmission of information provided on the application or other information transmitted from the other agency.

(5) Determine the individual's eligibility for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions, promptly and without undue delay, and in accordance with this subpart.

(6) Follow a streamlined process for eligibility determinations regardless of the agency that initially received an application.

(h) *Adherence to state decision regarding Medicaid and CHIP.* The Exchange and the Exchange appeals entity must adhere to the eligibility determination or appeals decision for Medicaid or CHIP made by the State Medicaid or CHIP agency, or the appeals entity for such agency.

(i) *Standards for sharing information between the Exchange and the agencies administering Medicaid, CHIP, and the BHP.* (1) The Exchange must utilize a secure electronic interface to exchange data with the agencies administering Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, including to verify whether an applicant for insurance affordability programs has been determined eligible for Medicaid, CHIP, or the BHP, as specified in §155.320(b)(1)(ii), and for other functions required under this subpart.

(2) *Model agreements.* The Exchange may utilize any model agreements as established by HHS for the purpose of sharing data as described in this section.

(j) *Transition from the Pre-existing Condition Insurance Plan (PCIP).* The Exchange must follow procedures established in accordance with 45 CFR 152.45 to transition PCIP enrollees to the Exchange to ensure that there are no lapses in health coverage.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 78 FR 42320, July 15, 2013; 78 FR 54136, Aug. 30, 2013]

§155.350 Special eligibility standards and process for Indians.

(a) *Eligibility for cost-sharing reductions.* (1) The Exchange must determine an applicant who is an Indian eligible for cost-sharing reductions if he or she—

(i) Meets the requirements specified in §155.305(a) and §155.305(f);

(ii) Is expected to have a household income, as defined in 26 CFR 1.36B–1(e) that does not exceed 300 percent of the FPL for the benefit year for which coverage is requested.

(2) The Exchange may only provide cost-sharing reductions to an individual who is an Indian if he or she is enrolled in a QHP through the Exchange.

(b) *Special cost-sharing rule for Indians regardless of income.* The Exchange must determine an applicant eligible for the special cost-sharing rule described in section 1402(d)(2) of the Affordable Care Act if he or she is an Indian, without requiring the applicant to request an eligibility determination for insurance affordability programs in accordance with §155.310(b) in order to qualify for this rule.

(c) *Verification related to Indian status.* To the extent that an applicant attests that he or she is an Indian, the Exchange must verify such attestation by—

(1) Utilizing any relevant documentation verified in accordance with §155.315(f);

(2) Relying on any electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently accurate and offer less administrative complexity than paper verification; or

(3) To the extent that approved data sources are unavailable, an individual

is not represented in available data sources, or data sources are not reasonably compatible with an applicant's attestation, the Exchange must follow the procedures specified in §155.315(f) and verify documentation provided by the applicant in accordance with the standards for acceptable documentation provided in section 1903(x)(3)(B)(v) of the Social Security Act.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42321, July 15, 2013]

§ 155.355 Right to appeal.

Individual appeals. The Exchange must include the notice of the right to appeal and instructions regarding how to file an appeal in any eligibility determination notice issued to the applicant in accordance with §155.310(g), §155.330(e)(1)(ii), or §155.335(h)(1)(ii).

Subpart E—Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

§ 155.400 Enrollment of qualified individuals into QHPs.

(a) *General requirements.* The Exchange must accept a QHP selection from an applicant who is determined eligible for enrollment in a QHP in accordance with subpart D, and must—

(1) Notify the issuer of the applicant's selected QHP; and

(2) Transmit information necessary to enable the QHP issuer to enroll the applicant.

(b) *Timing of data exchange.* The Exchange must:

(1) Send eligibility and enrollment information to QHP issuers and HHS promptly and without undue delay; and

(2) Establish a process by which a QHP issuer acknowledges the receipt of such information.

(3) Send updated eligibility and enrollment information to HHS promptly and without undue delay, in a manner and timeframe as specified by HHS.

(c) *Records.* The Exchange must maintain records of all enrollments in QHP issuers through the Exchange.

(d) *Reconcile files.* The Exchange must reconcile enrollment information with QHP issuers and HHS no less than on a monthly basis.

(e) *Premium payment.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform will, require payment of a binder payment to effectuate an enrollment or to add coverage retroactively to an already effectuated enrollment. Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange or State-Based Exchange on the Federal Platform:

(i) For prospective coverage to be effectuated under regular coverage effective dates, as provided for in §155.410(f), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date, and no later than 30 calendar days from the coverage effective date.

(ii) For prospective coverage to be effectuated under special effective dates, as provided for in §155.420(b)(2) and (3), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later.

(iii) For coverage to be effectuated under retroactive effective dates, as provided for in §155.420(b)(2), including when retroactive effective dates are due to a delay until after special enrollment period verification, the binder payment must consist of the premium due for all months of retroactive coverage through the first prospective month of coverage, and the deadline for making the binder payment must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with §155.420(b)(3).

(2) *Premium payment deadline extension.* Exchanges may, and the Federally-facilitated Exchanges and State-

based Exchanges on the Federal platform will, allow issuers experiencing billing or enrollment problems due to high volume or technical errors, or issuers directed to do so by applicable State or Federal authorities, to implement a reasonable extension of the binder payment and other premium payment deadlines.

(f) *Processing enrollment transactions.* The Exchange may provide requirements to QHP issuers regarding the instructions for processing electronic enrollment-related transactions.

(g) *Premium payment threshold.* Exchanges may, and the Federally-facilitated Exchanges and State-Based Exchanges on the Federal Platform will, allow issuers to implement, a premium payment threshold policy under which issuers can consider enrollees to have paid all amounts due if the enrollees pay an amount sufficient to maintain a percentage of total premium paid out of the total premium owed equal to or greater than a level prescribed by the issuer, provided that the level is reasonable and that the level and the policy are applied in a uniform manner to all enrollees. If an applicant or enrollee satisfies the premium payment threshold policy, the issuer may:

(1) Effectuate an enrollment based on payment of the binder payment under paragraph (e) of this section.

(2) Avoid triggering a grace period for non-payment of premium, as described by §156.270(d) of this subchapter or a grace period governed by State rules.

(3) Avoid terminating the enrollment for non-payment of premium as, described by §§156.270(g) of this subchapter and 155.430(b)(2)(ii)(A) and (B).

(h) *Requirements.* A State Exchange may rely on HHS to carry out the requirements of this section and other requirements contained within this subpart through a Federal platform agreement.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42321, July 15, 2013; 79 FR 30348, May 27, 2014; 80 FR 10866, Feb. 27, 2015; 81 FR 12343, Mar. 8, 2016; 81 FR 94177, Dec. 22, 2016; 82 FR 18381, Apr. 18, 2017; 85 FR 29260, May 14, 2020; 89 FR 26423, Apr. 15, 2024]

§155.405 Single streamlined application.

(a) *The application.* The Exchange must use a single streamlined application to determine eligibility and to collect information necessary for:

(1) Enrollment in a QHP;

(2) Advance payments of the premium tax credit;

(3) Cost-sharing reductions; and

(4) Medicaid, CHIP, or the BHP, where applicable.

(b) *Alternative application.* If the Exchange seeks to use an alternative application, such application, as approved by HHS, must request the minimum information necessary for the purposes identified in paragraph (a) of this section.

(c) *Filing the single streamlined application.* The Exchange must—

(1) Accept the single streamlined application from an application filer;

(2) Provide the tools to file an application—

(i) Via an Internet Web site;

(ii) By telephone through a call center;

(iii) By mail; and

(iv) In person, with reasonable accommodations for those with disabilities, as defined by the Americans with Disabilities Act.

§155.410 Initial and annual open enrollment periods.

(a) *General requirements.* (1) The Exchange must provide an initial open enrollment period and annual open enrollment periods consistent with this section, during which qualified individuals may enroll in a QHP and enrollees may change QHPs.

(2) The Exchange may only permit a qualified individual to enroll in a QHP or an enrollee to change QHPs during the initial open enrollment period specified in paragraph (b) of this section, the annual open enrollment period specified in paragraph (e) of this section, or a special enrollment period described in §155.420 of this subpart for which the qualified individual has been determined eligible.

(b) *Initial open enrollment period.* The initial open enrollment period begins October 1, 2013 and extends through March 31, 2014.

(c) *Effective coverage dates for initial open enrollment period*—(1) *Regular effective dates.* For a QHP selection received by the Exchange from a qualified individual—

(i) On or before December 23, 2013, the Exchange must ensure a coverage effective date of January 1, 2014.

(ii) Between the first and fifteenth day of any subsequent month during the initial open enrollment period, the Exchange must ensure a coverage effective date of the first day of the following month.

(iii) Between the sixteenth and last day of the month for any month between January 2014 and March 31, 2014 or between the twenty-fourth and the thirty-first of the month of December 2013, the Exchange must ensure a coverage effective date of the first day of the second following month.

(iv) Notwithstanding the requirement of paragraph (c)(1)(i) of this section, an Exchange or SHOP operated by a State may require a January 1, 2014 effective date for plan selection dates later than December 23, 2013; a SHOP may also establish plan selection dates as early as December 15, 2013 for enrollment in SHOP QHPs for a January 1, 2014 coverage effective date.

(v) Notwithstanding the regular effective dates set forth in this section, an Exchange may allow issuers to provide for a coverage effective date of January 1, 2014 for plan selections received after December 23, 2013 and on or before January 31, 2014, if a QHP issuer is willing to accept such enrollments.

(2) *Option for earlier effective dates.* Subject to the Exchange demonstrating to HHS that all of its participating QHP issuers agree to effectuate coverage in a timeframe shorter than discussed in paragraphs (c)(1)(ii) and (iii) of this section, the Exchange may do one or both of the following for all applicable individuals:

(i) For a QHP selection received by the Exchange from a qualified individual in accordance with the dates specified in paragraph (c)(1)(ii) or (iii) of this section, the Exchange may provide a coverage effective date for a qualified individual earlier than specified in such paragraphs, provided that either—

(A) The qualified individual has not been determined eligible for advance payments of the premium tax credit or cost-sharing reductions; or

(B) The qualified individual pays the entire premium for the first partial month of coverage as well as all cost sharing, thereby waiving the benefit of advance payments of the premium tax credit and cost-sharing reduction payments until the first of the next month.

(ii) For a QHP selection received by the Exchange from a qualified individual on a date set by the Exchange after the fifteenth of the month for any month between December 2013 and March 31, 2014, the Exchange may provide a coverage effective date of the first of the following month.

(d) *Notice of annual open enrollment period.* Starting in 2014, the Exchange must provide a written annual open enrollment notification to each enrollee no earlier than the first day of the month before the open enrollment period begins and no later than the first day of the open enrollment period.

(e) *Annual open enrollment period.* (1) For the benefit year beginning on January 1, 2015, the annual open enrollment period begins on November 15, 2014, and extends through February 15, 2015.

(2) For the benefit years beginning on January 1, 2016 and January 1, 2017, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year, and extends through January 31 of the benefit year.

(3) For the benefit years beginning on January 1, 2018 through January 1, 2021, the annual open enrollment period begins on November 1 and extends through December 15 of the calendar year preceding the benefit year.

(4) For the benefit years beginning on or after January 1, 2022—

(i) Subject to paragraphs (e)(4)(ii) and (iii) of this section, the annual open enrollment period begins on November 1 of the calendar year preceding the benefit year and extends through January 15 of the benefit year.

(ii) For State Exchanges, for the benefit years beginning on or after January 1, 2025, a later annual open enrollment period end date may be adopted, such that the open enrollment period

begins on November 1 of the calendar year preceding the benefit year and ends after January 15 of the benefit year.

(iii) For any State Exchange with an annual open enrollment period that began before November 1, 2023, and ended before January 15, 2024, for the 2024 benefit year, that State Exchange may continue to begin open enrollment before November 1 for consecutive future benefit years, so long as the open enrollment period continues uninterrupted for at least 11 weeks. If such State Exchange changes the date(s) of their annual open enrollment period, it must comply with paragraphs (e)(4)(i) and (ii) for all future annual open enrollment periods.

(f) *Effective date.* (1) For the benefit year beginning on January 1, 2015, the Exchange must ensure coverage is effective—

(i) January 1, 2015, for QHP selections received by the Exchange on or before December 15, 2014.

(ii) February 1, 2015, for QHP selections received by the Exchange from December 16, 2014 through January 15, 2015.

(iii) March 1, 2015, for QHP selections received by the Exchange from January 16, 2015 through February 15, 2015.

(2) For the benefit years beginning on January 1, 2016 through January 1, 2021, the Exchange must ensure coverage is effective—

(i) January 1, for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(ii) February 1, for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(iii) March 1, for QHP selections received by the Exchange from January 16 through January 31 of the benefit year.

(3) For benefit years beginning on or after January 1, 2022, the Exchange must ensure that coverage is effective—

(i) Subject to paragraph (f)(3)(ii) of this section—

(A) January 1, for QHP selections received by the Exchange on or before December 15 of the calendar year preceding the benefit year.

(B) February 1, for QHP selections received by the Exchange from December 16 of the calendar year preceding the benefit year through January 15 of the benefit year.

(C) The first of the following month, for QHP selections received by the 15 of a month after January, if applicable under paragraph (e)(4)(ii) of this section.

(D) The first of the second following month, for plan selections received between the 16th and the end of a month, beginning January 16 of the benefit year, if applicable under paragraph (e)(4)(ii) of this section.

(ii) For State Exchanges not utilizing the Federal platform, for a QHP selection received by the Exchange during the open enrollment period for which effective dates specified in paragraph (f)(3)(i) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

(g) *Automatic enrollment.* The Exchange may automatically enroll qualified individuals, at such time and in such manner as HHS may specify, and subject to the Exchange demonstrating to HHS that it has good cause to perform such automatic enrollments.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 76218, Dec. 17, 2013; 79 FR 13838, Mar. 11, 2014; 79 FR 30348, May 27, 2014; 80 FR 10866, Feb. 27, 2015; 81 FR 12343, Mar. 8, 2016; 82 FR 18381, Apr. 18, 2017; 86 FR 53503, Sept. 27, 2021; 89 FR 26423, Apr. 15, 2024]

§ 155.415 Allowing issuer or direct enrollment entity application assisters to assist with eligibility applications.

(a) *Exchange option.* An Exchange, to the extent permitted by State law, may permit issuer application assisters and direct enrollment entity application assisters, as defined at § 155.20, to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and

insurance affordability programs, provided that such issuer application assisters or direct enrollment entity application assisters meet the requirements set forth in paragraph (b) of this section.

(b) *Application assister requirements.* If permitted by an Exchange under paragraph (a) of this section, and to the extent permitted by State law, an issuer may permit its issuer application assisters and a direct enrollment entity may permit its direct enrollment entity application assisters to assist individuals in the individual market with applying for a determination or redetermination of eligibility for coverage through the Exchange and for insurance affordability programs, provided that such issuer or direct enrollment entity ensures that each of its issuer application assisters or direct enrollment entity application assisters at least—

(1) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations, and for application assisters providing assistance in the Federally-facilitated Exchanges or a State Exchange using the Federal platform, the assisters must fulfill this requirement by completing registration and training in a form and manner to be specified by HHS;

(2) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260; and

(3) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including any State licensure laws applicable to the functions to be performed by the issuer application assister or direct enrollment entity application assister, as well as State law related to confidentiality and conflicts of interest.

[84 FR 17567, Apr. 25, 2019]

§ 155.420 Special enrollment periods.

(a) *General requirements*—(1) *General parameters.* The Exchange must provide special enrollment periods consistent with this section, during which qualified individuals may enroll in QHPs and enrollees may change QHPs.

(2) *Definition of dependent.* For the purpose of this section, ''dependent'', has the same meaning as it does in 26 CFR 54.9801–2, referring to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee.

(3) *Use of special enrollment periods.* Except in the circumstances specified in paragraph (a)(4) of this section, the Exchange must allow a qualified individual or enrollee, and when specified in paragraph (d) of this section, his or her dependent to enroll in a QHP if one of the triggering events specified in paragraph (d) of this section occur.

(4) *Use of special enrollment periods by enrollees.* (i) If an enrollee has gained a dependent in accordance with paragraph (d)(2)(i) of this section, the Exchange must allow the enrollee to add the dependent to his or her current QHP, or, if the current QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or, at the option of the enrollee or dependent, enroll the dependent in any separate QHP.

(A) If an enrollee or their dependents become newly eligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and the enrollee or their dependents are not enrolled in a silver-level QHP, the Exchange must allow the enrollee and their dependents to change to a silver-level QHP if they elect to change their QHP enrollment; or

(B) Beginning January 2022, if an enrollee or their dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and the enrollee or his or her dependents are enrolled in a silver-level QHP, the Exchange must allow the enrollee and their dependents to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment;

(C) No later than January 1, 2024, if an enrollee or his or her dependents become newly ineligible for advance payments of the premium tax credit in accordance with paragraph (d)(6)(i) or (ii) of this section, the Exchange must

allow the enrollee and his or her dependents to change to a QHP of any metal level, if they elect to change their QHP enrollment; or

(D) If an enrollee or his or her enrolled dependents qualify for a special enrollment period in accordance with paragraph (d)(16) of this section, the Exchange must allow the enrollee and his or her enrolled dependents to change to any available silver-level QHP if they elect to change their QHP enrollment. If a qualified individual or a dependent who is not an enrollee qualifies for a special enrollment period in accordance with paragraph (d)(16) of this section and has one or more household members who are enrollees, the Exchange must allow the enrollee to add the newly enrolling household member to his or her current QHP; or, to change to a silver-level QHP and add the newly enrolling household member to this silver-level QHP; or, to change to a silver level QHP and enroll the newly enrolling qualified individual or dependent in a separate QHP;

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), and (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs and paragraphs (d)(8), (9), (10), (12), (14), and (16) of this section:

(A) If an enrollee qualifies for a special enrollment period, the Exchange must allow the enrollee and his or her dependents, if applicable, to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in §156.140(b) of this subchapter;

(B) If a dependent qualifies for a special enrollment period, and an enrollee who does not also qualify for a special enrollment period is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in §156.140(b) of this subchapter, or enroll the new qualified individual in a separate QHP; or

(C) If a qualified individual who is not an enrollee qualifies for a special enrollment period and has one or more dependents who are enrollees who do not also qualify for a special enrollment period, the Exchange must allow the newly enrolling qualified individual to add himself or herself to a dependent's current QHP; or, if the QHP's business rules do not allow the qualified individual to enroll in the dependent's current QHP, to enroll with his or her dependent(s) in another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in §156.140(b) of this subchapter, or enroll himself or herself in a separate QHP.

(5) *Prior coverage requirement.* Qualified individuals who are required to demonstrate coverage in the 60 days prior to a qualifying event can either demonstrate that they had minimum essential coverage as described in 26 CFR 1.5000A–1(b) or demonstrate that they had coverage as described in paragraphs (d)(1)(iii) or (iv) of this section for 1 or more days during the 60 days preceding the date of the qualifying event; lived in a foreign country or in a United States territory for 1 or more days during the 60 days preceding the date of the qualifying event; are an Indian as defined by section 4 of the Indian Health Care Improvement Act; or lived for 1 or more days during the 60 days preceding the qualifying event or during their most recent preceding enrollment period, as specified in §§155.410 and 155.420, in a service area where no qualified health plan was available through the Exchange.

(b) *Effective dates*—(1) *Regular effective dates.* Except as specified in paragraphs (b)(2) and (3) of this section, for a QHP selection received by the Exchange from a qualified individual, the Exchange must ensure a coverage effective date of the first day of the month following the QHP selection; except that before January 1, 2025, for a QHP selection received by the Exchange from a qualified individual between the sixteenth and the last day of any month, the Exchange may ensure a coverage effective date of the first day

of the second month following QHP selection.

(2) *Special effective dates.* (i) In the case of birth, adoption, placement for adoption, placement in foster care, or child support or other court order as described in paragraph (d)(2)(i) of this section, the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the date of birth, adoption, placement for adoption, placement in foster care, or effective date of court order; or it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following plan selection; or in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee to elect a coverage effective date of either the first of the month following the date of plan selection or in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the qualified individual or enrollee.

(ii) In the case of marriage as described in paragraph (d)(2) of this section the Exchange must ensure that coverage is effective for a qualified individual or enrollee on the first day of the month following plan selection.

(iii) In the case of a qualified individual or enrollee eligible for a special enrollment period as described in paragraph (d)(4), (5), (9), (11), (12), or (13) of this section, the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period.

(iv) If a qualified individual, enrollee, or dependent, as applicable, loses coverage as described in paragraph (d)(1) or (d)(6)(iii) of this section, or is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, or for which a government entity is providing subsidies, and the employer contributions or government subsidies completely cease as described in paragraph (d)(15) of this section, gains access to a new QHP as described in paragraph (d)(7) of this section, becomes newly eligible for enrollment in a QHP through the Exchange in accordance with §155.305(a)(2) as described in paragraph (d)(3) of this section, becomes newly eligible for advance payments of the premium tax credit in conjunction with a permanent move as described in paragraph (d)(6)(iv) of this section, and if the plan selection is made on or before the day of the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month following the date of the triggering event. If the plan selection is made after the date of the triggering event, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the following month, at the option of the Exchange. Notwithstanding the requirements of this paragraph (b)(2)(iv) with respect to losses of coverage as described at paragraphs (d)(1), (d)(6)(iii), and (d)(15) of this section, at the option of the Exchange, if the plan selection is made on or before the last day of the month preceding the triggering event, the Exchange must ensure that the coverage effective date is the first day of the month in which the triggering event occurs.

(v) If an enrollee or his or her dependent dies as described in paragraph (d)(2)(ii) of this section, the Exchange must ensure that coverage is effective on the first day of the month following the plan selection, or it may permit the enrollee or his or her dependent to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the enrollee or his or her dependent to elect a coverage effective date in accordance with paragraph (b)(1) of this section, the Exchange must ensure coverage is effective on the date duly selected by the enrollee or his or her dependent.

(vi) If a qualified individual, enrollee, or dependent newly gains access to an individual coverage HRA or is newly provided a QSEHRA, each as described in paragraph (d)(14) of this section, and if the plan selection is made before the day of the triggering event, the Exchange must ensure that coverage is effective on the first day of the month following the date of the triggering event or, if the triggering event is on the first day of a month, on the date of the triggering event. If the plan selection is made on or after the day of the triggering event, the Exchange must

ensure that coverage is effective on the first day of the month following plan selection.

(vii) If a qualified individual or enrollee, or the dependent of a qualified individual or enrollee, who is eligible for advance payments of the premium tax credit, and whose household income, as defined in 26 CFR 1.36B–1(e), is expected to be no greater than 150 percent of the Federal poverty level, enrolls in a QHP or changes from one QHP to another one time per month in accordance with paragraph (d)(16) of this section, the Exchange must ensure that coverage is effective in accordance with paragraph (b)(1) of this section or on the first day of the month following plan selection, at the option of the Exchange.

(3) *Option for earlier effective dates.* (i) For a QHP selection received by the Exchange under a special enrollment period for which the effective dates of coverage specified in paragraph (b)(1) or (b)(2)(i) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

(ii) For a QHP selection received by the Exchange under a special enrollment period for which special effective dates specified in paragraph (b)(2)(ii) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

(4) *Advance payments of the premium tax credit and cost-sharing reductions.* Notwithstanding the standards of this section, the Exchange must ensure that advance payments of the premium tax credit and cost-sharing reductions adhere to the effective dates specified in §155.330(f).

(5) *Option for earlier effective dates due to untimely notice of triggering event.* At the option of a qualified individual, enrollee or dependent who is eligible to select a plan during a period provided for under paragraph (c)(5) of this section, the Exchange must provide the earliest effective date that would have been available under paragraph (b) of this section, based on the applicable triggering event under paragraph (d) of this section.

(c) *Availability and length of special enrollment periods*—(1) *General rule.* Unless specifically stated otherwise herein, a qualified individual or enrollee has 60 days from the date of a triggering event to select a QHP.

(2) *Advanced availability.* A qualified individual or their dependent who is described in paragraph (d)(1), (d)(6)(iii), or (d)(15) of this section has 60 days before and, unless the Exchange exercises the option in paragraph (c)(6) of this section, 60 days after the triggering event to select a QHP. At the option of the Exchange, a qualified individual or their dependent who is described in paragraph (d)(7) of this section; who is described in paragraph (d)(6)(iv) of this section becomes newly eligible for advance payments of the premium tax credit as a result of a permanent move to a new State; or who is described in paragraph (d)(3) of this section and becomes newly eligible for enrollment in a QHP through the Exchange because they newly satisfy the requirements under §155.305(a)(2), has 60 days before or after the triggering event to select a QHP.

(3) *Advanced availability for individuals with an individual coverage HRA or QSEHRA.* A qualified individual, enrollee, or his or her dependent who is described in paragraph (d)(14) of this section has 60 days before the triggering event to select a QHP, unless the HRA or QSEHRA was not required to provide the notice setting forth its terms to such individual or enrollee at least 90 days before the beginning of the plan year, as specified in 45 CFR 146.123(c)(6), 26 CFR 54.9802–4(c)(6), and 29 CFR 2590.702–2(c)(6) or section 9831(d)(4) of the Internal Revenue Code, as applicable, in which case the qualified individual, enrollee, or his or her dependent has 60 days before or after the triggering event to select a QHP.

(4) *Special rule.* In the case of a qualified individual or enrollee who is eligible for a special enrollment period as described in paragraphs (d)(4), (5), or (9) of this section, the Exchange may define the length of the special enrollment period as appropriate based on the circumstances of the special enrollment period, but in no event may the length of the special enrollment period exceed 60 days.

(5) *Availability for individuals who did not receive timely notice of triggering*

events. If a qualified individual, enrollee, or dependent did not receive timely notice of an event that triggers eligibility for a special enrollment period under this section, and otherwise was reasonably unaware that a triggering event described in paragraph (d) of this section occurred, the Exchange must allow the qualified individual, enrollee, or when applicable, his or her dependent to select a new plan within 60 days of the date that he or she knew, or reasonably should have known, of the occurrence of the triggering event.

(6) *Special rule for individuals losing Medicaid or CHIP.* Beginning January 1, 2024, or earlier, at the option of the Exchange, a qualified individual or their dependent(s) who is described in paragraph (d)(1)(i) of this section and whose loss of coverage is a loss of Medicaid or CHIP coverage shall have 90 days after the triggering event to select a QHP. If a State Medicaid or CHIP Agency allows or provides for a Medicaid or CHIP reconsideration period greater than 90 days, the Exchange in that State may elect to provide a qualified individual or their dependent(s) who is described in paragraph (d)(1)(i) of this section and whose loss of coverage is a loss of Medicaid or CHIP coverage additional time to select a QHP, up to the number of days provided for the applicable Medicaid or CHIP reconsideration period.

(d) *Triggering events.* Subject to paragraphs (a)(3) through (5) of this section, as applicable, the Exchange must allow a qualified individual or enrollee, and, when specified below, his or her dependent, to enroll in or change from one QHP to another if one of the triggering events occur:

(1) The qualified individual or his or her dependent either:

(i) Loses minimum essential coverage. The date of the loss of coverage is the last day the consumer would have coverage under his or her previous plan or coverage;

(ii) Is enrolled in any non-calendar year group health plan, individual health insurance coverage, or qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code); even if the qualified individual or his or her dependent has the option to renew or re-enroll in such coverage. The date of the loss of coverage is the last day of the plan year;

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)) or loses access to health care services through coverage provided to a pregnant woman's unborn child, based on the definition of a child in 42 CFR 457.10. The date of the loss of coverage is the last day the qualified individual would have pregnancy-related coverage or access to health care services through the unborn child coverage; or

(iv) Loses medically needy coverage as described under section 1902(a)(10)(C) of the Social Security Act only once per calendar year. The date of the loss of coverage is the last day the consumer would have medically needy coverage.

(2)(i) The qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, or placement in foster care, or through a child support order or other court order.

(A) In the case of marriage, at least one spouse must demonstrate having minimum essential coverage as described in 26 CFR 1.5000A–1(b) for 1 or more days during the 60 days preceding the date of marriage.

(B) [Reserved]

(ii) At the option of the Exchange, the enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation as defined by State law in the State in which the divorce or legal separation occurs, or if the enrollee, or his or her dependent, dies.

(3) The qualified individual, or his or her dependent, becomes newly eligible for enrollment in a QHP through the Exchange because he or she newly satisfies the requirements under § 155.305(a)(1) or (2);

(4) The qualified individual's or his or her dependent's, enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, misconduct, or inaction of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-

Exchange entity providing enrollment assistance or conducting enrollment activities. For purposes of this provision, misconduct includes the failure to comply with applicable standards under this part, part 156 of this subchapter, or other applicable Federal or State laws as determined by the Exchange.

(5) The enrollee or, his or her dependent adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of its contract in relation to the enrollee;

(6)(i) The enrollee is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions;

(ii) The enrollee's dependent enrolled in the same QHP is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions;

(iii) A qualified individual or his or her dependent who is enrolled in an eligible employer-sponsored plan is determined newly eligible for advance payments of the premium tax credit based in part on a finding that such individual is ineligible for qualifying coverage in an eligible-employer sponsored plan in accordance with 26 CFR 1.36B–2(c)(3), including as a result of his or her employer discontinuing or changing available coverage within the next 60 days, provided that such individual is allowed to terminate existing coverage;

(iv) A qualified individual who was previously ineligible for advance payments of the premium tax credit solely because of a household income below 100 percent of the FPL and who, during the same timeframe, was ineligible for Medicaid because he or she was living in a non-Medicaid expansion State, who either experiences a change in household income or moves to a different State resulting in the qualified individual becoming newly eligible for advance payments of the premium tax credit; or

(v) At the option of the Exchange, the qualified individual, or his or her dependent—

(A) Experiences a decrease in household income;

(B) Is newly determined eligible by the Exchange for advance payments of the premium tax credit; and

(C) Had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for one or more days during the 60 days preceding the date of the financial change.

(7) The qualified individual or enrollee, or his or her dependent, gains access to new QHPs as a result of a permanent move and—

(i) Had minimum essential coverage as described in 26 CFR 1.5000A–1(b) for one or more days during the 60 days preceding the date of the permanent move.

(ii) [Reserved]

(8) The qualified individual—

(i) Who gains or maintains status as an Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to another one time per month; or

(ii) Who is or becomes a dependent of an Indian, as defined by section 4 of the Indian Health Care Improvement Act and is enrolled or is enrolling in a QHP through an Exchange on the same application as the Indian, may change from one QHP to another one time per month, at the same time as the Indian;

(9) The qualified individual or enrollee, or his or her dependent, demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide;

(10) A qualified individual or enrollee—

(i) Is a victim of domestic abuse or spousal abandonment as defined by 26 CFR 1.36B–2 or a dependent or unmarried victim within a household, is enrolled in minimum essential coverage, and sought to enroll in coverage separate from the perpetrator of the abuse or abandonment; or

(ii) Is a dependent of a victim of domestic abuse or spousal abandonment, on the same application as the victim, may enroll in coverage at the same time as the victim;

(11) A qualified individual or dependent—

(i) Applies for coverage on the Exchange during the annual open enrollment period or due to a qualifying event, is assessed by the Exchange as potentially eligible for Medicaid or the Children's Health Insurance Program (CHIP), and is determined ineligible for Medicaid or CHIP by the State Medicaid or CHIP agency either after open enrollment has ended or more than 60 days after the qualifying event; or

(ii) Applies for coverage at the State Medicaid or CHIP agency during the annual open enrollment period, and is determined ineligible for Medicaid or CHIP after open enrollment has ended;

(12) The enrollment in a QHP through the Exchange was influenced by a material error related to plan benefits, service area, cost-sharing, or premium. A material error is one that is likely to have influenced a qualified individual's, enrollee's, or their dependent's enrollment in a QHP.

(13) At the option of the Exchange, the qualified individual provides satisfactory documentary evidence to verify his or her eligibility for an insurance affordability program or enrollment in a QHP through the Exchange following termination of Exchange enrollment due to a failure to verify such status within the time period specified in §155.315 or is under 100 percent of the Federal poverty level and did not enroll in coverage while waiting for HHS to verify his or her citizenship, status as a national, or lawful presence; or

(14) The qualified individual, enrollee, or dependent newly gains access to an individual coverage HRA (as defined in 45 CFR 146.123(b)) or is newly provided a qualified small employer health reimbursement arrangement (QSEHRA) (as defined in section 9831(d)(2) of the Internal Revenue Code). The triggering event is the first day on which coverage for the qualified individual, enrollee, or dependent under the individual coverage HRA can take effect, or the first day on which coverage under the QSEHRA takes effect. An individual, enrollee, or dependent will qualify for this special enrollment period regardless of whether they were previously offered or enrolled in an individual coverage HRA or previously provided a QSEHRA, so long as the individual, enrollee, or dependent is not enrolled in the individual coverage HRA or covered by the QSEHRA on the day immediately prior to the triggering event.

(15) The qualified individual or his or her dependent is enrolled in COBRA continuation coverage for which an employer is paying all or part of the premiums, or for which a government entity is providing subsidies, and the employer completely ceases its contributions to the qualified individual's or dependent's COBRA continuation coverage or government subsidies completely cease. The triggering event is the last day of the period for which COBRA continuation coverage is paid for or subsidized, in whole or in part, by an employer or government entity. For purposes of this paragraph, ''COBRA continuation coverage'' has the meaning provided for in §144.103 of this subchapter and includes coverage under a similar State program.

(16) At the option of the Exchange, a qualified individual or enrollee, or the dependent of a qualified individual or enrollee, who is eligible for advance payments of the premium tax credit, and whose household income, as defined in 26 CFR 1.36B–1(e), is expected to be at or below 150 percent of the Federal poverty level, may enroll in a QHP or change from one QHP to another one time per month.

(e) *Loss of coverage.* Loss of coverage described in paragraph (d)(1) of this section includes those circumstances described in 26 CFR 54.9801–6(a)(3)(i) through (iii) and in paragraphs (d)(1)(ii) through (iv) of this section. Loss of coverage does not include voluntary termination of coverage or other loss due to—

(1) Failure to pay premiums on a timely basis, including COBRA continuation coverage premiums prior to expiration of COBRA continuation coverage, except for circumstances in which an employer completely ceases its contributions to COBRA continuation coverage, or government subsidies of COBRA continuation coverage completely cease as described in paragraph (d)(15) of this section, or

(2) Situations allowing for a rescission as specified in 45 CFR 147.128.

(f) For purposes of this section, references to eligibility for advance payments of the premium tax credit refer to being eligible for such advance payments in an amount greater than zero dollars per month. References to ineligibility for advance payments of the premium tax credit refer to being ineligible for such payments or being eligible for such payments but being eligible for a maximum of zero dollars per month of such payments.

(g) *Pre-enrollment special enrollment period verification.* At the option of the Exchange, an Exchange may verify prior to processing a qualified individual's plan selection that the qualified individual is eligible for a special enrollment period under this section. In circumstances where the Exchange determines that such pre-enrollment special enrollment period verification may cause undue burden on qualified individuals, the Exchange may provide an exception to the pre-enrollment special enrollment period verification process, provided it does so in a manner consistent with the non-discrimination requirements under §155.120(c). Exchanges on the Federal platform will conduct pre-enrollment special enrollment verification of eligibility only for special enrollment periods under paragraph (d)(1) of this section.

[77 FR 18444, Mar. 27, 2012]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §155.420, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§155.430 Termination of Exchange enrollment or coverage.

(a) *General requirements.* The Exchange must determine the form and manner in which enrollment in a QHP through the Exchange may be terminated.

(b) *Termination events*—(1) *Enrollee-initiated terminations.* (i) The Exchange must permit an enrollee to terminate his or her coverage or enrollment in a QHP through the Exchange, including as a result of the enrollee obtaining other minimum essential coverage. To the extent the enrollee has the right to terminate the coverage under applicable State laws, including ''free look'' cancellation laws, the enrollee may do so, in accordance with such laws.

(ii) The Exchange must provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage and the enrollee does not request termination in accordance with paragraph (b)(1)(i) of this section. If an enrollee does not choose to remain enrolled in a QHP in such situation, the Exchange must initiate termination of his or her enrollment in the QHP upon completion of the process specified in §155.330(e)(2).

(iii) The Exchange must establish a process to permit individuals, including enrollees' authorized representatives, to report the death of an enrollee for purposes of initiating termination of the enrollee's Exchange enrollment. The Exchange may require the reporting party to submit documentation of the death. Any applicable premium refund, or premium due, must be processed by the deceased enrollee's QHP in accordance with State law.

(iv) The Exchange must permit an enrollee to retroactively terminate or cancel the enrollee's coverage or enrollment in a QHP in the following circumstances:

(A) The enrollee demonstrates to the Exchange that he or she attempted to terminate his or her coverage or enrollment in a QHP and experienced a technical error that did not allow the enrollee to terminate his or her coverage or enrollment through the Exchange, and requests retroactive termination within 60 days after he or she discovered the technical error.

(B) The enrollee demonstrates to the Exchange that his or her enrollment in a QHP through the Exchange was unintentional, inadvertent, or erroneous and was the result of the error or misconduct of an officer, employee, or agent of the Exchange or HHS, its instrumentalities, or a non-Exchange entity providing enrollment assistance or conducting enrollment activities. Such enrollee must request cancellation within 60 days of discovering the unintentional, inadvertent, or erroneous enrollment. For purposes of this paragraph (b)(1)(iv)(B), misconduct includes the failure to comply with applicable

standards under this part, part 156 of this subchapter, or other applicable Federal or State requirements as determined by the Exchange.

(C) The enrollee demonstrates to the Exchange that he or she was enrolled in a QHP without his or her knowledge or consent by any third party, including third parties who have no connection with the Exchange, and requests cancellation within 60 days of discovering of the enrollment.

(D) In a Federally-facilitated Exchange or a State-based Exchange on the Federal platform, if HHS elects to permit such terminations, and in a State Exchange that elects to permit such terminations, the enrollee demonstrates to the Exchange that the enrollee enrolled in Medicare Part A or B coverage with a retroactive effective date, and requests retroactive termination of QHP coverage within 60 days of the enrollment. The effective date of the retroactive termination must be no earlier than the later of the day before the first day of coverage under Medicare Part A or B, and the day that is six months before the retroactive termination in QHP coverage is requested. A retroactive termination date as described in this paragraph is not available for enrollments in stand-alone dental plans.

(2) *Exchange-initiated terminations.* The Exchange may initiate termination of an enrollee's enrollment in a QHP through the Exchange, and must permit a QHP issuer to terminate such coverage or enrollment, in the following circumstances:

(i) The enrollee is no longer eligible for coverage in a QHP through the Exchange;

(ii) Non-payment of premiums for coverage of the enrollee, and

(A) The exhaustion of the 3-month grace period, as described in §156.270(d) and (g) of this subchapter, required for enrollees, who when first failing to timely pay premiums, are receiving advance payments of the premium tax credit.

(B) Any other grace period not described in paragraph (b)(2)(ii)(A) of this section has been exhausted;

(iii) The enrollee's coverage is rescinded in accordance with §147.128 of this subchapter, after a QHP issuer demonstrates, to the reasonable satisfaction of the Exchange, if required by the Exchange, that the rescission is appropriate;

(iv) The QHP terminates or is decertified as described in §155.1080; or

(v) The enrollee changes from one QHP to another during an annual open enrollment period or special enrollment period in accordance with §155.410 or §155.420.

(vi) The enrollee was enrolled in a QHP without his or her knowledge or consent by a third party, including by a third party with no connection with the Exchange.

(vii) Any other reason for termination of coverage described in §147.106 of this subchapter.

(3) *Prohibition of issuer-initiated terminations due to aging-off.* Exchanges on the Federal platform must, and State Exchanges using their own platform may, prohibit QHP issuers from terminating dependent coverage of a child before the end of the plan year in which the child attains age 26 (or, if higher, the maximum age a QHP issuer is required to make available dependent coverage of children under applicable State law or the issuer's business rules), on the basis of the child's age, unless otherwise permitted.

(c) *Termination of coverage or enrollment tracking and approval.* The Exchange must—

(1) Establish mandatory procedures for QHP issuers to maintain records of termination of enrollment in a QHP through the Exchange;

(2) Send termination information to the QHP issuer and HHS, promptly and without undue delay in accordance with §155.400(b).

(3) Require QHP issuers to make reasonable accommodations for all individuals with disabilities (as defined by the Americans with Disabilities Act) before terminating enrollment of such individuals through the Exchange; and

(4) Retain records in order to facilitate audit functions.

(d) *Effective dates for termination of coverage or enrollment.* (1) For purposes of this section—

(i) Reasonable notice is defined as at least fourteen days before the requested effective date of termination; and

(ii) Changes in eligibility for advance payments of the premium tax credit and cost sharing reductions, including terminations, must adhere to the effective dates specified in §155.330(f).

(2) In the case of a termination in accordance with paragraph (b)(1) of this section, the last day of enrollment through the Exchange is—

(i) The termination date specified by the enrollee, if the enrollee provides reasonable notice;

(ii) If the enrollee does not provide reasonable notice, fourteen days after the termination is requested by the enrollee; or

(iii) At the option of the Exchange, on the date on which the termination is requested by the enrollee, or on another prospective date selected by the enrollee; or

(iv) If an Exchange does not require an earlier termination date in accordance with paragraph (d)(2)(iii) of this section, at the option of the QHP issuer, on a date on or after the termination is requested by the enrollee that is less than 14 days after the termination is requested by the enrollee, if the enrollee requests an earlier termination date; or

(v) At the option of the Exchange, for an individual who is newly determined eligible for Medicaid, CHIP, or the Basic Health Program, if a Basic Health Program is operating in the service area of the Exchange, the day before the enrollee's date of eligibility for Medicaid, CHIP, or the Basic Health Program.

(vi) The retroactive termination date requested by the enrollee, if specified by applicable State laws.

(3) In the case of a termination in accordance with paragraph (b)(2)(i) of this section, the last day of enrollment in a QHP through the Exchange is the last day of eligibility, as described in §155.330(f), unless the individual requests an earlier termination effective date per paragraph (b)(1) of this section.

(4) In the case of a termination in accordance with paragraph (b)(2)(ii)(A) of this section, the last day of enrollment in a QHP through the Exchange will be the last day of the first month of the 3-month grace period.

(5) In the case of a termination in accordance with paragraph (b)(2)(ii)(B) of this section, the last day of enrollment in a QHP through the Exchange should be consistent with existing State laws regarding grace periods.

(6) In the case of a termination in accordance with paragraph (b)(2)(v) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP, including any retroactive enrollments effectuated under §155.420(b)(2)(iii).

(7) In the case of a termination due to death, the last day of enrollment in a QHP through the Exchange is the date of death.

(8) In cases of retroactive termination dates, the Exchange will ensure that appropriate actions are taken to make necessary adjustments to advance payments of the premium tax credit, cost-sharing reductions, premiums, claims, and user fees.

(9) In case of a retroactive termination in accordance with paragraph (b)(1)(iv)(A) of this section, the termination date will be no sooner than the date that would have applied under paragraph (d)(2) of this section, based on the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, had the technical error not occurred.

(10) In case of a retroactive cancellation or termination in accordance with paragraph (b)(1)(iv)(B) or (C) of this section, the cancellation date or termination date will be the original coverage effective date or a later date, as determined appropriate by the Exchange, based on the circumstances of the cancellation or termination.

(11) In the case of cancellation in accordance with paragraph (b)(2)(vi) of this section, the Exchange may cancel the enrollee's enrollment upon its determination that the enrollment was performed without the enrollee's knowledge or consent and following reasonable notice to the enrollee (where possible). The termination date will be the original coverage effective date.

(12) In the case of retroactive cancellations or terminations in accordance with paragraphs (b)(1)(iv)(A), (B) and (C) of this section, such terminations or cancellations for the preceding coverage year must be initiated within a timeframe established by the Exchange based on a balance of operational needs and consumer protection. This timeframe will not apply to cases adjudicated through the appeals process.

(e) *Termination, cancellation, and reinstatement.* The Exchange may establish operational instructions as to the form, manner, and method for addressing each of the following:

(1) *Termination.* A termination is an action taken after a coverage effective date that ends an enrollee's enrollment through the Exchange for a date after the original coverage effective date, resulting in a period during which the individual was enrolled in coverage through the Exchange.

(2) *Cancellation.* A cancellation is specific type of termination action that ends a qualified individual's enrollment through the Exchange on the date such enrollment became effective resulting in enrollment through the Exchange never having been effective.

(3) *Reinstatement.* A reinstatement is a correction of an erroneous termination or cancellation action and results in restoration of an enrollment with no break in coverage.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 78 FR 42322, July 15, 2013; 79 FR 30348, May 27, 2014; 80 FR 10867, Feb. 27, 2015; 81 FR 12343, Mar. 8, 2016; 81 FR 94179, Dec. 22, 2016; 83 FR 17063, Apr. 17, 2018; 85 FR 29260, May 14, 2020; 88 FR 25920, Apr. 27, 2023; 89 FR 26423, Apr. 15, 2024]

Subpart F—Appeals of Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

SOURCE: 78 FR 54136, Aug. 30, 2013, unless otherwise noted.

§ 155.500 Definitions.

In addition to those definitions in §§ 155.20 and 155.300, for purposes of this subpart and § 155.740 of subpart H, the following terms have the following meanings:

Appeal record means the appeal decision, all papers and requests filed in the proceeding, and, if a hearing was held, the transcript or recording of hearing testimony or an official report containing the substance of what happened at the hearing, and any exhibits introduced at the hearing.

Appeal request means a clear expression, either orally or in writing, by an applicant, enrollee, employer, or small business employer or employee to have any eligibility determination or redetermination contained in a notice issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) or (f), or § 155.716(e) reviewed by an appeals entity.

Appeals entity means a body designated to hear appeals of eligibility determinations or redeterminations contained in notices issued in accordance with § 155.310(g), § 155.330(e)(1)(ii), § 155.335(h)(1)(ii), § 155.610(i), § 155.715(e) and (f), or § 155.716(e).

Appellant means the applicant or enrollee, the employer, or the small business employer or employee who is requesting an appeal.

De novo review means a review of an appeal without deference to prior decisions in the case.

Evidentiary hearing means a hearing conducted where evidence may be presented.

Vacate means to set aside a previous action.

[78 FR 54136, Aug. 30, 2013, as amended at 83 FR 17063, Apr. 17, 2018]

§ 155.505 General eligibility appeals requirements.

(a) *General requirements.* Unless otherwise specified, the provisions of this subpart apply to Exchange eligibility appeals processes, regardless of whether the appeals process is provided by a State Exchange appeals entity or by the HHS appeals entity.

(b) *Right to appeal.* An applicant or enrollee must have the right to appeal—

(1) An eligibility determination made in accordance with subpart D, including—

(i) An initial determination of eligibility, including the amount of advance payments of the premium tax credit

and level of cost-sharing reductions, made in accordance with the standards specified in §155.305(a) through (h); and

(ii) A redetermination of eligibility, including the amount of advance payments of the premium tax credit and level of cost-sharing reductions, made in accordance with §§155.330 and 155.335;

(iii) A determination of eligibility for an enrollment period, made in accordance with §155.305(b);

(2) An eligibility determination for an exemption made in accordance §155.605;

(3) A failure by the Exchange to provide timely notice of an eligibility determination in accordance with §155.310(g), §155.330(e)(1)(ii), §155.335(h)(1)(ii), or §155.610(i); and

(4) A denial of a request to vacate dismissal made by a State Exchange appeals entity in accordance with §155.530(d)(2), made under paragraph (c)(2)(i) of this section; and

(5) An appeal decision issued by a State Exchange appeals entity in accordance with §155.545(b), consistent with §155.520(c).

(c) *Options for Exchange appeals.* Exchange eligibility appeals may be conducted by—

(1) A State Exchange appeals entity, or an eligible entity described in paragraph (d) of this section that is designated by the Exchange, if the Exchange establishes an appeals process in accordance with the requirements of this subpart; or

(2) The HHS appeals entity—

(i) Upon exhaustion of the State Exchange appeals process;

(ii) If the Exchange has not established an appeals process in accordance with the requirements of this subpart; or

(iii) If the Exchange has delegated appeals of exemption determinations made by HHS pursuant to §155.625(b) to the HHS appeals entity, and the appeal is limited to a determination of eligibility for an exemption.

(d) *Eligible entities.* An appeals process established under this subpart must comply with §155.110(a).

(e) *Representatives.* An appellant may represent himself or herself, or be represented by an authorized representative under §155.227, or by legal counsel, a relative, a friend, or another spokesperson, during the appeal.

(f) *Accessibility requirements.* Appeals processes established under this subpart must comply with the accessibility requirements in §155.205(c).

(g) *Review of Exchange eligibility appeal decisions.* Review of appeal decisions issued by an impartial official as described in §155.535(c)(4) is available as follows:

(1) *Administrative review.* The Administrator may review an Exchange eligibility appeal decision as follows:

(i) *Request by a party to the appeal.* (A) Within 14 calendar days of the date of the Exchange eligibility appeal decision issued by an impartial official as described in §155.535(c)(4), a party to the appeal may request review of the Exchange eligibility appeal decision by the CMS Administrator. Such a request may be made even if the CMS Administrator has already at their initiative declined review as described in paragraph (g)(1)(ii)(B)(*1*) of this section. If the CMS Administrator accepts that party's request for a review after having declined review, then the CMS Administrator's initial declination to review the eligibility appeal decision is void.

(B) Within 30 days of the date of the party's request for administrative review, the CMS Administrator must:

(*1*) Decline to review the Exchange eligibility appeal decision;

(*2*) Render a final decision as described in §155.545(a)(1) based on their review of the eligibility appeal decision; or

(*3*) Choose to take no action on the request for review.

(C) The Exchange eligibility appeal decision of the impartial official as described in §155.535(c)(4) is final as of the date of the impartial official's decision if the CMS Administrator declines the party's request for review or if the CMS Administrator does not take any action on the party's request for review by the end of the 30-day period described in paragraphs (g)(1)(i)(B)(*1*) and (*3*) of this section.

(ii) *Review at the discretion of the CMS Administrator.* (A) Within 14 calendar days of the date of the Exchange eligibility appeal decision issued by an impartial official as described in

§ 155.535(c)(4), the CMS Administrator may initiate a review of an eligibility appeal decision at their discretion.

(B) Within 30 days of the date the CMS Administrator initiates a review, the CMS Administrator may:

(*1*) Decline to review the Exchange eligibility appeal decision;

(*2*) Render a final decision as described in § 155.545(a)(1) based on their review of the eligibility appeal decision; or

(*3*) Choose to take no action on the Exchange eligibility appeal decision.

(C) The eligibility Exchange appeal decision of the impartial official as described in § 155.535(c)(4) is final as of the date of the Exchange eligibility appeal decision if the CMS Administrator declines to review the eligibility appeal decision or chooses to take no action by the end of the 30-day period described in paragraphs (g)(1)(i)(B)(*1*) and (*3*) of this section.

(iii) *Effective dates.* If a party requests a review of an Exchange eligibility appeal decision by the CMS Administrator or the CMS Administrator initiates a review of an Exchange eligibility appeal decision at their own discretion, the eligibility appeal decision is effective as follows:

(A) If an Exchange eligibility appeal decision is final pursuant to paragraphs (g)(1)(i)(C) and (g)(1)(ii)(C) in this section, the Exchange eligibility appeal decision of the impartial official as described in § 155.535(c)(4) is effective as of the date of the impartial official's decision.

(B) If the CMS Administrator renders a final decision after reviewing an Exchange eligibility appeal decision as described in paragraphs (g)(1)(i)(B)(*2*) and (g)(1)(ii)(B)(*2*) of this section, the CMS Administrator may choose to change the effective date of the Exchange eligibility appeal decision as described in § 155.545(a)(5).

(iv) *Informal resolution decision.* Informal resolution decisions as described in § 155.535(a)(4) are not subject to administrative review by the CMS Administrator.

(2) *Judicial review.* To the extent it is available by law, an appellant may seek judicial review of a final Exchange eligibility appeal decision.

(3) *Implementation date.* The administrative review process is available for eligibility appeal decisions issued on or after January 1, 2024.

(h) *Electronic requirements.* If the Exchange appeals entity cannot fulfill the electronic requirements of subparts C, D, F, and H of this part related to acceptance of telephone- or Internet-based appeal requests, the provision of appeals notices electronically, or the secure electronic transfer of eligibility and appeal records between appeals entities and Exchanges or Medicaid or CHIP agencies, the Exchange appeals entity may fulfill those requirements that it cannot fulfill electronically using a secure and expedient paper-based process.

[78 FR 54136, Aug. 30, 2013, as amended at 79 FR 30349, May 27, 2014; 81 FR 12344, Mar. 8, 2016; 81 FR 94179, Dec. 22, 2016; 88 FR 25920, Apr. 27, 2023]

§ 155.510 Appeals coordination.

(a) *Agreements.* The appeals entity or the Exchange must enter into agreements with the agencies administering insurance affordability programs regarding the appeals processes for such programs as are necessary to fulfill the requirements of this subpart. Such agreements must include a clear delineation of the responsibilities of each entity to support the eligibility appeals process, and must—

(1) Minimize burden on appellants, including not asking the appellant to provide duplicative information or documentation that he or she already provided to an agency administering an insurance affordability program or eligibility appeals process, unless the appeals entity, Exchange, or agency does not have access to the information or documentation and cannot reasonably obtain it, and such information is necessary to properly adjudicate an appeal;

(2) Ensure prompt issuance of appeal decisions consistent with timeliness standards established under this subpart; and

(3) Comply with the requirements set forth in—

(i) 42 CFR 431.10(d), if the state Medicaid agency delegates authority to hear fair hearings under 42 CFR

431.10(c)(ii) to the Exchange appeals entity; or

(ii) 42 CFR 457.348(b), if the state CHIP agency delegates authority to review appeals under §457.1120 to the Exchange appeals entity.

(b) *Coordination for Medicaid and CHIP appeals.* (1) Where the Medicaid or CHIP agency has delegated appeals authority to the Exchange appeals entity consistent with 42 CFR 431.10(c)(1)(ii) or 457.1120, and the Exchange appeals entity has accepted such delegation—

(i) The Exchange appeals entity will conduct the appeal in accordance with—

(A) Medicaid and CHIP MAGI-based income standards and standards for citizenship and immigration status, in accordance with the eligibility and verification rules and procedures, consistent with 42 CFR parts 435 and 457.

(B) Notice standards identified in this subpart, subpart D, and by the State Medicaid or CHIP agency, consistent with applicable law.

(ii) Consistent with 42 CFR 431.10(c)(1)(ii), an appellant who has been determined ineligible for Medicaid must be informed of the option to opt into pursuing his or her appeal of the adverse Medicaid eligibility determination with the Medicaid agency, and if the appellant elects to do so, the appeals entity transmits the eligibility determination and all information provided via secure electronic interface, promptly and without undue delay, to the Medicaid agency.

(2) Where the Medicaid or CHIP agency has not delegated appeals authority to the appeals entity and the appellant seeks review of a denial of Medicaid or CHIP eligibility, the appeals entity must transmit the eligibility determination and all relevant information provided as part of the initial application or appeal, if applicable, via secure electronic interface, promptly and without undue delay, to the Medicaid or CHIP agency, as applicable.

(3) The Exchange must consider an appellant determined or assessed by the appeals entity as not potentially eligible for Medicaid or CHIP as ineligible for Medicaid and CHIP based on the applicable Medicaid and CHIP MAGI-based income standards for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions.

(c) *Data exchange.* The appeals entity must—

(1) Ensure that all data exchanges that are part of the appeals process, comply with the data exchange requirements in §§155.260, 155.270, and 155.345(i); and

(2) Comply with all data sharing requests made by HHS.

[78 FR 54136, Aug. 30, 2013, as amended at 81 FR 12344, Mar. 8, 2016]

§ 155.515 Notice of appeal procedures.

(a) *Requirement to provide notice of appeal procedures.* The Exchange must provide notice of appeal procedures at the time that the—

(1) Applicant submits an application; and

(2) Notice of eligibility determination is sent under §§155.310(g), 155.330(e)(1)(ii), 155.335(h)(1)(ii), and 155.610(i).

(b) *General content on right to appeal and appeal procedures.* Notices described in paragraph (a) of this section must contain—

(1) An explanation of the applicant or enrollee's appeal rights under this subpart;

(2) A description of the procedures by which the applicant or enrollee may request an appeal;

(3) Information on the applicant or enrollee's right to represent himself or herself, or to be represented by legal counsel or another representative;

(4) An explanation of the circumstances under which the appellant's eligibility may be maintained or reinstated pending an appeal decision, as described in §155.525; and

(5) An explanation that an appeal decision for one household member may result in a change in eligibility for other household members and that such a change will be handled as a redetermination of eligibility for all household members in accordance with the standards specified in §155.305.

§ 155.520 Appeal requests.

(a) *General standards for appeal requests.* The Exchange and the appeals entity—

(1) Must accept appeal requests submitted—

(i) By telephone;

(ii) By mail;

(iii) In person, if the Exchange or the appeals entity, as applicable, is capable of receiving in-person appeal requests; and

(iv) Via the Internet.

(2) Must assist the applicant or enrollee in making the appeal request, if requested;

(3) Must not limit or interfere with the applicant or enrollee's right to make an appeal request; and

(4) Must consider an appeal request to be valid for the purpose of this subpart, if it is submitted in accordance with the requirements of paragraphs (b) and (c) of this section and §155.505(b).

(b) *Appeal request.* The Exchange and the appeals entity must allow an applicant or enrollee to request an appeal within—

(1) 90 days of the date of the notice of eligibility determination; or

(2) A timeframe consistent with the state Medicaid agency's requirement for submitting fair hearing requests, provided that timeframe is no less than 30 days, measured from the date of the notice of eligibility determination.

(c) *Appeal of a State Exchange appeals entity decision to HHS.* If the appellant disagrees with the appeal decision of a State Exchange appeals entity, he or she may make an appeal request to the HHS appeals entity within 30 days of the date of the State Exchange appeals entity's notice of appeal decision or notice of denial of a request to vacate a dismissal.

(d) *Acknowledgement of appeal request.* (1) Upon receipt of a valid appeal request pursuant to paragraph (b), (c), or (d)(3)(i) of this section, the appeals entity must—

(i) Send timely acknowledgment to the appellant of the receipt of his or her valid appeal request, including—

(A) Information regarding the appellant's eligibility pending appeal pursuant to §155.525; and

(B) An explanation that any advance payments of the premium tax credit paid on behalf of the tax filer pending appeal are subject to reconciliation under 26 CFR 1.36B–4.

(ii) Send timely notice via secure electronic interface of the appeal request and, if applicable, instructions to provide eligibility pending appeal pursuant to §155.525, to the Exchange and to the agencies administering Medicaid or CHIP, where applicable.

(iii) If the appeal request is made pursuant to paragraph (c) of this section, send timely notice via secure electronic interface of the appeal request to the State Exchange appeals entity.

(iv) Promptly confirm receipt of the records transferred pursuant to paragraph (d)(3) or (4) of this section to the Exchange or the State Exchange appeals entity, as applicable.

(2) Upon receipt of an appeal request that is not valid because it fails to meet the requirements of this section or §155.505(b), the appeals entity must—

(i) Promptly and without undue delay, send written notice to the applicant or enrollee informing the appellant:

(A) That the appeal request has not been accepted;

(B) About the nature of the defect in the appeal request; and

(C) That the applicant or enrollee may cure the defect and resubmit the appeal request by the date determined under paragraph (b) or (c) of this section, as applicable, or within a reasonable timeframe established by the appeals entity.

(D) That, in the event the appeal request is not valid due to failure to submit by the date determined under paragraph (b) or (c) of this section, as applicable, the appeal request may be considered valid if the applicant or enrollee sufficiently demonstrates within a reasonable timeframe determined by the appeals entity that failure to timely submit was due to exceptional circumstances and should not preclude the appeal.

(ii) Treat as valid an amended appeal request that meets the requirements of this section and §155.505(b).

(3) Upon receipt of a valid appeal request pursuant to paragraph (b) of this section, or upon receipt of the notice under paragraph (d)(1)(ii) of this section, the Exchange must transmit via secure electronic interface to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the Exchange; and

(ii) The appellant's eligibility record.

(4) Upon receipt of the notice pursuant to paragraph (d)(1)(iii) of this section, the State Exchange appeals entity must transmit via secure electronic interface the appellant's appeal record, including the appellant's eligibility record as received from the Exchange, to the HHS appeals entity.

[78 FR 54136, Aug. 30, 2013, as amended at 81 FR 12344, Mar. 8, 2016]

§ 155.525 Eligibility pending appeal.

(a) *General standards.* After receipt of a valid appeal request or notice under §155.520(d)(1)(ii) that concerns an appeal of a redetermination under §155.330(e) or §155.335(h), the Exchange or the Medicaid or CHIP agency, as applicable, must continue to consider the appellant eligible while the appeal is pending in accordance with standards set forth in paragraph (b) of this section or as determined by the Medicaid or CHIP agency consistent with 42 CFR parts 435 and 457, as applicable.

(b) *Implementation.* If the tax filer or appellant, as applicable, accepts eligibility pending an appeal, the Exchange must continue the appellant's eligibility for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions, as applicable, in accordance with the level of eligibility immediately before the redetermination being appealed.

§ 155.530 Dismissals.

(a) *Dismissal of appeal.* The appeals entity must dismiss an appeal if the appellant—

(1) Withdraws the appeal request in writing or by telephone, if the appeals entity is capable of accepting telephonic withdrawals.

(i) Accepting telephonic withdrawals means the appeals entity—

(A) Records in full the appellant's statement and telephonic signature made under penalty of perjury; and

(B) Provides a written confirmation to the appellant documenting the telephonic interaction.

(ii) [Reserved]

(2) Fails to appear at a scheduled hearing without good cause;

(3) Fails to submit a valid appeal request as specified in §155.520(a)(4); or

(4) Dies while the appeal is pending, except if the executor, administrator, or other duly authorized representative of the estate requests to continue the appeal.

(b) *Notice of dismissal to the appellant.* If an appeal is dismissed under paragraph (a) of this section, the appeals entity must provide timely written notice to the appellant, including—

(1) The reason for dismissal;

(2) An explanation of the dismissal's effect on the appellant's eligibility; and

(3) An explanation of how the appellant may show good cause why the dismissal should be vacated in accordance with paragraph (d) of this section.

(c) *Notice of the dismissal to the Exchange, Medicaid, and CHIP.* If an appeal is dismissed under paragraph (a) of this section, the appeals entity must provide timely notice to the Exchange, and to the agency administering Medicaid or CHIP, as applicable, including instruction regarding—

(1) The eligibility determination to implement; and

(2) Discontinuing eligibility provided under §155.525, if applicable.

(d) *Vacating a dismissal.* The appeals entity must—

(1) Vacate a dismissal and proceed with the appeal if the appellant makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated; and

(2) Provide timely written notice of the denial of a request to vacate a dismissal to the appellant, if the request is denied.

[78 FR 54136, Aug. 30, 2013, as amended at 79 FR 30349, May 27, 2014; 81 FR 12344, Mar. 8, 2016]

§ 155.535 Informal resolution and hearing requirements.

(a) *Informal resolution.* The HHS appeals process will provide an opportunity for informal resolution and a hearing in accordance with the requirements of this section. A State Exchange appeals entity may also provide an informal resolution process prior to a hearing. Any information resolution

process must meet the following requirements:

(1) The process complies with the scope of review specified in paragraph (e) of this section;

(2) The appellant's right to a hearing is preserved in any case in which the appellant remains dissatisfied with the outcome of the informal resolution process;

(3) If the appeal advances to hearing, the appellant is not asked to provide duplicative information or documentation that he or she previously provided during the application or informal resolution process; and

(4) If the appeal does not advance to hearing, the informal resolution decision is final and binding.

(b) *Notice of hearing.* When a hearing is scheduled, the appeals entity must send written notice to the appellant and the appellant's authorized representative, if any, of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date unless—

(1) The appellant requests an earlier hearing date; or

(2) A hearing date sooner than 15 days is necessary to process an expedited appeal, as described in §155.540(a), and the appeals entity has contacted the appellant to schedule a hearing on a mutually agreed upon date, time, and location or format.

(c) *Conducting the hearing.* All hearings under this subpart must be conducted—

(1) At a reasonable date, time, and location or format;

(2) After notice of the hearing, pursuant to paragraph (b) of this section;

(3) As an evidentiary hearing, consistent with paragraph (e) of this section; and

(4) By one or more impartial officials who have not been directly involved in the eligibility determination or any prior Exchange appeal decisions in the same matter.

(d) *Procedural rights of an appellant.* The appeals entity must provide the appellant with the opportunity to—

(1) Review his or her appeal record, including all documents and records to be used by the appeals entity at the hearing, at a reasonable time before the date of the hearing as well as during the hearing;

(2) Bring witnesses to testify;

(3) Establish all relevant facts and circumstances;

(4) Present an argument without undue interference; and

(5) Question or refute any testimony or evidence, including the opportunity to confront and cross-examine adverse witnesses.

(e) *Information and evidence to be considered.* The appeals entity must consider the information used to determine the appellant's eligibility as well as any additional relevant evidence presented during the course of the appeals process, including at the hearing.

(f) *Standard of review.* The appeals entity will review the appeal *de novo* and will consider all relevant facts and evidence adduced during the appeals process.

[78 FR 54136, Aug. 30, 2013, as amended at 81 FR 12344, Mar. 8, 2016]

§ 155.540 Expedited appeals.

(a) *Expedited appeals.* The appeals entity must establish and maintain an expedited appeals process for an appellant to request an expedited process where there is an immediate need for health services because a standard appeal could jeopardize the appellant's life, health, or ability to attain, maintain, or regain maximum function.

(b) *Denial of a request for expedited appeal.* If the appeals entity denies a request for an expedited appeal, it must—

(1) Handle the appeal request under the standard process and issue the appeal decision in accordance with §155.545(b)(1); and

(2) Inform the appellant, promptly and without undue delay, through electronic or oral notification, if possible, of the denial and, if notification is oral, follow up with the appellant by written notice, within the timeframe established by the Secretary. Written notice of the denial must include—

(i) The reason for the denial;

(ii) An explanation that the appeal request will be transferred to the standard process; and

(iii) An explanation of the appellant's rights under the standard process.

§ 155.545 Appeal decisions.

(a) *Appeal decisions.* Appeal decisions must—

(1) Be based exclusively on the information and evidence specified in §155.535(e) and the eligibility requirements under subpart D or G of this part, as applicable, and if the Medicaid or CHIP agencies delegate authority to conduct the Medicaid fair hearing or CHIP review to the appeals entity in accordance with 42 CFR 431.10(c)(1)(ii) or 457.1120, the eligibility requirements under 42 CFR parts 435 and 457, as applicable;

(2) State the decision, including a plain language description of the effect of the decision on the appellant's eligibility;

(3) Summarize the facts relevant to the appeal;

(4) Identify the legal basis, including the regulations that support the decision;

(5) State the effective date of the decision; and

(6) If the appeals entity is a State Exchange appeals entity—

(i) Provide an explanation of the appellant's right to pursue the appeal before the HHS appeals entity, including the applicable timeframe, if the appellant remains dissatisfied with the eligibility determination; and

(ii) Indicate that the decision of the State Exchange appeals entity is final, unless the appellant pursues the appeal before the HHS appeals entity.

(b) *Notice of appeal decision.* The appeals entity—

(1) Must issue written notice of the appeal decision to the appellant within 90 days of the date an appeal request under §155.520(b) or (c) is received, as administratively feasible.

(2) In the case of an appeal request submitted under §155.540 that the appeals entity determines meets the criteria for an expedited appeal, must issue the notice as expeditiously as reasonably possible, consistent with the timeframe established by the Secretary.

(3) Must provide notice of the appeal decision and instructions to cease pended eligibility to the appellant, if applicable, via secure electronic interface, to the Exchange or the Medicaid or CHIP agency, as applicable.

(c) *Implementation of appeal decisions.* The Exchange, upon receiving the notice described in paragraph (b), must promptly—

(1) Implement the appeal decision effective—

(i) Prospectively, on the first day of the month following the date of the notice of appeal decision, or consistent with §155.330(f)(2), (3), (4), or (5), if applicable; or

(ii) Retroactively, to the coverage effective date the appellant did receive or would have received if the appellant had enrolled in coverage under the incorrect eligibility determination that is the subject of the appeal, at the option of the appellant.

(2) Redetermine the eligibility of household members who have not appealed their own eligibility determinations but whose eligibility may be affected by the appeal decision, in accordance with the standards specified in §155.305.

[78 FR 54136, Aug. 30, 2013, as amended at 81 FR 12345, Mar. 8, 2016]

§ 155.550 Appeal record.

(a) *Appellant access to the appeal record.* Subject to the requirements of all applicable Federal and State laws regarding privacy, confidentiality, disclosure, and personally identifiable information, the appeals entity must make the appeal record accessible to the appellant at a convenient place and time.

(b) *Public access to the appeal decision.* The appeals entity must provide public access to all appeal decisions, subject to all applicable Federal and State laws regarding privacy, confidentiality, disclosure, and personally identifiable information.

§ 155.555 Employer appeals process.

(a) *General requirements.* The provisions of this section apply to employer appeals processes through which an employer may, in response to a notice under §155.310(h), appeal a determination that the employer does not provide minimum essential coverage through an employer-sponsored plan or that the employer does provide that coverage but it is not affordable coverage with respect to an employee.

(b) *Exchange employer appeals process.* An Exchange may establish an employer appeals process in accordance with the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c). Where an Exchange has not established an employer appeals process, HHS will provide an employer appeals process that meets the requirements of this section and §§ 155.505(f) through (h) and 155.510(a)(1) and (2) and (c).

(c) *Appeal request.* The Exchange and appeals entity, as applicable, must—

(1) Allow an employer to request an appeal within 90 days from the date the notice described under § 155.310(h) is sent;

(2) Allow an employer to submit relevant evidence to support the appeal;

(3) Allow an employer to submit an appeal request to—

(i) The Exchange or the Exchange appeals entity, if the Exchange establishes an employer appeals process; or

(ii) The HHS appeals entity, if the Exchange has not established an employer appeals process;

(4) Comply with the requirements of § 155.520(a)(1) through (3); and

(5) Consider an appeal request valid if it is submitted in accordance with paragraph (c)(1) of this section and with the purpose of appealing the determination identified in the notice specified in § 155.310(h).

(d) *Notice of appeal request.* (1) Upon receipt of a valid appeal request, the appeals entity must—

(i) Send timely acknowledgement of the receipt of the appeal request to the employer, including an explanation of the appeals process;

(ii) Send timely notice to the employee of the receipt of the appeal request, including—

(A) An explanation of the appeals process;

(B) Instructions for submitting additional evidence for consideration by the appeals entity; and

(C) An explanation of the potential effect of the employer's appeal on the employee's eligibility.

(iii) Promptly notify the Exchange of the appeal, if the employer did not initially make the appeal request to the Exchange.

(2) Upon receipt of an invalid appeal request, the appeals entity must promptly and without undue delay send written notice to the employer that the appeal request is not valid because it fails to meet the requirements of this section. The written notice must inform the employer—

(i) That the appeal request has not been accepted;

(ii) About the nature of the defect in the appeal request; and

(iii) That the employer may cure the defect and resubmit the appeal request by the date determined under paragraph (c) of this section, or within a reasonable timeframe established by the appeals entity.

(iv) Treat as valid an amended appeal request that meets the requirements of this section, including standards for timeliness.

(e) *Transmittal and receipt of records.* (1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (d)(1)(iii) of this section, the Exchange must promptly transmit via secure electronic interface to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the Exchange; and

(ii) The employee's eligibility record.

(2) The appeals entity must promptly confirm receipt of records transmitted pursuant to paragraph (e)(1) of this section to the entity that transmitted the records.

(f) *Dismissal of appeal.* The appeals entity—

(1) Must dismiss an appeal under the circumstances specified in § 155.530(a)(1) or if the request fails to comply with the standards in paragraph (c)(4) of this section.

(2) Must provide timely notice of the dismissal to the employer, employee, and Exchange including the reason for dismissal; and

(3) May vacate a dismissal if the employer makes a written request within 30 days of the date of the notice of dismissal showing good cause as to why the dismissal should be vacated.

(g) *Procedural rights of the employer.* The appeals entity must provide the employer the opportunity to—

(1) Provide relevant evidence for review of the determination of an employee's eligibility for advance payments of the premium tax credit or cost-sharing reductions;

(2) Review—

(i) The information described in §155.310(h)(1);

(ii) Information regarding whether the employee's income is above or below the threshold by which the affordability of employer-sponsored minimum essential coverage is measured, as set forth by standards described in 26 CFR 1.36B; and

(iii) Other data used to make the determination described in §155.305(f) or (g), to the extent allowable by law, except the information described in paragraph (h) of this section.

(h) *Confidentiality of employee information.* Neither the Exchange nor the appeals entity may make available to an employer any tax return information of an employee as prohibited by section 6103 of the Code.

(i) *Adjudication of employer appeals.* Employer appeals must—

(1) Be reviewed by one or more impartial officials who have not been directly involved in the employee eligibility determination implicated in the appeal;

(2) Consider the information used to determine the employee's eligibility as well as any additional relevant evidence provided by the employer or the employee during the course of the appeal; and

(3) Be reviewed *de novo.*

(j) *Appeal decisions.* Employer appeal decisions must—

(1) Be based exclusively on the information and evidence described in paragraph (i)(2) of this section and the eligibility standards in 45 CFR part 155, subpart D;

(2) State the decision, including a plain language description of the effect of the decision on the employee's eligibility; and

(3) Comply with the requirements set forth in §155.545(a)(3) through (5).

(k) *Notice of appeal decision.* The appeals entity must provide written notice of the appeal decision within 90 days of the date the appeal request is received, as administratively feasible, to—

(1) The employer. Such notice must include—

(i) The appeal decision; and

(ii) An explanation that the appeal decision does not foreclose any appeal rights the employer may have under subtitle F of the Code.

(2) The employee. Such notice must include—

(i) The appeal decision; and

(ii) An explanation that the employee and his or her household members, if applicable, may appeal a redetermination of eligibility that occurs as a result of the appeal decision.

(3) The Exchange.

(l) *Implementation of the appeal decision.* After receipt of the notice under paragraph (k)(3) of this section, if the appeal decision affects the employee's eligibility, the Exchange must promptly:

(1) Redetermine the employee's eligibility and the eligibility of the employee's household members, if applicable, in accordance with the standards specified in §155.305; or

(2) Notify the employee of the requirement to report changes in eligibility as described in §155.330(b)(1).

(m) *Appeal record.* Subject to the requirements of §155.550 and paragraph (h) of this section, the appeal record must be accessible to the employer and to the employee in a convenient format and at a convenient time.

[78 FR 54136, Aug. 30, 2013, as amended at 79 FR 30349, May 27, 2014; 81 FR 12345, Mar. 8, 2016; 81 FR 94179, Dec. 22, 2016]

Subpart G—Exchange Functions in the Individual Market: Eligibility Determinations for Exemptions

SOURCE: 78 FR 39523, July 1, 2013, unless otherwise noted.

§155.600 Definitions and general requirements.

(a) *Definitions.* For purposes of this subpart, the following terms have the following meaning:

Applicant means an individual who is seeking an exemption for him or herself through an application submitted to the Exchange.

Application filer means an applicant, an individual who is liable for the shared responsibility payment in accordance with section 5000A of the Code for an applicant, an authorized representative, or if the applicant is a minor or incapacitated, someone acting responsibly for an applicant.

Exemption means an exemption from the shared responsibility payment.

Health care sharing ministry has the same meaning as it does in section 5000A(d)(2)(B)(ii) of the Code.

Indian tribe has the same meaning as it does in section 45A(c)(6) of the Code.

Required contribution has the same meaning as it does in section 5000A(e)(1)(B) of the Code.

Required contribution percentage means the product of eight percent and the rate of premium growth over the rate of income growth for the calendar year, rounded to the nearest one-hundredth of one percent.

Shared responsibility payment means the payment imposed with respect to a non-exempt individual who does not maintain minimum essential coverage in accordance with section 5000A(b) of the Code.

Tax filer has the same meaning as it does in § 155.300(a).

(b) *Attestation.* For the purposes of this subpart, any attestation that an applicant is to provide under this subpart may be made by the application filer on behalf of the applicant.

(c) *Reasonably compatible.* For purposes of this subpart, the Exchange must consider information through electronic data sources, other information provided by the applicant, or other information in the records of the Exchange to be reasonably compatible with an applicant's attestation if the difference or discrepancy does not impact the eligibility of the applicant for the exemption or exemptions for which he or she applied.

(d) *Accessibility.* Information, including notices, forms, and applications, must be provided to applicants in accordance with the standards specified in § 155.205(c).

(e) *Notices.* Any notice required to be sent by the Exchange to an individual in accordance with this subpart must be provided in accordance with the standards specified in § 155.230.

[78 FR 39523, July 1, 2013, as amended at 79 FR 30349, May 27, 2014]

§ 155.605 Eligibility standards for exemptions.

(a) *Eligibility for an exemption through the Exchange.* Except as specified in paragraph (g) of this section, the Exchange must determine an applicant eligible for and issue a certificate of exemption for any month if the Exchange determines that he or she meets the requirements for one or more of the categories of exemptions described in this section for at least one day of the month.

(b) *Duration of single exemption.* Except as specified in paragraphs (c)(2) and (d) of this section, the Exchange may provide a certificate of exemption only for the calendar year in which an applicant submitted an application for such exemption.

(c) *Religious conscience.* (1) The Exchange must determine an applicant eligible for an exemption for any month if the applicant is a member of a recognized religious sect or division described in section 1402(g)(1) of the Code, and an adherent of established tenets or teachings of such sect or division, for such month in accordance with section 5000A(d)(2)(A) of the Code.

(2) *Duration of exemption for religious conscience.* (i) The Exchange must grant the certificate of exemption specified in this paragraph to an applicant who meets the standards provided in paragraph (c)(1) of this section for a month on a continuing basis, until the month after the month of the individual's 21st birthday, or until such time that an individual reports that he or she no longer meets the standards provided in paragraph (c)(1) of this section.

(ii) If the Exchange granted a certificate of exemption in this category to an applicant prior to his or her reaching the age of 21, the Exchange must send the applicant a notice upon reaching the age of 21 informing the applicant that he or she must submit a new exemption application to maintain the certificate of exemption.

(3) The Exchange must make an exemption in this category available prospectively or retrospectively.

(d) *Hardship*—(1) *General.* The Exchange must grant a hardship exemption to an applicant eligible for an exemption for at least the month before, the month or months during which, and the month after a specific event or circumstance, if the Exchange determines that:

(i) He or she experienced financial or domestic circumstances, including an unexpected natural or human-caused event, such that he or she had a significant, unexpected increase in essential expenses that prevented him or her from obtaining coverage under a qualified health plan;

(ii) The expense of purchasing a qualified health plan would have caused him or her to experience serious deprivation of food, shelter, clothing or other necessities; or

(iii) He or she has experienced other circumstances that prevented him or her from obtaining coverage under a qualified health plan.

(2) *Lack of affordable coverage based on projected income.* The Exchange must determine an applicant eligible for an exemption for a month or months during which he or she, or another individual the applicant attests will be included in the applicant's family, as defined in 26 CFR 1.36B–1(d), is unable to afford coverage in accordance with the standards specified in section 5000A(e)(1) of the Code, provided that—

(i) Eligibility for this exemption is based on projected annual household income;

(ii) An eligible employer-sponsored plan is only considered under paragraphs (d)(4)(iii) and (iv) of this section if it meets the minimum value standard described in §156.145 of this subchapter.

(iii) For an individual who is eligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage such that—

(A) An individual who uses tobacco is treated as not earning any premium incentive related to participation in a wellness program designed to prevent or reduce tobacco use that is offered by an eligible employer-sponsored plan;

(B) Wellness incentives offered by an eligible employer-sponsored plan that do not relate to tobacco use are treated as not earned;

(C) In the case of an employee who is eligible to purchase coverage under an eligible employer-sponsored plan sponsored by the employee's employer, the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost self-only coverage.

(D) In the case of an individual who is eligible to purchase coverage under an eligible employer-sponsored plan as a member of the employee's family, as defined in 26 CFR 1.36B–1(d), the required contribution is the portion of the annual premium that the employee would pay (whether through salary reduction or otherwise) for the lowest cost family coverage that would cover the employee and all other individuals who are included in the employee's family who have not otherwise been granted an exemption through the Exchange.

(iv) For an individual who is ineligible to purchase coverage under an eligible employer-sponsored plan, the Exchange determines the required contribution for coverage in accordance with section 5000A(e)(1)(B)(ii) of the Code, inclusive of all members of the family, as defined in 26 CFR 1.36B–1(d), who have not otherwise been granted an exemption through the Exchange and who are not treated as eligible to purchase coverage under an eligible employer-sponsored plan, in accordance with paragraph (d)(4)(ii) of this section. If there is not a bronze level plan offered through the Exchange in the individual's county, the Exchange must use the annual premium for the lowest cost Exchange metal level plan, excluding catastrophic coverage, available in the individual market through the Exchange in the State in the county in which the individual resides to determine whether coverage exceeds the affordability threshold specified in section 5000A(e)(1) of the Code; and

(v) The applicant applies for this exemption prior to the last date on which he or she could enroll in a QHP through the Exchange for the month or

months of a calendar year for which the exemption is requested.

(vi) The Exchange must make an exemption in this category available prospectively, and provide it for all remaining months in a coverage year, notwithstanding any change in an individual's circumstances.

(3) *Ineligible for Medicaid based on a State's decision not to expand.* The Exchange must determine an applicant eligible for an exemption for a calendar year if he or she would be determined ineligible for Medicaid for one or more months during the benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act.

(e) *Eligibility for an exemption through the IRS.* Hardship exemptions in this paragraph (e) can be claimed on a Federal income tax return without obtaining an exemption certificate number. The IRS may allow an individual to claim the hardship exemptions described in this paragraph (e) without requiring an exemption certificate number from the Exchange.

(1) *Filing threshold.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published September 18, 2014, entitled, ''Shared Responsibility Guidance—Filing Threshold Hardship Exemption,'' and in IRS Notice 2014–76, section B (see *https://www.cms.gov/cciio/*).

(2) *Self-only coverage in an eligible employer-sponsored plan.* The IRS may allow an applicant to claim an exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section A (see *https://www.cms.gov/cciio/*).

(3) *Eligible for services through an Indian health care provider.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 18, 2014, entitled, ''Shared Responsibility Guidance—Exemption for Individuals Eligible for Services through an Indian Health Care Provider,'' and in IRS Notice 2014–76, section E (see *https://www.cms.gov/cciio/*).

(4) *Ineligible for Medicaid based on a State's decision not to expand.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published November 21, 2014, entitled, ''Guidance on Hardship Exemptions for Persons Meeting Certain Criteria,'' and in IRS Notice 2014–76, section F (see *https://www.cms.gov/cciio/*).

(5) *General hardship.* The IRS may allow an applicant to claim the exemption specified in HHS Guidance published September 12, 2018, entitled, ''Guidance on Claiming a Hardship Exemption through the Internal Revenue Service (IRS)'' (see *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Authority-to-Grant-HS-Exemptions-2018-Final-91218.pdf*) and in IRS Notice 2019–05 (see *https://www.irs.gov/pub/irs-drop/n-19-05.pdf*), for the 2018 tax year.

[78 FR 39523, July 1, 2013, as amended at 79 FR 30349, May 27, 2014; 80 FR 10868, Feb. 27, 2015; 81 FR 12345, Mar. 8, 2016; 83 FR 17063, Apr. 17, 2018; 84 FR 17567, Apr. 25, 2019]

§ 155.610 Eligibility process for exemptions.

(a) *Application.* Except as specified in paragraphs (b) and (c) of this section, the Exchange must use an application established by HHS to collect information necessary for determining eligibility for and granting certificates of exemption as described in § 155.605.

(b) *Alternative application.* If the Exchange seeks to use an alternative application, such application, as approved by HHS, must request the minimum information necessary for the purposes identified in paragraph (a) of this section.

(c) *Exemptions through the eligibility process for coverage.* If an individual submits the application described in § 155.405 and then requests an exemption, the Exchange must use information collected for purposes of the eligibility determination for enrollment in a QHP and for insurance affordability programs in making the exemption eligibility determination, and must not request duplicate information or conduct repeat verifications to the extent that the Exchange finds that such information is still applicable, where the standards for such verifications adhere to the standards specified in this subpart.

(d) *Filing the exemption application.* The Exchange must—

(1) Accept the application from an application filer; and

(2) Provide the tools to file an application.

(3) For applications submitted before October 15, 2014, the Exchange must, at a minimum, accept the application by mail.

(e) *Collection of Social Security numbers.* (1) The Exchange must require an applicant who has a Social Security number to provide such number to the Exchange.

(2) The Exchange may not require an individual who is not seeking an exemption for himself or herself to provide a Social Security number, except as specified in paragraph (e)(3) of this section.

(3) The Exchange must require an application filer to provide the Social Security number of a tax filer who is not an applicant only if an applicant attests that the tax filer has a Social Security number and filed a tax return for the year for which tax data would be utilized for verification of household income and family size for an exemption under §155.605(g)(2) that requires such verification.

(f) *Determination of eligibility; granting of certificates.* The Exchange must determine an applicant's eligibility for an exemption in accordance with the standards specified in §155.605, and grant a certificate of exemption to any applicant determined eligible.

(g) *Timeliness standards.* (1) The Exchange must determine eligibility for exemption promptly and without undue delay.

(2) The Exchange must assess the timeliness of eligibility determinations made under this subpart based on the period from the date of application to the date the Exchange notifies the applicant of its decision.

(h) *Exemptions for previous tax years.* (1) Except for the exemptions described in §155.605(c) and (d), after December 31 of a given calendar year, the Exchange may decline to accept an application for an exemption that is available retrospectively for months for such calendar year, and must provide information to individuals regarding how to claim an exemption through the tax filing process.

(2) The Exchange will only accept an application for an exemption described in §155.605(d)(1) during one of the 3 calendar years after the month or months during which the applicant attests that the hardship occurred.

(i) *Notification of eligibility determination for exemptions.* The Exchange must provide timely written notice to an applicant of any eligibility determination made in accordance with this subpart. In the case of a determination that an applicant is eligible for an exemption, this notification must include the exemption certificate number for the purposes of tax administration.

(j) *Retention of records for tax compliance.* (1) An Exchange must notify an individual to retain the records that demonstrate receipt of the certificate of exemption and qualification for the underlying exemption.

(2) In the case of any factor of eligibility that is verified through use of the special circumstances exception described in §155.615(h), the records that demonstrate qualification for the underlying exemption are the information submitted to the Exchange regarding the circumstances that warranted the use of the exception, as well as records of the Exchange decision to allow such exception.

(k) *Incomplete application.* (1) If an applicant submits an application that does not include sufficient information for the Exchange to conduct a determination for eligibility of an exemption the Exchange must—

(i) Provide notice to the applicant indicating that information necessary to complete an eligibility determination is missing, specifying the missing information, and providing instructions on how to provide the missing information; and

(ii) Provide the applicant with a period of no less than 30 and no more than 90 days, in the reasonable discretion of the Exchange, from the date on which the notice described in paragraph (k)(1) of this section is sent to the applicant to provide the information needed to complete the application to the Exchange; and

(iii) Not proceed with the applicant's eligibility determination during the period described in paragraph (k)(2) of this section.

(2) If the Exchange does not receive the requested information within the time allotted in paragraph (k)(1)(ii) of this section, the Exchange must notify the applicant in writing that the Exchange cannot process the application and provide appeal rights to the applicant.

[78 FR 39523, July 1, 2013, as amended at 81 FR 12346, Mar. 8, 2016; 83 FR 17064, Apr. 17, 2018]

§ 155.615 Verification process related to eligibility for exemptions.

(a) *General rule.* Unless a request for modification is granted under paragraph (i) of this section, the Exchange must verify or obtain information as provided in this section in order to determine that an applicant is eligible for an exemption.

(b) *Verification related to exemption for religious conscience.* For any applicant who requests an exemption based on religious conscience, the Exchange must verify that he or she meets the standards specified in §155.605(c) by—

(1) Except as specified in paragraph (b)(2) of this section, accepting a form that reflects that he or she is exempt from Social Security and Medicare taxes under section 1402(g)(1) of the Code;

(2) Except as specified in paragraphs (b)(3) and (4) of this section, accepting his or her attestation of membership in a religious sect or division, and verifying that the religious sect or division to which the applicant attests membership is recognized by the Social Security Administration as an approved religious sect or division under section 1402(g)(1) of the Code.

(3) If information provided by an applicant regarding his or her membership in a religious sect or division is not reasonably compatible with other information provided by the individual or in the records of the Exchange, the Exchange must follow the procedures specified in paragraph (g) of this section.

(4) If an applicant attests to membership in a religious sect or division that is not recognized by the Social Security Administration as an approved religious sect or division under section 1402(g)(1) of the Code, the Exchange must provide the applicant with information regarding how his or her religious sect or division can pursue recognition under section 1402(g)(1) of the Code, and determine the applicant ineligible for this exemption until such time as the Exchange obtains information indicating that the religious sect or division has been approved.

(c) *Verification related to exemption for hardship*—(1) *In general.* For any applicant who requests an exemption based on hardship, except for the hardship exemptions described in §155.605(d)(1)(i) and (iv), the Exchange must verify whether he or she has experienced the hardship to which he or she is attesting.

(2) *Lack of affordable coverage based on projected income.* (i) For any applicant who requests an exemption based on the hardship described in §155.605(g)(2), the Exchange must verify the unavailability of affordable coverage through the procedures used to determine eligibility for advance payments of the premium tax credit, as specified in subpart D of this part, including the procedures described in §155.315(c)(1), and the procedures used to verify eligibility for qualifying coverage in an eligible employer-sponsored plan, as specified in §155.320(d), except as specified in §155.615(f)(2)(ii).

(ii) The Exchange must accept an application filer's attestation for an applicant regarding eligibility for minimum essential coverage other than through an eligible employer-sponsored plan, instead of following the procedures specified in §155.320(b).

(3) [Reserved]

(4) To the extent that the Exchange is unable to verify any of the information needed to determine an applicant's eligibility for an exemption based on hardship, the Exchange must follow the procedures specified in paragraph (g) of this section.

(d) *Inability to verify necessary information.* Except as otherwise specified in this subpart, for an applicant for whom the Exchange cannot verify information required to determine eligibility for an exemption, including but not limited to when electronic data is required in accordance with this subpart but data for individuals relevant to the eligibility determination for an exemption are not included in such data

sources or when electronic data is required but it is not reasonably expected that data sources will be available within the time period as specified in §155.315(f), the Exchange—

(1) Must make a reasonable effort to identify and address the causes of such inconsistency, including typographical or other clerical errors, by contacting the application filer to confirm the accuracy of the information submitted by the application filer;

(2) If unable to resolve the inconsistency through the process described in paragraph (g)(1) of this section, must—

(i) Provide notice to the applicant regarding the inconsistency; and

(ii) Provide the applicant with a period of 90 days from the date on which the notice described in paragraph (g)(2)(i) of this section is sent to the applicant to either present satisfactory documentary evidence via the channels available for the submission of an application, as described in §155.610(d), except for by telephone, or otherwise to resolve the inconsistency.

(3) May extend the period described in paragraph (g)(2)(ii) of this section for an applicant if the applicant demonstrates that a good faith effort has been made to obtain the required documentation during the period.

(4) During the period described in paragraph (g)(1) and (g)(2)(ii) of this section, must not grant a certificate of exemption based on the information subject to this paragraph.

(5) If, after the period described in paragraph (g)(2)(ii) of this section, the Exchange remains unable to verify the attestation, the Exchange must determine the applicant's eligibility for an exemption based on any information available from the data sources used in accordance with this subpart, if applicable, unless such applicant qualifies for the exception provided under paragraph (h) of this section, and notify the applicant of such determination in accordance with the notice requirements specified in §155.610(i), including notice that the Exchange is unable to verify the attestation.

(e) *Exception for special circumstances.* For an applicant who does not have documentation with which to resolve the inconsistency through the process described in paragraph (g)(2) of this section because such documentation does not exist or is not reasonably available and for whom the Exchange is unable to otherwise resolve the inconsistency, the Exchange must provide an exception, on a case-by-case basis, to accept an applicant's attestation as to the information which cannot otherwise be verified along with an explanation of circumstances as to why the applicant does not have documentation.

(f) *Flexibility in information collection and verification.* HHS may approve an Exchange Blueprint in accordance with §155.105(d) or a significant change to the Exchange Blueprint in accordance with §155.105(e) to modify the methods to be used for collection of information and verification as set forth in this subpart, as well as the specific information required to be collected, provided that HHS finds that such modification would reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, and that applicable requirements under §§155.260, 155.270, and paragraph (j) of this section, and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information will be met.

(g) *Applicant information.* The Exchange may not require an applicant to provide information beyond the minimum necessary to support the eligibility process for exemptions as described in this subpart.

(h) *Validation of Social Security number.* (1) For any individual who provides his or her Social Security number to the Exchange, the Exchange must transmit the Social Security number and other identifying information to HHS, which will submit it to the Social Security Administration.

(2) To the extent that the Exchange is unable to validate an individual's Social Security number through the Social Security Administration, or the Social Security Administration indicates that the individual is deceased, the Exchange must follow the procedures specified in paragraph (g) of this section, except that the Exchange must provide the individual with a period of 90 days from the date on which the notice described in paragraph (g)(2)(i) of

this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration. The date on which the notice is received means 5 days after the date on the notice, unless the individual demonstrates that he or she did not receive the notice within the 5 day period.

[78 FR 39523, July 1, 2013, as amended at 78 FR 42322, July 15, 2013; 81 FR 12346, Mar. 8, 2016]

§ 155.620 Eligibility redeterminations for exemptions during a calendar year.

(a) *General requirement.* The Exchange must redetermine the eligibility of an individual with an exemption granted by the Exchange if it receives and verifies new information reported by such an individual, except for the exemption described in § 155.605(g)(2).

(b) *Requirement for individuals to report changes.* (1) Except as specified in paragraph (b)(2) of this section, the Exchange must require an individual who has a certificate of exemption from the Exchange to report any change with respect to the eligibility standards for the exemption as specified in § 155.605, except for the exemption described in § 155.605(g)(2), within 30 days of such change.

(2) The Exchange must allow an individual with a certificate of exemption to report changes via the channels available for the submission of an application, as described in § 155.610(d).

(c) *Verification of reported changes.* The Exchange must—

(1) Verify any information reported by an individual with a certificate of exemption in accordance with the processes specified in § 155.615 prior to using such information in an eligibility redetermination.

(2) Notify an individual in accordance with § 155.610(i) after redetermining his or her eligibility based on a reported change.

(3) Provide periodic electronic notifications regarding the requirements for reporting changes and an individual's opportunity to report any changes, to an individual who has a certificate of exemption for which changes must be reported in accordance with § 155.620(b) and who has elected to receive electronic notifications, unless he or she has declined to receive such notifications.

(d) *Effective date of changes.* The Exchange must implement a change resulting from a redetermination under this section for the month or months after the month in which the redetermination occurs, such that a certificate that was provided for the month in which the redetermination occurs, and for prior months remains effective.

§ 155.625 Options for conducting eligibility determinations for exemptions.

(a) *Options for conducting eligibility determinations.* The Exchange may satisfy the requirements of this subpart—

(1) Directly or through contracting arrangements in accordance with § 155.110(a); or

(2) By use of the HHS service under paragraph (b) of this section.

(b) *Use of HHS service.* Notwithstanding the requirements of this subpart, the Exchange may adopt an exemption eligibility determination made by HHS.

(c) *Administration of hardship exemption based on affordability.* States may choose to administer the hardship exemption under § 155.605(d)(2) only and delegate to HHS all other exemption determinations generally administered by HHS.

[79 FR 30349, May 27, 2014, as amended at 81 FR 12346, Mar. 8, 2016]

§ 155.630 Reporting.

Requirement to provide information related to tax administration. If the Exchange grants an individual a certificate of exemption in accordance with § 155.610(i), the Exchange must transmit to the IRS at such time and in such manner as the IRS may specify—

(a) The individual's name, Social Security number, and exemption certificate number;

(b) Any other information required in guidance published by the Secretary of the Treasury in accordance with 26 CFR 601.601(d)(2).

§ 155.635 Right to appeal.

(a) For an application submitted before October 15, 2014, the Exchange

must include the notice of the right to appeal and instructions regarding how to file an appeal in any notification issued in accordance with §155.610(i).

(b) For an application submitted on or after October 15, 2014, the Exchange must include the notice of the right to appeal and instructions regarding how to file an appeal in any notification issued in accordance with §§155.610(i) and 155.625(b)(2)(i).

Subpart H—Exchange Functions: Small Business Health Options Program (SHOP)

SOURCE: 77 FR 18464, Mar. 27, 2012, unless otherwise noted.

§155.700 Standards for the establishment of a SHOP.

(a) *General requirement.* (1) For plan years beginning before January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

(2) For plan years beginning on or after January 1, 2018, an Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers in facilitating the enrollment of their employees in qualified health plans.

(b) *Definition.* For the purposes of this subpart:

Group participation rate means the minimum percentage of all eligible individuals or employees of an employer that must be enrolled.

SHOP application filer means an applicant, an authorized representative, an agent or broker of the employer, or an employer filing for its employees where not prohibited by other law.

[77 FR 18464, Mar. 27, 2012, as amended at 78 FR 54141, Aug. 30, 2013; 80 FR 10868, Feb. 27, 2015; 83 FR 17064, Apr. 17, 2018]

§155.705 Functions of a SHOP for plan years beginning prior to January 1, 2018.

(a) *Exchange functions that apply to SHOP.* The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, K, and M of this part, except:

(1) Requirements related to individual eligibility determinations in subpart D of this part;

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to issue certificates of exemption in accordance with §155.200(b); and

(4) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under §155.240.

(b) *Unique functions of a SHOP.* The SHOP must also provide the following unique functions:

(1) Enrollment and eligibility functions. The SHOP must adhere to the requirements outlined in subpart H.

(2) *Employer choice requirements.* With regard to QHPs offered through the SHOP for plan years beginning on or after January 1, 2015, the SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer, unless the SHOP makes an election pursuant to paragraph (b)(3)(vi) of this section.

(3) *SHOP options with respect to employer choice requirements.* (i) For plan years beginning before January 1, 2015, a SHOP may allow a qualified employer to make one or more QHPs available to qualified employees:

(A) By the method described in paragraph (b)(2) of this section, or

(B) By a method other than the method described in paragraph (b)(2) of this section.

(ii) Unless the SHOP makes an election pursuant to paragraph (b)(3)(vi) of this section, for plan years beginning on or after January 1, 2015, a SHOP:

(A) Must allow an employer to make available to qualified employees all QHPs at the level of coverage selected by the employer as described in paragraph (b)(2) of this section, and

(B) May allow an employer to make one or more QHPs available to qualified employees by a method other than

the method described in paragraph (b)(2) of this section.

(iii) For plan years beginning before January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer the choice to make available to qualified employees a single QHP.

(iv) Unless the Secretary makes an election pursuant to paragraph (b)(3)(vi) of this section, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make QHPs available to qualified employees:

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section, or

(B) The employer may choose a single QHP.

(v) For plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees and their dependents:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in §156.150(b)(2) of this subchapter.

(vi) For plan years beginning in 2015 only, the SHOP may elect to provide employers only with the option set forth at paragraph (b)(3)(ii)(B) of this section, or in the case of a Federally-facilitated SHOP, only with the option set forth at paragraph (b)(3)(iv)(B) of this section, only if the State Insurance Commissioner submits a written recommendation to the SHOP adequately explaining that it is the State Insurance Commissioner's expert judgment, based on a documented assessment of the full landscape of the small group market in his or her State, that not implementing employee choice would be in the best interests of small employers and their employees and dependents, given the likelihood that implementing employee choice would cause issuers to price products and plans higher in 2015 due to the issuers' beliefs about adverse selection. A State Insurance Commissioner's recommendation must be based on concrete evidence, including but not limited to discussions with those issuers expected to participate in the SHOP in 2015.

(vii) For plan years beginning in 2015 only, a State Insurance Commissioner should submit the recommendation specified in paragraph (b)(3)(vi) of this section, and the SHOP should make a decision based on that recommendation sufficiently in advance of the end of the QHP certification application window such that issuers can make informed decisions about whether to participate in the SHOP. In a Federally-facilitated-SHOP, State Insurance Commissioners must submit to HHS the recommendation specified in paragraph (b)(3)(vi) of this section on or before June 2, 2014, and HHS will make a decision based on any recommendations submitted by that deadline before the close of the QHP certification application window.

(viii) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of at least the two methods to make QHPs available to qualified employees and their dependents described in paragraphs (b)(3)(viii)(A) and (B) of this section, and may also provide a qualified employer with a choice of a third method to make QHPs available to qualified employees and their dependents as described in paragraph (b)(3)(viii)(C) of this section.

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section;

(B) The employer may choose a single QHP; or

(C) The employer may offer its qualified employees a choice of all QHPs offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in section 1302(d)(1) of the Affordable Care Act and implemented in §156.140(b) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of

the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(ix) For plan years beginning on or after January 1, 2017, a Federally-facilitated SHOP will provide a qualified employer a choice of at least the two methods to make stand-alone dental plans available to qualified employees and their dependents described in paragraphs (b)(3)(ix)(A) and (B) of this section, and may also provide a qualified employer with a choice of a third method to make stand-alone dental plans available to qualified employees and their dependents as described in paragraph (b)(3)(ix)(C) of this section.

(A) The employer may choose to make available a single stand-alone dental plan;

(B) The employer may choose to make available all stand-alone dental plans offered through a Federally-facilitated SHOP at a level of coverage as described in §156.150(b)(2) of this subchapter; or

(C) The employer may offer its qualified employees a choice of all stand-alone dental plans offered through a Federally-facilitated SHOP by a single issuer across all available levels of coverage, as described in §156.150(b)(2) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(x) States operating a State-based Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP, except that a State with a State-based Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering the employer choice models specified in paragraphs (b)(3)(viii)(C) and (b)(3)(ix)(C) of this section in that State, provided that the State notifies HHS of that decision in advance of the annual QHP certification application deadline, by a date to be established by HHS.

(4)(i) *Premium aggregation.* Consistent with the effective dates set forth in paragraph (b)(4)(ii) of this section, the SHOP must perform the following functions related to premium payment administration:

(A) Provide each qualified employer with a bill on a monthly basis that identifies the employer contribution, the employee contribution, and the total amount that is due to the QHP issuers from the qualified employer;

(B) Collect from each employer the total amount due and make payments to QHP issuers in the SHOP for all enrollees except as provided for in paragraph (b)(4)(ii)(A) of this section; and

(C) Maintain books, records, documents, and other evidence of accounting procedures and practices of the premium aggregation program for each benefit year for at least 10 years.

(ii) The SHOP may establish one or more standard processes for premium calculation, premium payment, and premium collection.

(A) The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan, and remitting premium payments for this coverage to QHP issuers. A Federally-facilitated SHOP may elect to limit this service to the collection of premiums related to continuation coverage required under 29 U.S.C. 1161, *et seq.*

(B) Qualified employers in a Federally-facilitated SHOP must make premium payments according to a timeline and process established by HHS:

(*1*) In a Federally-facilitated SHOP, payment for the group's first month of

coverage must be received by the premium aggregation services vendor on or before the 20th day of the month prior to the month that coverage begins.

(*2*) In a Federally-facilitated SHOP, when coverage is effectuated retroactively, payment for the first month's coverage and all months of the retroactive coverage must be received and processed no later than 30 days after the event that triggers the eligibility for retroactive coverage. If payment is received on or before the 20th day of a month, coverage will be effectuated upon the first day of the following month retroactive to the effective date of coverage. If payment is received after the 20th day of a month, coverage will be effectuated upon the first day of the second following month retroactive to the effective date of coverage, provided that the payment includes the premium for the intervening month.

(C) For a Federally-facilitated SHOP, the premium for coverage lasting less than 1 month must equal the product of:

(*1*) The premium for 1 month of coverage divided by the number of days in the month; and

(*2*) The number of days for which coverage is being provided in the month described in paragraph (b)(4)(ii)(C)(*1*) of this section.

(iii) *Effective dates.* (A) A State-based SHOP may elect to perform these functions for plan years beginning before January 1, 2015, but need not do so.

(B) A Federally-facilitated SHOP will perform these functions only in plan years beginning on or after January 1, 2015.

(5) *QHP Certification.* With respect to certification of QHPs in the small group market, the SHOP must ensure each QHP meets the requirements specified in §156.285 of this subchapter.

(6) *Rates and rate changes.* The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year, beginning with rates effective no sooner than July 1, 2014. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

(ii) Prohibit all QHP issuers from varying rates for a qualified employer during the employer's plan year.

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit a qualified employee to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

(8) *QHP availability in unmerged markets.* If a State does not merge the individual and small group market risk pools, the SHOP must permit each qualified employee to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market.* If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017 provided that a large employer meets the qualified employer requirements other than that it be a small employer.

(10) *Participation rules.* Subject to §147.104 of this subchapter, the SHOP may authorize a uniform group participation rate for the offering of health insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) For plan years beginning before January 1, 2016, subject to §147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of qualified employees accepting coverage under the employer's group health plan, divided by the number of qualified employees offered coverage, excluding from the calculation

any employee who, at the time the employer submits the SHOP application, is enrolled in coverage through another employer's group health plan or through a governmental plan such as Medicare, Medicaid, or TRICARE. For purposes of this calculation, qualified employees who are former employees will not be counted.

(ii) For plan years beginning on or after January 1, 2016, subject to §147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

(iii) Notwithstanding paragraphs (b)(10)(i) and (ii) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

(11) *Premium calculator.* In the SHOP, the premium calculator described in §155.205(b)(6) must facilitate the comparison of available QHPs after the application of any applicable employer contribution in lieu of any advance payment of the premium tax credit and any cost sharing reductions.

(i) To determine the employer and employee contributions, a SHOP may establish one or more standard methods that employers may use to define their contributions toward employee and dependent coverage.

(ii) A Federally-facilitated SHOP must use the following method for employer contributions:

(A) When the employer offers a single plan to qualified employees, the employer must use a fixed contribution methodology under which the employer contributes a fixed percentage of the plan's premium for each qualified employee and, if applicable, for each dependent of a qualified employee. The employer's contribution is calculated based on an enrollee's premium before any applicable tobacco surcharge, based on the total premium owed for the enrollee, is applied.

(B) When the employer offers a choice of plans to qualified employees, the employer may use a fixed contribution methodology or a reference plan contribution methodology. Under the fixed contribution methodology, the employer contributes a fixed percentage of the premiums for each qualified employee and, if applicable, for each dependent of a qualified employee, across all plans in which any qualified employee, and, if applicable, any dependent of a qualified employee, is enrolled. Under the reference plan contribution methodology, the employer will select a plan from among the plans offered by the employer as described in paragraphs (b)(2) and (3) of this section to serve as a reference plan on which contributions will be based, and then will define a percentage contribution toward premiums under the reference plan; the resulting contribution amounts under the reference plan will be applied toward any plan in which a qualified employee or, if applicable, any dependent of a qualified employee, is enrolled, up to the lesser of the contribution amount or the total amount of any premium for the selected plan before application of a tobacco surcharge, if applicable. The employer's contribution is calculated based on an enrollee's premium before any applicable tobacco surcharge, based on the total premium owed for the enrollee, is applied.

(C) The employer will define a percentage contribution toward premiums for employee-only coverage and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage. To the extent permitted by other applicable law, for plan years beginning on or after January 1, 2015, a Federally-facilitated SHOP may permit an employer to define a different percentage contribution for full-time employees from the percentage contribution it defines for

non-full-time employees, and it may permit an employer to define a different percentage contribution for dependent coverage for full-time employees from the percentage contribution it defines for dependent coverage for non-full-time employees.

(D) A Federally-facilitated SHOP may permit employers to base contributions on a calculated composite premium for employees, for adult dependents, and for dependents below age 21.

(c) *Coordination with individual market Exchange for eligibility determinations.* A SHOP must provide data related to eligibility and enrollment of a qualified employee to the individual market Exchange that corresponds to the service area of the SHOP, unless the SHOP is operated pursuant to §155.100(a)(2).

(d) *Duties of Navigators in the SHOP.* In States that have elected to operate only a SHOP pursuant to §155.100(a)(2), at State option and if State law permits the Navigator duties described in §155.210(e)(3) and (4) may be fulfilled through referrals to agents and brokers.

(e) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.706 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18464, Mar. 27, 2012, as amended at 78 FR 15533, Mar. 11, 2013; 78 FR 33239, June 4, 2013; 78 FR 54141, Aug. 30, 2013; 78 FR 79620, Dec. 31, 2013; 79 FR 13838, Mar. 11, 2014; 79 FR 30349, May 27, 2014; 79 FR 59138, Oct. 1, 2014; 80 FR 10868, Feb. 27, 2015; 81 FR 12346, Mar. 8, 2016; 83 FR 17064, Apr. 17, 2018]

§155.706 Functions of a SHOP for plan years beginning on or after January 1, 2018.

(a) *Exchange functions that apply to SHOP.* The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, K, and M of this part, except:

(1) Requirements related to individual eligibility determinations in subpart D of this part;

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to issue certificates of exemption in accordance with §155.200(b); and

(4) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under §155.240.

(b) *Unique functions of a SHOP.* The SHOP must also provide the following unique functions:

(1) *Enrollment and eligibility functions.* The SHOP must adhere to the requirements outlined in subpart H.

(2) *Employer choice requirements.* The SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer.

(3) *SHOP options with respect to employer choice requirements.* (i) A SHOP:

(A) Must allow an employer to make available to qualified employees all QHPs at the level of coverage selected by the employer as described in paragraph (b)(2) of this section, and

(B) May allow an employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(ii) A Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make QHPs available to qualified employees:

(A) The employer may choose a level of coverage as described in paragraph (b)(2) of this section, or

(B) The employer may choose a single QHP.

(iii) A SHOP may, and a Federally-facilitated SHOP will provide a qualified employer a choice of two methods to make stand-alone dental plans available to qualified employees:

(A) The employer may choose to make available a single stand-alone dental plan.

(B) The employer may choose to make available all stand-alone dental plans offered through a SHOP.

(iv) A SHOP may also provide a qualified employer with a choice of a third method to make QHPs available to qualified employees by offering its qualified employees a choice of all QHPs offered through the SHOP by a single issuer across all available levels of coverage, as described in section

1302(d)(1) of the Affordable Care Act and implemented in §156.140(b) of this subchapter. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(v) A SHOP may also provide a qualified employer with a choice of a third method to make stand-alone dental plans available to qualified employees by offering its qualified employees a choice of all stand-alone dental plans offered through the SHOP by a single issuer. A State with a Federally-facilitated SHOP may recommend that the Federally-facilitated SHOP not make this additional option available in that State, by submitting a letter to HHS in advance of the annual QHP certification application deadline, by a date to be established by HHS. The State's letter must describe and justify the State's recommendation, based on the anticipated impact this additional option would have on the small group market and consumers.

(vi) States operating a State Exchange utilizing the Federal platform for SHOP enrollment functions will have the same employer choice models available as States with a Federally-facilitated SHOP, except that a State with a State Exchange utilizing the Federal platform for SHOP enrollment functions may decide against offering the employer choice models specified in paragraphs (b)(3)(iv) and (v) of this section in that State, provided that the State notifies HHS of that decision in advance of the annual QHP certification application deadline, by a date to be established by HHS.

(4) *Continuation of Coverage.* The SHOP may, upon an election by a qualified employer, enter into an agreement with a qualified employer to facilitate the administration of continuation coverage by collecting premiums for continuation coverage enrolled in through the SHOP directly from a person enrolled in continuation coverage through the SHOP consistent with applicable law and the terms of the group health plan, and remitting premium payments for this coverage to QHP issuers.

(5) *QHP Certification.* With respect to certification of QHPs in the small group market, the SHOP must ensure each QHP meets the requirements specified in §156.285 of this subchapter.

(6) *Rates and rate changes.* The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is no more frequently than quarterly.

(A) In a Federally-facilitated SHOP, rates may be updated quarterly with effective dates of January 1, April 1, July 1, or October 1 of each calendar year. The updated rates must be submitted to HHS at least 60 days in advance of the effective date of the rates.

(B) [Reserved]

(ii) Prohibit all QHP issuers from varying rates for a qualified employer during the employer's plan year.

(7) *QHP availability in merged markets.* If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit employer groups to enroll in any QHP meeting level of coverage requirements described in section 1302(d) of the Affordable Care Act.

(8) *QHP availability in unmerged markets.* If a State does not merge the individual and small group market risk pools, the SHOP must permit employer groups to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market.* If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017 provided that a large employer meets the qualified employer requirements other than that it be a small employer.

(10) *Participation rules.* Subject to §147.104 of this subchapter, the SHOP may authorize a uniform group participation rate for the offering of health

insurance coverage in the SHOP, which must be a single, uniform rate that applies to all groups and issuers in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(i) Subject to §147.104 of this subchapter, a Federally-facilitated SHOP must use a minimum participation rate of 70 percent, calculated as the number of full-time employees accepting coverage offered by a qualified employer plus the number of full-time employees who, at the time the employer submits the SHOP group enrollment, are enrolled in coverage through another group health plan, governmental coverage (such as Medicare, Medicaid, or TRICARE), coverage sold through the individual market, or in other minimum essential coverage, divided by the number of full-time employees offered coverage.

(ii) Notwithstanding paragraphs (b)(10)(i) of this section, a Federally-facilitated SHOP may utilize a different minimum participation rate in a State if there is evidence that a State law sets a minimum participation rate or that a higher or lower minimum participation rate is customarily used by the majority of QHP issuers in that State for products in the State's small group market outside the SHOP.

(11) *Premium calculator.* In the SHOP, the premium calculator described in §155.205(b)(6) must facilitate the comparison of available QHPs.

(c) *Coordination with individual market Exchange for eligibility determinations.* A SHOP that collects employee eligibility or enrollment data must provide data related to eligibility and enrollment of a qualified employee to the individual market Exchange that corresponds to the service area of the SHOP, unless the SHOP is operated pursuant to §155.100(a)(2).

(d) *Duties of Navigators in the SHOP.* In States that have elected to operate only a SHOP pursuant to §155.100(a)(2), at State option and if State law permits the Navigator duties described in §155.210(e)(3) and (4) may be fulfilled through referrals to agents and brokers.

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17064, Apr. 17, 2018]

§155.710 Eligibility standards for SHOP.

(a) *General requirement.* The SHOP must permit qualified employers to purchase coverage for qualified employees through the SHOP.

(b) *Employer eligibility requirements.* An employer is a qualified employer eligible to purchase coverage through a SHOP if such employer—

(1) Is a small employer;

(2) Elects to offer, at a minimum, all full-time employees coverage in a QHP through a SHOP; and

(3) Either—

(i) Has its principal business address in the Exchange service area and offers coverage to all its full-time employees through that SHOP; or

(ii) Offers coverage to each eligible employee through the SHOP serving that employee's primary worksite.

(c) *Participating in multiple SHOPs.* If an employer meets the criteria in paragraph (b) of this section and makes the election described in (b)(3)(ii) of this section, a SHOP shall allow the employer to offer coverage to those employees whose primary worksite is in the SHOP's service area.

(d) *Continuing eligibility.* The SHOP must treat a qualified employer which ceases to be a small employer solely by reason of an increase in the number of employees of such employer as a qualified employer until the qualified employer otherwise fails to meet the eligibility criteria of this section or elects to no longer purchase coverage for qualified employees through the SHOP.

(e) *Employee eligibility requirements.* An employee is a qualified employee eligible to enroll in coverage through a SHOP if such employee receives an offer of coverage from a qualified employer. A qualified employee is eligible to enroll his or her dependents in coverage through a SHOP if the offer from

the qualified employer includes an offer of dependent coverage.

[77 FR 18464, Mar. 27, 2012, as amended at 80 FR 10869, Feb. 27, 2015]

§ 155.715 Eligibility determination process for SHOP for plan years beginning prior to January 1, 2018.

(a) *General requirement.* Before permitting the purchase of coverage in a QHP, the SHOP must determine that the employer or individual who requests coverage is eligible in accordance with the requirements of § 155.710.

(b) *Applications.* The SHOP must accept a SHOP single employer application form from employers and the SHOP single employee application form from employees wishing to elect coverage through the SHOP, in accordance with the relevant standards of § 155.730.

(c) *Verification of eligibility.* For the purpose of verifying employer and employee eligibility, the SHOP—

(1) Must verify that an individual applicant is identified by the employer as an employee to whom the qualified employer has offered coverage and must otherwise accept the information attested to within the application unless the information is inconsistent with the employer-provided information;

(2) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application;

(3) Must collect only the minimum information necessary for verification of eligibility in accordance with the eligibility standards described in § 155.710; and

(4) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) *Eligibility adjustment period.* (1) When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must—

(i) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(ii) Notify the employer of the inconsistency;

(iii) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(1)(ii) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(1)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(A) Notify the employer of its denial of eligibility in accordance with paragraph (e) of this section and of the employer's right to appeal such determination; and

(B) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the SHOP at the end of the month following the month in which the notice is sent.

(2) When the information submitted on the SHOP single employee application is inconsistent with information collected from third-party data sources through the verification process described in § 155.715(c)(2), the SHOP must–

(i) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(ii) Notify the individual of the inability to substantiate his or her employee status;

(iii) Provide the employee with a period of 30 days from the date on which the notice described in paragraph (d)(2)(ii) of this section is sent to the employee to either present satisfactory documentary evidence to support the employee's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(2)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must notify the employee of its denial of eligibility in accordance with paragraph (f) of this section.

(e) *Notification of employer eligibility.* The SHOP must provide an employer

requesting eligibility to purchase coverage with a notice of approval or denial of eligibility and the employer's right to appeal such eligibility determination.

(f) *Notification of employee eligibility.* The SHOP must notify an employee seeking to enroll in a QHP offered through the SHOP of the determination by the SHOP whether the individual is eligible in accordance with §155.710 and the employee's right to appeal such determination.

(g) *Notification of employer withdrawal from SHOP.* If a qualified employer ceases to purchase coverage through the SHOP, the SHOP must ensure that—

(1) Each QHP terminates the enrollment through the SHOP of the employer's enrollees enrolled in a QHP through the SHOP; and

(2) Each of the employer's qualified employees enrolled in a QHP through the SHOP is notified of the termination of coverage prior to such termination. Such notification must also provide information about other potential sources of coverage, including access to individual market coverage through the Exchange.

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.716 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18464, Mar. 27, 2012, as amended at 79 FR 13839, Mar. 11, 2014; 81 FR 12347, Mar. 8, 2016; 83 FR 17065, Apr. 17, 2018]

§155.716 Eligibility determination process for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirement.* The SHOP must determine whether an employer requesting a determination of eligibility to participate in a SHOP is eligible in accordance with the requirements of §155.710.

(b) *Applications.* The SHOP must accept a SHOP single employer application form from employers, in accordance with the relevant standards of §155.730.

(c) *Verification of eligibility.* For the purpose of verifying employer eligibility, the SHOP—

(1) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application;

(2) Must collect only the minimum information necessary for verification of eligibility in accordance with the eligibility standards described in §155.710; and

(3) May not perform individual market Exchange eligibility determinations or verifications described in subpart D of this part.

(d) *Eligibility adjustment period.* When the information submitted on the SHOP single employer application is inconsistent with information collected from third-party data sources through the verification process described in paragraph (c)(1) of this section or otherwise received by the SHOP, the SHOP must—

(1) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(2) Notify the employer of the inconsistency;

(3) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(2) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(4) If, after the 30-day period described in paragraph (d)(2) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(i) Notify the employer of its denial or termination of eligibility in accordance with paragraph (e) of this section and of the employer's right to appeal such determination; and

(ii) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the SHOP at the end of the month following the month in which the notice is sent.

(e) *Notification of employer eligibility.* The SHOP must provide an employer requesting eligibility to purchase coverage through the SHOP with a notice of approval or denial or termination of eligibility and the employer's right to appeal such eligibility determination.

(f) *Validity of Eligibility Determination.* An employer's determination of eligibility to participate in SHOP remains valid until the employer makes a change that could end its eligibility under §155.710(b) or withdraws from participation in the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17065, Apr. 17, 2018]

§ 155.720 Enrollment of employees into QHPs under SHOP for plan years beginning prior to January 1, 2018.

(a) *General requirements.* The SHOP must process the SHOP single employee applications of qualified employees to the applicable QHP issuers and facilitate the enrollment of qualified employees in QHPs. All references to QHPs in this section refer to QHPs offered through the SHOP.

(b) *Enrollment timeline and process.* The SHOP must establish a uniform enrollment timeline and process for all QHP issuers and qualified employers to follow, which includes the following activities that must occur before the effective date of coverage for qualified employees:

(1) Determination of employer eligibility for purchase of coverage in the SHOP as described in §155.715;

(2) Qualified employer selection of QHPs offered through the SHOP to qualified employees, consistent with §155.705(b)(2) and (3);

(3) Provision of a specific timeframe during which the qualified employer can select the level of coverage or QHP offering, as appropriate;

(4) Provision of a specific timeframe for qualified employees to provide relevant information to complete the application process;

(5) Determination and verification of employee eligibility for enrollment through the SHOP; and

(6) Processing enrollment of qualified employees into selected QHPs.

(c) *Transfer of enrollment information.* In order to enroll qualified employees of a qualified employer participating in the SHOP, the SHOP must—

(1) Transmit enrollment information on behalf of qualified employees to QHP issuers in accordance with the timeline and process described in paragraph (b) of this section; and

(2) Follow requirements set forth in §155.400(c) of this part.

(d) *Payment.* The SHOP must—

(1) Follow requirements set forth in §155.705(b)(4) of this part; and

(2) Terminate participation of qualified employers that do not comply with the process established in §155.705(b)(4).

(e) *Notification of effective date.* (1) For plan years beginning before January 1, 2017, the SHOP must ensure that a QHP issuer notifies a qualified employee enrolled in a QHP through the SHOP of the effective date of his or her coverage.

(2) For plan years beginning on or after January 1, 2017, the SHOP must ensure that a QHP issuer notifies an enrollee enrolled in a QHP through the SHOP of the effective date of his or her coverage.

(3) When a primary subscriber and his or her dependents live at the same address, a separate notice of the effective date of coverage need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the coverage effective date for the primary subscriber and his or her dependents at that address.

(f) *Records.* The SHOP must receive and maintain for at least 10 years records of enrollment in QHPs, including identification of—

(1) Qualified employers participating in the SHOP; and

(2) Qualified employees enrolled in QHPs.

(g) *Reconcile files.* The SHOP must reconcile enrollment information and employer participation information with QHPs on no less than a monthly basis.

(h) *Employee termination of coverage from a QHP.* If any employee terminates coverage from a QHP, the SHOP must notify the employee's employer.

(i) *Reporting requirement for tax administration purposes.* The SHOP must report to the IRS employer participation, employer contribution, and employee enrollment information in a time and format to be determined by HHS.

(j) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.721 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18464, Mar. 27, 2012, as amended at 80 FR 10869, Feb. 27, 2015; 83 FR 17066, Apr. 17, 2018]

§ 155.721 Record retention and IRS Reporting for plan years beginning on or after January 1, 2018.

(a) *Records.* The SHOP must receive and maintain for at least 10 years records of qualified employers participating in the SHOP.

(b) *Reporting requirement for tax administration purposes.* The SHOP must, at the request of the IRS, report information to the IRS about employer eligibility to participate in SHOP coverage.

(c) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17066, Apr. 17, 2018]

§ 155.725 Enrollment periods under SHOP for plan years beginning prior to January 1, 2018.

(a) *General requirements.* The SHOP must ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with this section.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case the plan year will end on December 31 of the calendar year in which coverage first became effective.

(c) *Annual employer election period.* The SHOP must provide qualified employers with a standard election period prior to the completion of the employer's plan year and before the annual employee open enrollment period, in which the qualified employer may change its participation in the SHOP for the next plan year, including—

(1) The method by which the qualified employer makes QHPs available to qualified employees pursuant to §155.705(b)(2) and (3);

(2) The employer contribution towards the premium cost of coverage;

(3) The level of coverage offered to qualified employees as described in §155.705(b)(2) and (3); and

(4) The QHP or QHPs offered to qualified employees in accordance with §155.705.

(d) *Annual employer election period notice.* The SHOP must provide notification to a qualified employer of the annual election period in advance of such period.

(e) *Annual employee open enrollment period.* (1) The SHOP must establish a standardized annual open enrollment period for qualified employees prior to the completion of the applicable qualified employer's plan year and after that employer's annual election period.

(2) Qualified employers in a Federally-facilitated SHOP must provide qualified employees with an annual open enrollment period of at least one week.

(f) *Annual employee open enrollment period notice.* The SHOP must provide notification to a qualified employee of the annual open enrollment period in advance of such period.

(g) *Newly qualified employees.* (1) In a State Exchange that does not use the Federal platform for SHOP functions, the following rules apply with respect to enrollment and coverage effective dates for newly qualified employees.

(i) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period an enrollment period beginning on the first day of becoming a qualified employee. A newly qualified employee must have at least 30 days from the beginning of his or her enrollment period to select a QHP. The enrollment period must end no sooner than 15 days prior to the date that any applicable employee waiting period longer than 45 days would end if the employee made a plan selection on the first day of becoming eligible.

(ii) The effective date of coverage for a QHP selection received by the SHOP

from a newly qualified employee must always be the first day of a month, and must generally be determined in accordance with paragraph (h) of this section, unless the employee is subject to a waiting period consistent with §147.116 of this subchapter, in which case the effective date may be on the first day of a later month, but in no case may the effective date fail to comply with §147.116 of this subchapter.

(iii) Waiting periods in the SHOP are calculated beginning on the date the employee becomes a qualified employee who is otherwise eligible for coverage, regardless of when a qualified employer notifies the SHOP about a newly qualified employee.

(2) In a Federally-facilitated SHOP or in a State Exchange that uses the Federal platform for SHOP functions, the following rules apply with respect to enrollment and coverage effective dates for newly qualified employees.

(i) The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period with a 30-day enrollment period beginning on the date the qualified employer notifies the SHOP about the newly qualified employee. Qualified employers must notify the SHOP about a newly qualified employee on or before the thirtieth day after the day that the employee becomes a newly qualified employee.

(ii) The effective date of coverage for a QHP selection received by the SHOP from a newly qualified employee is the first day of the month following plan selection, unless the employee is subject to a waiting period consistent with §147.116 of this subchapter and paragraph (g)(2)(iii) of this section, in which case the effective date will be on the first day of the month following the end of the waiting period, but in no case may the effective date fail to comply with §147.116 of this subchapter. If a newly qualified employee's waiting period ends on the first day of a month and the employee has already made a plan selection by that date, coverage must take effect on that date. If a newly qualified employee makes a plan selection on the first day of a month and any applicable waiting period has ended by that date, coverage must be effective on the first day of the following month. If a qualified employer with variable hour employees makes regularly having a specified number of hours of service per period, or working full-time, a condition of employee eligibility for coverage offered through the SHOP, any measurement period that the qualified employer elects to use under §147.116(c)(3)(i) to determine whether an employee meets the applicable eligibility conditions with respect to coverage offered through the SHOP must not exceed 10 months, beginning on any date between the employee's start date and the first day of the first calendar month following the employee's start date.

(iii) Waiting periods in the SHOP are calculated beginning on the date the employee becomes a qualified employee who is otherwise eligible for coverage, regardless of when a qualified employer notifies the SHOP about a newly qualified employee, and must not exceed 60 days in length. Waiting periods must be 0, 15, 30, 45 or 60 days in length.

(h) *Initial and annual open enrollment effective dates.* (1) The SHOP must establish effective dates of coverage for qualified employees enrolling in coverage for the first time, and for qualified employees enrolling during the annual open enrollment period described in paragraph (e) of this section.

(2) For a group enrollment received by the Federally-facilitated SHOP from a qualified employer at the time of an initial group enrollment or renewal:

(i) Between the first and fifteenth day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the following month unless the employer opts for a later effective date within a quarter for which small group market rates are available.

(ii) Between the 16th and last day of any month, the Federally-facilitated SHOP must ensure a coverage effective date of the first day of the second following month unless the employer opts for a later effective date within a quarter for which small group market rates are available.

(i) *Renewal of coverage.* (1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for

enrollment through the SHOP in coverage offered by the same qualified employer, the SHOP may provide for a process under which the employee will remain in the QHP selected the previous year, unless—

(i) The qualified employee terminates coverage from such QHP in accordance with standards identified in § 155.430;

(ii) The qualified employee enrolls in another QHP if such option exists; or

(iii) The QHP is no longer available to the qualified employee.

(2) The SHOP may treat a qualified employer offering coverage through the SHOP as offering the same coverage under § 155.705(b)(3) at the same level of contribution under § 155.705(b)(11) unless:

(i) The qualified employer is no longer eligible to offer such coverage through the SHOP;

(ii) The qualified employer elects to offer different coverage or a different contribution through the SHOP;

(iii) The qualified employer withdraws from the SHOP; or

(iv) In the case of a qualified employer offering a single QHP, the single QHP is no longer available through the SHOP.

(j)(1) *Special enrollment periods.* The SHOP must provide special enrollment periods consistent with this section, during which certain qualified employees or a dependent of a qualified employee may enroll in QHPs and enrollees may change QHPs.

(2) The SHOP must provide a special enrollment period for a qualified employee or dependent of a qualified employee who:

(i) Experiences an event described in § 155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in § 155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

(ii) Loses eligibility for coverage under a Medicaid plan under title XIX of the Social Security Act or a State child health plan under title XXI of the Social Security Act; or

(iii) Becomes eligible for assistance, with respect to coverage under a SHOP, under such Medicaid plan or a State child health plan (including any waiver or demonstration project conducted under or in relation to such a plan).

(3) A qualified employee or dependent of a qualified employee who experiences a qualifying event described in paragraph (j)(2) of this section has:

(i) Thirty (30) days from the date of a triggering event described in paragraph (j)(2)(i) of this section to select a QHP through the SHOP; and

(ii) Sixty (60) days from the date of a triggering event described in paragraph (j)(2)(ii) or (iii) of this section to select a QHP through the SHOP;

(4) A dependent of a qualified employee is not eligible for a special election period if the employer does not extend the offer of coverage to dependents.

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of § 155.420(b).

(6) Loss of minimum essential coverage is determined using the provisions of § 155.420(e).

(7) Notwithstanding anything to the contrary in § 155.420(d), § 155.420(a)(4) and (d)(2)(i)(A) do not apply to special enrollment periods in the SHOP.

(k) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under § 155.705(b)(10).

(l) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.726 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18464, Mar. 27, 2012, as amended at 78 FR 33239, June 4, 2013; 78 FR 65095, Oct. 30, 2013; 79 FR 30350, May 27, 2014; 79 FR 42986, July 24, 2014; 80 FR 10869, Feb. 27, 2015; 81 FR 12347, Mar. 8, 2016; 81 FR 94179, Dec. 22, 2016; 82 FR 18382, Apr. 18, 2017; 83 FR 17066, Apr. 17, 2018]

§ 155.726 Enrollment periods under SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* The SHOP must ensure that issuers offering QHPs through the SHOP adhere to applicable enrollment periods, including special enrollment periods.

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must

consist of the 12-month period beginning with the qualified employer's effective date of coverage, unless the plan is issued in a State that has elected to merge its individual and small group risk pools under section 1312(c)(3) of the Affordable Care Act, in which case the plan year will end on December 31 of the calendar year in which coverage first became effective.

(c) *Special enrollment periods.* (1) The SHOP must ensure that issuers offering QHPs through the SHOP provide special enrollment periods consistent with the section, during which certain qualified employees or dependents of qualified employees may enroll in QHPs and enrollees may change QHPs.

(2) The SHOP must ensure that issuers offering QHPs through a SHOP provide a special enrollment period for a qualified employee or a dependent of a qualified employee who;

(i) Experiences an event described in §155.420(d)(1) (other than paragraph (d)(1)(ii)), or experiences an event described in §155.420(d)(2), (4), (5), (7), (8), (9), (10), (11), or (12);

(ii) Loses eligibility for coverage under a Medicaid plan under title XIX of the Social Security Act or a State child health plan under title XXI of the Social Security Act; or

(iii) Becomes eligible for assistance, with respect to coverage under a SHOP, under such Medicaid plan or a State child health plan (including any waiver or demonstration project conducted under or in relation to such a plan).

(3) A qualified employee or dependent of a qualified employee who experiences a qualifying event described in paragraph (j)(2) of this section has:

(i) Thirty (30) days from the date of a triggering event described in paragraph (c)(2)(i) of this section to select a QHP through the SHOP; and

(ii) Sixty (60) days from the date of a triggering event described in paragraph (c)(2)(ii) or (iii) of this section to select a QHP through the SHOP;

(4) A dependent of a qualified employee is not eligible for a special enrollment period if the employer does not extend the offer of coverage to dependents.

(5) The effective dates of coverage for special enrollment periods are determined using the provisions of §155.420(b).

(6) Loss of minimum essential coverage is determined using the provisions of §155.420(e).

(d) *Limitation.* Qualified employees will not be able to enroll unless the employer group meets any applicable minimum participation rate implemented under §155.706(b)(10).

(e) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17066, Apr. 17, 2018]

§155.730 Application standards for SHOP for plan year beginning prior to January 1, 2018.

(a) *General requirements.* Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application.* The SHOP must use a single application to determine employer eligibility and to collect information necessary for purchasing coverage. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Number of employees;

(3) Employer Identification Number (EIN); and

(4) A list of qualified employees and their taxpayer identification numbers.

(c) *Single employee application.* The SHOP must use a single application for eligibility determination, QHP selection and enrollment for qualified employees and their dependents.

(d) *Model application.* The SHOP may use the model single employer application and the model single employee application provided by HHS.

(e) *Alternative employer and employee application.* The SHOP may use an alternative application if such application is approved by HHS and collects the following:

(1) In the case of the employer application, the information in described in paragraph (b); and

(2) In the case of the employee application, the information necessary to establish eligibility of the employee as a qualified employee and to complete the enrollment of the qualified employee and any dependents to be enrolled.

(f) *Filing.* The SHOP must:

(1) Accept applications from SHOP application filers; and

(2) Provide the tools to file an application via an Internet Web site.

(g) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on the employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or single employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.731 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18464, Mar. 27, 2012, as amended at 78 FR 54141, Aug. 30, 2013; 79 FR 13839, Mar. 11, 2014; 83 FR 17066, Apr. 17, 2018]

§ 155.731 Application standards for SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application.* The SHOP must use a single application to determine employer eligibility. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Information sufficient to confirm the employer is a small employer;

(3) Employer Identification Number (EIN); and

(4) Information sufficient to confirm that the employer is offering, at a minimum, all full-time employees coverage in a QHP through a SHOP.

(c) *Model application.* The SHOP may use the model single employer application provided by HHS.

(d) *Alternative employer application.* The SHOP may use an alternative application if such application is approved by HHS and collects the information described in paragraph (b).

(e) *Filing.* The SHOP must:

(1) Accept applications from SHOP application filers; and

(2) Provide the tools to file an employer eligibility application via an internet website.

(f) *Additional safeguards.* (1) The SHOP may not provide to the employer any information collected on an employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

(2) The SHOP is not permitted to collect information on the single employer or on an employee application unless that information is necessary to determine SHOP eligibility or effectuate enrollment through the SHOP.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17066, Apr. 17, 2018]

§ 155.735 Termination of SHOP enrollment or coverage for plan years beginning prior to January 1, 2018.

(a) *General requirements.* The SHOP must determine the timing, form, and manner in which coverage or enrollment in a QHP through the SHOP may be terminated.

(b) *Termination of employer group health coverage or enrollment at the request of the employer.* (1) The SHOP must establish policies for advance notice of termination required from the employer and effective dates of termination.

(2) In the Federally-facilitated SHOP, an employer may terminate coverage or enrollment for all enrollees covered by the employer group health plan effective on the last day of any month, provided that the employer has given notice to the Federally-facilitated SHOP on or before the 15th day of any month. If notice is given after the 15th of the month, the Federally-facilitated SHOP may terminate the coverage or enrollment on the last day of the following month.

(c) *Termination of employer group health coverage for non-payment of premiums.* (1) The SHOP must establish policies for termination for non-payment of premiums, including but not limited to policies regarding due dates for payment of premiums to the SHOP, grace periods, employer and employee notices, and reinstatement provisions.

(2) In an FF–SHOP, for premium payments other than payments for the first month of coverage—

(i) For a given month of coverage, premium payment is due by the first day of the coverage month.

(ii) If premium payment is not received 31 days from the first of the coverage month, the Federally-facilitated SHOP may terminate the qualified employer for lack of payment. The termination would take effect on the last day of the month for which the Federally-facilitated SHOP received full payment.

(iii) If a qualified employer is terminated due to lack of premium payment, but within 30 days following its termination the qualified employer requests reinstatement, pays all premiums owed including any prior premiums owed for coverage during the grace period, and pays the premium for the next month's coverage, the Federally-facilitated SHOP must reinstate the qualified employer in its previous coverage. A qualified employer may be reinstated in the Federally-facilitated SHOP only once per calendar year.

(iv) Enrollees enrolled in continuation coverage required under 29 U.S.C. 1161, *et seq.* through the Federally-facilitated SHOP may not be terminated if timely payment is made to the Federally-facilitated SHOP in an amount that is not less than $50 less than the amount the plan requires to be paid for a period of coverage unless the Federally-facilitated SHOP notifies the enrollee of the amount of the deficiency and the enrollee does not pay the deficiency within 30 days of such notice, pursuant to the notice requirements in § 155.230.

(3) *Payment for COBRA Continuation Coverage.* Nothing in this section modifies existing obligations related to the administration of coverage required under 29 U.S.C. 1161, *et seq.*, as described in 26 CFR part 54.

(d) *Termination of employee or dependent coverage or enrollment.* (1) The SHOP must establish consistent policies regarding the process for and effective dates of termination of employee or dependent coverage or enrollment in the following circumstances:

(i) The employee or dependent is no longer eligible for coverage under the employer's group health plan;

(ii) The employee requests that the SHOP terminate the coverage of the employee or a dependent of the employee under the employer's group health plan;

(iii) The QHP in which the enrollee is enrolled terminates, is decertified as described in § 155.1080, or its certification as a QHP is not renewed;

(iv) The enrollee changes from one QHP to another during the employer's annual open enrollment period or during a special enrollment period in accordance with § 155.725(j); or

(v) The enrollee's coverage is rescinded in accordance with § 147.128 of this subtitle.

(2) In the FF–SHOP, termination is effective:

(i) In the case of a termination in accordance with paragraphs (d)(1)(i), (ii), (iii), and (v) of this section, termination is effective on the last day of the month in which the Federally-facilitated SHOP receives notice of the event described in paragraph (d)(1)(i), (ii), (iii), or (v) of this section.

(ii) In the case of a termination in accordance with paragraph (d)(1)(iv) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP, including for any retroactive enrollments effectuated under § 155.725(j)(5).

(iii) The FF–SHOP will send qualified employees a notice notifying them in advance of a child dependent's loss of eligibility for dependent child coverage under their plan because of age. The notice will be sent 90 days in advance of the date when the dependent enrollee would lose eligibility for dependent child coverage. The enrollee will also receive a separate termination notice when coverage is terminated, under § 155.735(g).

(e) *Termination of enrollment or coverage tracking and approval.* The SHOP must comply with the standards described in § 155.430(c).

(f) *Applicability date.* The provisions of this section apply to coverage—

(1) Beginning on or after January 1, 2015; and

(2) In any SHOP providing qualified employers with the option described in §155.705(b)(2) or the option described in §155.705(b)(4) before January 1, 2015, beginning with the date that option is offered.

(g) *Notice of termination.* Beginning January 1, 2016:

(1) Except as provided in paragraph (g)(3) of this section, if any enrollee's coverage or enrollment through the SHOP is terminated due to non-payment of premiums or due to a loss of the enrollee's eligibility to participate in the SHOP, including where an enrollee loses his or her eligibility because a qualified employer has lost its eligibility, the SHOP must notify the enrollee of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent.

(2) Except as provided in paragraph (g)(3) of this section, if an employer group's coverage or enrollment through the SHOP is terminated due to non-payment of premiums or, where applicable, due to a loss of the qualified employer's eligibility to offer coverage through the SHOP, the SHOP must notify the employer of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent.

(3) Where State law requires a QHP issuer to send the notices described in paragraphs (g)(1) and (2) of this section, a SHOP is not required to send such notices.

(4) When a primary subscriber and his or her dependents live at the same address, a separate termination notice need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the termination for the primary subscriber and his or her dependents at that address.

(h) *Applicability date.* The provisions of this section apply for plan years beginning before January 1, 2018.

[78 FR 54141, Aug. 30, 2013, as amended at 80 FR 10870, Feb. 27, 2015; 81 FR 12348, Mar. 8, 2016; 83 FR 17067, Apr. 17, 2018]

§ 155.740 SHOP employer and employee eligibility appeals requirements for plan years beginning prior to January 1, 2018.

(a) *Definitions.* The definitions in §§155.20, 155.300, and 155.500 apply to this section.

(b) *General requirements.* (1) A State, establishing an Exchange that provides for the establishment of a SHOP pursuant to §155.100 must provide an eligibility appeals process for the SHOP. Where a State has not established an Exchange that provides for the establishment of a SHOP pursuant to §155.100, HHS will provide an eligibility appeals process for the SHOP that meets the requirements of this section and the requirements in paragraph (b)(2) of this section.

(2) The appeals entity must conduct appeals in accordance with the requirements established in this section and §§155.505(e) through (h) and 155.510(a)(1) and (2) and (c).

(c) *Employer right to appeal.* An employer may appeal—

(1) A notice of denial of eligibility under §155.715(e); or

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with §155.715(e).

(d) *Employee right to appeal.* An employee may appeal—

(1) A notice of denial of eligibility under §155.715(f); or

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with §155.715(f).

(e) *Appeals notice requirement.* Notices of the right to appeal a denial of eligibility under §155.715(e) or (f) must be written and include—

(1) The reason for the denial of eligibility, including a citation to the applicable regulations; and

(2) The procedure by which the employer or employee may request an appeal of the denial of eligibility.

(f) *Appeal request.* The SHOP and appeals entity must—

(1) Allow an employer or employee to request an appeal within 90 days from the date of the notice of denial of eligibility to—

(i) The SHOP or the appeals entity; or

(ii) HHS, if no State Exchange that provides for establishment of a SHOP has been established;

(2) Accept appeal requests submitted through any of the methods described in §155.520(a)(1);

(3) Comply with the requirements of §155.520(a)(2) and (3); and

(4) Consider an appeal request valid if it is submitted in accordance with paragraph (f)(1) of this section.

(g) *Notice of appeal request.* (1) Upon receipt of a valid appeal request, the appeals entity must—

(i) Send timely acknowledgement to the employer, or employer and employee if an employee is appealing, of the receipt of the appeal request, including—

(A) An explanation of the appeals process; and

(B) Instructions for submitting additional evidence for consideration by the appeals entity.

(ii) Promptly notify the SHOP of the appeal, if the appeal request was not initially made to the SHOP.

(2) Upon receipt of an appeal request that is not valid because it fails to meet the requirements of this section, the appeals entity must—

(i) Promptly and without undue delay, send written notice to the employer or employee that is appealing that—

(A) The appeal request has not been accepted,

(B) The nature of the defect in the appeal request; and

(C) An explanation that the employer or employee may cure the defect and resubmit the appeal request if it meets the timeliness requirements of paragraph (f) of this section, or within a reasonable timeframe established by the appeals entity.

(ii) Treat as valid an amended appeal request that meets the requirements of this section.

(h) *Transmittal and receipt of records.* (1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (g)(2) of this section, the SHOP must promptly transmit, via secure electronic interface, to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the SHOP; and

(ii) The eligibility record of the employer or employee that is appealing.

(2) The appeals entity must promptly confirm receipt of records transmitted pursuant to paragraph (h)(1) of this section to the SHOP that transmitted the records.

(i) *Dismissal of appeal.* The appeals entity—

(1) Must dismiss an appeal if the employer or employee that is appealing—

(i) Withdraws the request in accordance with the standards set forth in §155.530(a)(1); or

(ii) Fails to submit an appeal request meeting the standards specified in paragraph (f) of this section.

(2) Must provide timely notice to the employer or employee that is appealing of the dismissal of the appeal request, including the reason for dismissal, and must notify the SHOP of the dismissal.

(3) May vacate a dismissal if the employer or employee makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated.

(j) *Procedural rights of the employer or employee.* The appeals entity must provide the employer, or the employer and employee if an employee is appealing, the opportunity to submit relevant evidence for review of the eligibility determination.

(k) *Adjudication of SHOP appeals.* SHOP appeals must—

(1) Comply with the standards set forth in §155.555(i)(1) and (3); and

(2) Consider the information used to determine the employer or employee's eligibility as well as any additional relevant evidence submitted during the course of the appeal by the employer or employee.

(l) *Appeal decisions.* Appeal decisions must—

(1) Be based solely on—

(i) The evidence referenced in paragraph (k)(2) of this section;

(ii) The eligibility requirements for the SHOP under §155.710(b) or (e), as applicable.

(2) Comply with the standards set forth in §155.545(a)(2) through (5); and

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made retroactive to the effective date of coverage or enrollment through the SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) For employee appeal decisions only, if an employee is found eligible under the decision, then at the employee's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made effective retroactive to the effective date of coverage or enrollment through the SHOP that the employee would have had if the employee had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(iii) If the employer or employee is found ineligible under the decision, then the appeal decision is effective as of the date of the notice of the appeal decision.

(m) *Notice of appeal decision.* The appeals entity must issue written notice of the appeal decision to the employer, or to the employer and employee if an employee is appealing, and to the SHOP within 90 days of the date the appeal request is received.

(n) *Implementation of SHOP appeal decisions.* The SHOP must promptly implement the appeal decision upon receiving the notice under paragraph (m) of this section.

(o) *Appeal record.* Subject to the requirements of §155.550, the appeal record must be accessible to the employer, or employer and employee if an employee is appealing, in a convenient format and at a convenient time.

(p) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 155.741 is applicable for plan years beginning on or after January 1, 2018.

[78 FR 54141, Aug. 30, 2013, as amended at 79 FR 30350, May 27, 2014; 81 FR 12348, Mar. 8, 2016; 81 FR 94180, Dec. 22, 2016; 83 FR 17067, Apr. 17, 2018]

§155.741 SHOP employer and employee eligibility appeals requirements for plan year beginning on or after January 1, 2018.

(a) *Definitions.* The definitions in §§155.20, 155.300, and 155.500 apply to this section.

(b) *General requirements.* (1) A State, establishing an Exchange that provides for the establishment of a SHOP pursuant to §155.100 must provide an eligibility appeals process for the SHOP. Where a State has not established an Exchange that provides for the establishment of a SHOP pursuant to §155.100, HHS will provide an eligibility appeals process for the SHOP that meets the requirements of this section and the requirements in paragraph (b)(2) of this section.

(2) The appeals entity must conduct appeals in accordance with the requirements established in this section and §§155.505(e) through (h) and 155.510(a)(1) and (2) and (c).

(c) *Employer right to appeal.* An employer may appeal—

(1) A notice of denial or termination of eligibility under §155.716(e); or

(2) A failure by the SHOP to provide a timely eligibility determination or a timely notice of an eligibility determination in accordance with §155.716(e).

(d) *Appeals notice requirement.* Notices of the right to appeal a denial of eligibility under §155.716(e) must be written and include—

(1) The reason for the denial or termination of eligibility, including a citation to the applicable regulations; and

(2) The procedure by which the employer may request an appeal of the denial or termination of eligibility.

(e) *Appeal request.* The SHOP and appeals entity must—

(1) Allow an employer to request an appeal within 90 days from the date of the notice of denial or termination of eligibility to—

(i) The SHOP or the appeals entity; or

(ii) HHS, if no State Exchange that provides for establishment of a SHOP has been established;

(2) Accept appeal requests submitted through any of the methods described in §155.520(a)(1);

(3) Comply with the requirements of §155.520(a)(2) and (3); and

(4) Consider an appeal request valid if it is submitted in accordance with paragraph (e)(1) of this section.

(f) *Notice of appeal request.* (1) Upon receipt of a valid appeal request, the appeals entity must—

(i) Send timely acknowledgement to the employer of the receipt of the appeal request, including—

(A) An explanation of the appeals process; and

(B) Instructions for submitting additional evidence for consideration by the appeals entity.

(ii) Promptly notify the SHOP of the appeal, if the appeal request was not initially made to the SHOP.

(2) Upon receipt of an appeal request that is not valid because it fails to meet the requirements of this section, the appeals entity must—

(i) Promptly and without undue delay, send written notice to the employer that is appealing that—

(A) The appeal request has not been accepted,

(B) The nature of the defect in the appeal request; and

(C) An explanation that the employer may cure the defect and resubmit the appeal request if it meets the timeliness requirements of paragraph (e) of this section, or within a reasonable timeframe established by the appeals entity.

(ii) Treat as valid an amended appeal request that meets the requirements of this section.

(g) *Transmittal and receipt of records.* (1) Upon receipt of a valid appeal request under this section, or upon receipt of the notice under paragraph (f)(2) of this section, the SHOP must promptly transmit, via secure electronic interface, to the appeals entity—

(i) The appeal request, if the appeal request was initially made to the SHOP; and

(ii) The eligibility record of the employer that is appealing.

(2) The appeals entity must promptly confirm receipt of records transmitted pursuant to paragraph (g)(1) of this section to the SHOP that transmitted the records.

(h) *Dismissal of appeal.* The appeals entity—

(1) Must dismiss an appeal if the employer that is appealing—

(i) Withdraws the request in accordance with the standards set forth in §155.530(a)(1); or

(ii) Fails to submit an appeal request meeting the standards specified in paragraph (e) of this section.

(2) Must provide timely notice to the employer that is appealing of the dismissal of the appeal request, including the reason for dismissal, and must notify the SHOP of the dismissal.

(3) May vacate a dismissal if the employer makes a written request within 30 days of the date of the notice of dismissal showing good cause why the dismissal should be vacated.

(i) *Procedural rights of the employer.* The appeals entity must provide the employer the opportunity to submit relevant evidence for review of the eligibility determination.

(j) *Adjudication of SHOP appeals.* SHOP appeals must—

(1) Comply with the standards set forth in §155.555(i)(1) and (3); and

(2) Consider the information used to determine the employer's eligibility as well as any additional relevant evidence submitted during the course of the appeal by the employer or employee.

(k) *Appeal decisions.* Appeal decisions must—

(1) Be based solely on—

(i) The evidence referenced in paragraph (j)(2) of this section;

(ii) The eligibility requirements for the SHOP under §155.710(b), as applicable.

(2) Comply with the standards set forth in §155.545(a)(2) through (5)

(3) Be effective as follows:

(i) If an employer is found eligible under the decision, then at the employer's option, the effective date of coverage or enrollment through the SHOP under the decision can either be made

retroactive to the effective date of coverage or enrollment through the SHOP that the employer would have had if the employer had been correctly determined eligible, or prospective to the first day of the month following the date of the notice of the appeal decision.

(ii) If the employer is found ineligible under the decision, then the appeal decision is effective as of the date of the notice of the appeal decision.

(l) *Notice of appeal decision.* The appeals entity must issue written notice of the appeal decision to the employer and to the SHOP within 90 days of the date the appeal request is received.

(m) *Implementation of SHOP appeal decisions.* The SHOP must promptly implement the appeal decision upon receiving the notice under paragraph (l) of this section.

(n) *Appeal record.* Subject to the requirements of §155.550, the appeal record must be accessible to the employer in a convenient format and at a convenient time.

(o) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17067, Apr. 17, 2018]

Subparts I–J [Reserved]

Subpart K—Exchange Functions: Certification of Qualified Health Plans

SOURCE: 77 FR 18467, Mar. 27, 2012, unless otherwise noted.

§155.1000 Certification standards for QHPs.

(a) *Definition.* The following definition applies in this subpart:

Multi-State plan means a health plan that is offered in accordance with section 1334 of the Affordable Care Act.

(b) *General requirement.* The Exchange must offer only health plans which have in effect a certification issued or are recognized as plans deemed certified for participation in an Exchange as a QHP, unless specifically provided for otherwise.

(c) *General certification criteria.* The Exchange may certify a health plan as a QHP in the Exchange if—

(1) The health insurance issuer provides evidence during the certification process in §155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156, as applicable; and

(2) The Exchange determines that making the health plan available is in the interest of the qualified individuals and qualified employers, except that the Exchange must not exclude a health plan—

(i) On the basis that such plan is a fee-for-service plan;

(ii) Through the imposition of premium price controls; or

(iii) On the basis that the health plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

(d) *Special rule for SHOP.* Except when a QHP is decertified by the Exchange pursuant to §155.1080, in a SHOP that certifies QHPs on a calendar-year basis, the certification shall remain in effect for the duration of any plan year beginning in the calendar year for which the QHP was certified, even if the plan year ends after the calendar year for which the QHP was certified.

[77 FR 18467, Mar. 27, 2012, as amended at 80 FR 10870, Feb. 27, 2015]

§155.1010 Certification process for QHPs.

(a) *Certification procedures.* The Exchange must establish procedures for the certification of QHPs consistent with §155.1000(c).

(1) *Completion date.* The Exchange must complete the certification of the QHPs that will be offered during the open enrollment period prior to the beginning of such period, as outlined in §155.410.

(2) *Ongoing compliance.* The Exchange must monitor the QHP issuers for demonstration of ongoing compliance with the certification requirements in §155.1000(c).

(b) *Exchange recognition of plans deemed certified for participation in an Exchange.* Notwithstanding paragraph (a) of this section, an Exchange must recognize as certified QHPs:

(1) A multi-State plan certified by and under contract with the U.S. Office of Personnel Management.

(2) A CO–OP QHP as described in subpart F of part 156 and deemed as certified under §156.520(e).

§ 155.1020 QHP issuer rate and benefit information.

(a) *Receipt and posting of rate increase justification.* The Exchange must ensure that a QHP issuer submits a justification for a rate increase for a QHP prior to the implementation of such an increase, except for multi-State plans, for which the U.S. Office of Personnel Management will provide a process for the submission of rate increase justifications. The Exchange must ensure that the QHP issuer has prominently posted the justification on its Web site as required under §156.210. To ensure consumer transparency, the Exchange must also provide access to the justification on its Internet Web site described in §155.205(b).

(b) *Rate increase consideration.* (1) The Exchange must consider rate increases in accordance with section 1311(e)(2) of the Affordable Care Act, which includes consideration of the following:

(i) A justification for a rate increase prior to the implementation of the increase;

(ii) Recommendations provided to the Exchange by the State in accordance with section 2794(b)(1)(B) of the PHS Act; and

(iii) Any excess of rate growth outside the Exchange as compared to the rate of such growth inside the Exchange.

(2) This paragraph does not apply to multi-State plans for which the U.S. Office of Personnel Management will provide a process for rate increase consideration.

(c) *Benefit and rate information.* The Exchange must receive the information described in this paragraph, at least annually, from QHP issuers for each QHP in a form and manner to be specified by HHS. Information about multi-State plans may be provided in a form and manner determined by the U.S. Office of Personnel Management. The information identified in this paragraph is:

(1) Rates;

(2) Covered benefits; and

(3) Cost-sharing requirements.

[77 FR 18467, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 155.1030 QHP certification standards related to advance payments of the premium tax credit and cost-sharing reductions.

(a) *Review of plan variations for cost-sharing reductions.* (1) An Exchange must ensure that each issuer that offers, or intends to offer a health plan at any level of coverage in the individual market on the Exchange submits the required plan variations for the health plan as described in §156.420 of this subchapter. The Exchange must certify that the plan variations meet the requirements of §156.420.

(2) The Exchange must provide to HHS the actuarial values of each QHP and silver plan variation, calculated under §156.135 of this subchapter, in the manner and timeframe established by HHS.

(b) *Information for administering advance payments of the premium tax credit and advance payments of cost-sharing reductions.* (1) The Exchange must collect and review annually the rate allocation and the actuarial memorandum that an issuer submits to the Exchange under §156.470 of this subchapter, to ensure that the allocation meets the standards set forth in §156.470(c) and (d) of this subchapter.

(2) The Exchange must submit, in the manner and timeframe established by HHS, to HHS the approved allocations and actuarial memorandum underlying the approved allocations for each health plan at any level of coverage or stand-alone dental plan offered, or intended to be offered in the individual market on the Exchange.

(3) The Exchange must use the methodology specified in the annual HHS notice of benefit and payment parameters to calculate advance payment amounts for cost-sharing reductions, and must transmit the advance payment amounts to HHS, in accordance with §156.340(a) of this subchapter.

(4) HHS may use the information provided to HHS by the Exchange under this section for oversight of advance payments of cost-sharing reductions and premium tax credits.

(c) *Multi-State plans.* The U.S. Office of Personnel Management will ensure compliance with the standards referenced in this section for multi-State plans, as defined in §155.1000(a).

[78 FR 15534, Mar. 11, 2013, as amended at 79 FR 13839, Mar. 11, 2014]

§ 155.1040 Transparency in coverage.

(a) *General requirement.* The Exchange must collect information relating to coverage transparency as described in §156.220 of this subtitle from QHP issuers, and from multi-State plans in a time and manner determined by the U.S. Office of Personnel Management.

(b) *Use of plain language.* The Exchange must determine whether the information required to be submitted and made available under paragraph (a) of this section is provided in plain language.

(c) *Transparency of cost-sharing information.* The Exchange must monitor whether a QHP issuer has made cost-sharing information available in a timely manner upon the request of an individual as required by §156.220(d) of this subtitle.

§ 155.1045 Accreditation timeline.

(a) *Timeline.* The Exchange must establish a uniform period following certification of a QHP within which a QHP issuer that is not already accredited must become accredited as required by §156.275 of this subchapter, except for multi-state plans. The U.S. Office of Personnel Management will establish the accreditation period for multi-state plans.

(b) *Federally-facilitated Exchange.* The accreditation timeline used in federally-facilitated Exchanges follows:

(1) During certification for an issuer's initial year of QHP certification (for example, in 2013 for the 2014 coverage year), a QHP issuer without existing commercial, Medicaid, or Exchange health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is applying to offer coverage must have scheduled or plan to schedule a review of QHP policies and procedures of the applying QHP issuer with a recognized accrediting entity.

(2) Prior to a QHP issuer's second year and third year of QHP certification (for example, in 2014 for the 2015 coverage year and 2015 for the 2016 coverage year), a QHP issuer must be accredited by a recognized accrediting entity on the policies and procedures that are applicable to their Exchange products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is offering Exchange coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP.

(3) Prior to the QHP issuer's fourth year of QHP certification and in every subsequent year of certification (for example, in 2016 for the 2017 coverage year and forward), a QHP issuer must be accredited in accordance with §156.275 of this subchapter.

[78 FR 12865, Feb. 25, 2013]

§ 155.1050 Establishment of Exchange network adequacy standards.

(a) Except with regard to multi-State plans:

(1) A federally facilitated Exchange must ensure that the provider network of each QHP meets the standards specified in §156.230 of this subtitle.

(2) State Exchanges and State-based Exchanges on the Federal Platform must ensure that the provider network of each QHP meets applicable standards specified in §156.230(a)(1)(ii), (a)(1)(iii), and (a)(4) of this sub*chapter*.

(i) For plan years beginning on or after January 1, 2026, to comply with the requirement under paragraph (a)(2) of this section, State Exchanges and State-based Exchanges on the Federal platform must:

(A) Establish and impose network adequacy time and distance standards for QHPs that are at least as stringent as standards for QHPs participating on the Federally-facilitated Exchanges under §156.230(a)(2)(i)(A) of this subchapter;

(B) Conduct, prior to QHP certification, quantitative network adequacy reviews to evaluate compliance with requirements under §156.230(a)(1)(ii),

(a)(1)(iii), and (a)(2)(i)(A) of this subchapter, while providing QHP certification applicants the flexibilities described under §156.230(a)(2)(ii) and (a)(3) and (4); and

(C) Require that all issuers seeking certification of a plan as a QHP submit information to the Exchange reporting whether or not network providers offer telehealth services.

(ii) For plan years beginning on or after January 1, 2026, HHS may grant an exception to the requirements described under paragraphs (a)(2)(i) of this section to a State Exchange or State-based Exchange on the Federal platform that demonstrates with evidence-based data, in a form and manner specified by HHS, that:

(A) the Exchange applies and enforces alternate quantitative network adequacy standards that are reasonably calculated to ensure a level of access to providers that is as great as that ensured by the Federal network adequacy standards established for QHPs under §156.230(a)(1)(iii), (a)(2)(i)(A), and (a)(4) of this subchapter; and

(B) the Exchange evaluates whether plans comply with applicable network adequacy standards prior to certifying any plan as a QHP.

(b) The U.S. Office of Personnel Management will ensure compliance with the standards specified in §156.230 of this subtitle for multi-State plans.

(c) A QHP issuer in an Exchange may not be prohibited from contracting with any essential community provider designated under §156.235(c) of this subtitle.

[77 FR 18467, Mar. 27, 2012, as amended at 89 FR 26423, Apr. 15, 2024]

§ 155.1055 Service area of a QHP.

The Exchange must have a process to establish or evaluate the service areas of QHPs to ensure such service areas meet the following minimum criteria:

(a) The service area of a QHP covers a minimum geographical area that is at least the entire geographic area of a county, or a group of counties defined by the Exchange, unless the Exchange determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers.

(b) The service area of a QHP has been established without regard to racial, ethnic, language, health status-related factors specified under section 2705(a) of the PHS Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations.

§ 155.1065 Stand-alone dental plans.

(a) *General requirements.* The Exchange must allow the offering of a limited scope dental benefits plan through the Exchange, if—

(1) The plan meets the requirements of section 9832(c)(2)(A) of the Code and 2791(c)(2)(A) of the PHS Act; and

(2) The plan covers at least the pediatric dental essential health benefit as defined in section 1302(b)(1)(J) of the Affordable Care Act, provided that, with respect to this benefit, the plan satisfies the requirements of section 2711 of the PHS Act; and

(3) The plan and issuer of such plan meets QHP certification standards, including §155.1020(c), except for any certification requirement that cannot be met because the plan covers only the benefits described in paragraph (a)(2) of this section.

(b) *Offering options.* The Exchange may allow the dental plan to be offered—

(1) As a stand-alone dental plan; or

(2) In conjunction with a QHP.

(c) *Sufficient capacity.* An Exchange must consider the collective capacity of stand-alone dental plans during certification to ensure sufficient access to pediatric dental coverage.

(d) *QHP Certification standards.* If a plan described in paragraph (a) of this section is offered through an Exchange, another health plan offered through such Exchange must not fail to be treated as a QHP solely because the plan does not offer coverage of benefits offered through the stand-alone plan that are otherwise required under section 1302(b)(1)(J) of the Affordable Care Act.

§ 155.1075 Recertification of QHPs.

(a) *Recertification process.* Except with respect to multi-State plans and CO–OP QHPs, an Exchange must establish a process for recertification of QHPs that, at a minimum, includes a review

of the general certification criteria as outlined in §155.1000(c). Upon determining the recertification status of a QHP, the Exchange must notify the QHP issuer.

(b) *Timing*. The Exchange must complete the QHP recertification process no later than 2 weeks prior to the beginning of the open enrollment date at §155.410(e)(2) of the applicable calendar year.

[77 FR 18467, Mar. 27, 2012, as amended at 80 FR 10870, Feb. 27, 2015]

§155.1080 Decertification of QHPs.

(a) *Definition*. The following definition applies to this section:

Decertification means the termination by the Exchange of the certification status and offering of a QHP.

(b) *Decertification process*. Except with respect to multi-State plans and CO–OP QHPs, the Exchange must establish a process for the decertification of QHPs, which, at a minimum, meets the requirements in this section.

(c) *Decertification by the Exchange*. The Exchange may at any time decertify a health plan if the Exchange determines that the QHP issuer is no longer in compliance with the general certification criteria as outlined in §155.1000(c).

(d) *Appeal of decertification*. The Exchange must establish a process for the appeal of a decertification of a QHP.

(e) *Notice of decertification*. Upon decertification of a QHP, the Exchange must provide notice of decertification to all affected parties, including:

(1) The QHP issuer;

(2) Exchange enrollees in the QHP who must receive information about a special enrollment period, as described in §155.420;

(3) HHS; and

(4) The State department of insurance.

[77 FR 18467, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§155.1090 Request for reconsideration.

(a) *Request for reconsideration of denial of certification specific to a Federally-facilitated Exchange*—(1) *Request for reconsideration*. The Federally-facilitated Exchanges will permit an issuer that has submitted a complete application to a Federally-facilitated Exchange for certification of a health plan as a QHP and is denied certification to request reconsideration of such action.

(2) *Form and manner of request*. An issuer submitting a request for reconsideration under paragraph (a)(1) of this section must submit a written request for reconsideration to HHS, in the form and manner specified by HHS, within 7 calendar days of the date of the written notice of denial of certification. The issuer must include any and all documentation the issuer wishes to provide in support of its request with its request for reconsideration.

(3) *HHS reconsideration decision*. HHS will provide the issuer with a written notice of the reconsideration decision. The decision will constitute HHS's final determination.

(b) [Reserved]

[81 FR 94180, Dec. 22, 2016]

Subpart L [Reserved]

Subpart M—Oversight and Program Integrity Standards for State Exchanges

SOURCE: 78 FR 65095, Oct. 30, 2013, unless otherwise noted.

§155.1200 General program integrity and oversight requirements.

(a) *General requirement*. A State Exchange must:

(1) Keep an accurate accounting of Exchange receipts and expenditures in accordance with generally accepted accounting principles (GAAP).

(2) Monitor and report to HHS on Exchange related activities.

(3) Collect and report to HHS performance monitoring data.

(b) *Reporting*. The State Exchange must, at least annually, provide to HHS, in a manner specified by HHS and by applicable deadlines specified by HHS, the following data and information:

(1) A financial statement presented in accordance with GAAP,

(2) Information showing compliance with Exchange requirements under this part 155 through submission of annual reports,

(3) Performance monitoring data, and

(4) If the Exchange is collecting premiums under §155.240, a report on instances in which it did not reduce an enrollee's premium by the amount of the advance payment of the premium tax credit in accordance with §155.340(g)(1) and (2).

(c) *External audits.* The State Exchange must engage an independent qualified auditing entity which follows generally accepted government auditing standards (GAGAS) to perform an annual independent external financial and programmatic audit and must make such information available to HHS for review. The State Exchange must:

(1) Provide to HHS the results of the annual external audit; and

(2) Inform HHS of any material weakness or significant deficiency identified in the audit and must develop and inform HHS of a corrective action plan for such material weakness or significant deficiency;

(3) Make public a summary of the results of the external audit.

(d) *External audit standard.* The State Exchange must ensure that independent audits of State Exchange financial statements and program activities in paragraph (c) of this section address:

(1) Compliance with paragraph (a)(1) of this section;

(2) Compliance with subparts D and E of this part 155, or other requirements under this part 155 as specified by HHS;

(3) Processes and procedures designed to prevent improper eligibility determinations and enrollment transactions, as applicable;

(4) Compliance with eligibility and enrollment standards through sampling, testing, or other equivalent auditing procedures that demonstrate the accuracy of eligibility determinations and enrollment transactions; and

(5) Identification of errors that have resulted in incorrect eligibility determinations, as applicable.

[78 FR 65095, Oct. 30, 2013, as amended at 84 FR 71710, Dec. 27, 2019]

§155.1210 Maintenance of records.

(a) *General.* The State Exchange must maintain and must ensure its contractors, subcontractors, and agents maintain for 10 years, documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, which are sufficient to do the following:

(1) Accommodate periodic auditing of the State Exchange's financial records; and

(2) Enable HHS or its designee(s) to inspect facilities, or otherwise evaluate the State- Exchange's compliance with Federal standards.

(b) *Records.* The State Exchange and its contractors, subcontractors, and agents must ensure that the records specified in paragraph (a) of this section include, at a minimum, the following:

(1) Information concerning management and operation of the State Exchange's financial and other record keeping systems;

(2) Financial statements, including cash flow statements, and accounts receivable and matters pertaining to the costs of operations;

(3) Any financial reports filed with other Federal programs or State authorities;

(4) Data and records relating to the State Exchange's eligibility verifications and determinations, enrollment transactions, appeals, and plan variation certifications; and

(5) Qualified health plan contracting (including benefit review) data and consumer outreach and Navigator grant oversight information.

(c) *Availability.* A State Exchange must make all records and must ensure its contractors, subcontractors, and agents must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

Subpart N—State Flexibility

§155.1300 Basis and purpose.

(a) *Statutory basis.* This subpart implements provisions of section 1332 of the Affordable Care Act, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose.* This subpart sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1302 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws.* A State may submit a single application to the Secretary for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for demonstrations under section 1115 of the Act, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary. Any application submitted to the Secretary that requests to waive sections 36B, 4980H, or 5000A of the Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary to the Secretary of the Treasury to be reviewed in accordance with 31 CFR part 33.

§ 155.1304 Definitions.

For the purposes of this subpart:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of the Treasury, as applicable, have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 155.1308(f).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 155.1312.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1308 Application procedures.

(a) *Acceptable formats for applications.* Applications for initial approval of a section 1332 waiver shall be submitted in electronic format to the Secretary.

(b) *Application timing.* Applications for initial approval of a section 1332 waiver must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.

(c) *Preliminary review.* Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of the Treasury, as applicable, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of the Treasury, as applicable, have made the preliminary determination that the application is complete.

(1) The Secretary and the Secretary of the Treasury, as applicable, will complete the preliminary review of the application within 45 days after it is submitted.

(2) If the Secretary and the Secretary of the Treasury, as applicable, determine that the application is not complete, the Secretary will send the State

a written notice of the elements missing from the application.

(3) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(d) *Notification of preliminary determination.* Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary will send the State a written notice informing the State that the Secretary and the Secretary of the Treasury, as applicable, have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(e) *Public notice of completed application.* Upon receipt of a complete application for an initial section 1332 waiver, the Secretary will—

(1) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(2) Indicate the status of the application.

(f) *Criteria for a complete application.* An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(1) Complies with paragraphs (a) through (f) of this section.

(2) Provides written evidence of the State's compliance with the public notice requirements set forth in §155.1312, including a description of the key issues raised during the State public notice and comment period.

(3) Provides all of the following:

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332 of PPACA. In analyzing whether the State has satisfied the requirement under section 1332(b)(2)(A) of PPACA that the State enact a law authorizing a waiver under section 1332 of PPACA, the Secretary and the Secretary of the Treasury, as applicable, may consider existing State legislation combined with duly-enacted State regulation or an executive order so long as the State legislation provides statutory authority to enforce PPACA provisions or the State plan;

(ii) A copy of the enacted State legislation that provides the State with authority to implement the proposed waiver, as required under section 1332(a)(1)(C) of the Affordable Care Act;

(iii) A list of the provisions of law that the State seeks to waive including a description of the reason for the specific requests; and

(iv) The analyses, actuarial certifications, data, assumptions, targets, and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver satisfies the general requirements for approval under section 1332(b)(1) of the Affordable Care Act consistent with the provisions of this paragraph;

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive. To satisfy the comprehensive coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as comprehensive overall for residents of the State as coverage absent the waiver;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide. To satisfy the affordability requirement,

the Secretary and the Secretary of the Treasury, as applicable, must determine that the coverage under the State plan is forecasted to be at least as affordable overall for State residents as coverage absent the waiver;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide. To satisfy the scope of coverage requirement, the Secretary and the Secretary of the Treasury, as applicable, must determine that the State plan will provide coverage to a comparable number of State residents under the waiver as would have coverage absent the waiver; and

(D) As prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), will not increase the Federal deficit.

(4) Contains the following supporting information:

(i) *Actuarial analyses and actuarial certifications.* Actuarial analyses and actuarial certifications to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, and the scope of coverage requirement;

(ii) *Economic analyses.* Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(B) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(iii) *Data and assumptions.* The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(B) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(iv) *Implementation timeline.* A detailed draft timeline for the State's implementation of the proposed waiver.

(v) *Additional information.* Additional information supporting the State's proposed waiver, including:

(A) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(B) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(C) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(D) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(E) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(vi) *Reporting targets.* Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement.

(vii) *Other information.* Other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(g) *Additional supporting information.* (1) During the Federal review process, the Secretary may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in §155.1316(b).

[77 FR 11718, Feb. 27, 2012, as amended at 86 FR 6177, Jan. 19, 2021; 86 FR 53504, Sept. 27, 2021]

§155.1312 State public notice requirements.

(a) *General.* (1) Prior to submitting an application for a new section 1332 waiver to the Secretary for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period.* The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings.* (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(3) Such public hearings shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

(d) *Submission of initial application.* After the State public notice and comment period has concluded, the State may submit an application to the Secretary for an initial waiver in accordance with the requirements set forth in §155.1308.

[77 FR 11718, Feb. 27, 2012, as amended at 89 FR 26424, Apr. 15, 2024]

§155.1316 Federal public notice and approval process.

(a) *General.* The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of the Treasury, as applicable, determine that all elements for a complete application were documented and submitted to the Secretary.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of the Treasury, as applicable, will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or

unnecessarily burdensome with respect to State compliance.

(2) At the beginning of the Federal notice and comment period, the Secretary will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application*. The final decision of the Secretary and the Secretary of the Treasury, as applicable, on a State application for a section 1332 waiver will be issued by the Secretary no later than 180 days after the determination by the Secretary and the Secretary of the Treasury, as applicable, that a complete application was received in accordance with § 155.1308.

§ 155.1318 Modification from the normal public notice requirements during an emergent situation.

(a) The Secretary and the Secretary of the Treasury may modify, in part, the State public notice requirements under § 155.1312(a)(1), (b), (c), and (d) and the Federal public notice procedures under § 155.1316(b) to expedite a decision on a proposed section 1332 waiver request during an emergent situation, when a delay would undermine or compromise the purpose of the proposed waiver request and be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(b) A State must meet all of the following criteria to request a modification under paragraph (a) of this section:

(1) The State must request a modification under paragraph (a) of this section, in the form and manner specified by the Secretaries.

(2) The State must have acted in good faith, and in a diligent, timely, and prudent manner in the preparation of the request for a modification under paragraph (a) of this section, and the waiver application request, as applicable.

(3) The State must, as applicable, detail in its request for a modification from State-level notice procedures under paragraph (a) of this section the justification for the request as it relates to the emergent situation and the alternative public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

(4) The State must, as applicable, detail in its request for a modification from Federal-level notice procedures under paragraph (a) of this section the justification for the request and the alternative public notice procedures it requests to be implemented at the Federal level.

(5) The State must explain in its request for a modification from State-level notice procedures under paragraph (a) of this section how the emergent circumstances underlying its request result from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life could not reasonably have been foreseen and how a delay would undermine or compromise the purpose of the waiver and be contrary to the interests of consumers.

(c) The Secretary and the Secretary of the Treasury will evaluate a State's request for a modification under paragraph (a) of this section and issue their

modification determination within approximately 15 calendar days after the request is received.

(d) The Secretary will publish on the CMS website any modification determinations within 15 calendar days of the Secretary and the Secretary of the Treasury making such a determination, as well as the approved revised timeline for public comment under the approved alternative State or Federal public notice procedures, as applicable.

(e) The State must publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as the approved revised timeline for public comment under the alternative State or Federal public notice procedures, as applicable.

(f) The State must, as applicable, implement the alternative public notice procedures at the State level if the State's modification request is approved and, if required, amend the waiver application request.

(g) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess ''reasonable foreseeability'' based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

[85 FR 71202, Nov. 6, 2020, as amended at 86 FR 53504, Sept. 27, 2021]

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws and regulations, unless expressly waived. A State must, within the timeframes specified in law and regulation come into compliance with any changes in Federal law and regulation affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) The Secretary and the Secretary of the Treasury will examine compliance with Federal and regulatory requirements consistent with §155.1308(f)(3)(iv) when conducting implementation reviews under paragraph (b) of this section.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of the Treasury, as applicable, will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of the Treasury, as applicable, will promptly share with a State any complaint that the Secretary and the Secretary of the Treasury has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within at least 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in §155.1324(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in §155.1324(b) that is associated with the year in which the forum was held. The public forum shall be conducted in an in-person, virtual (that is, one that uses telephonic, digital, and/or web-based platforms), or hybrid (that is, one that provides for both in-person and virtual attendance) format.

(1) *Notification requirements for public forum.* The State must publish the date, time, and location of the public forum in a prominent location on the State's public web site, at least 30 days prior to the date of the planned public forum.

(2) *Modification from the normal post award requirements during an emergent situation.* (i) The Secretary and the Secretary of the Treasury may modify,

in part, State post award requirements under this paragraph (c)(2) for an approved section 1332 waiver request during an emergent situation when the application of the post award public notice requirements would be contrary to the interests of consumers. These flexibilities are limited to emergent situations, including natural disasters; public health emergencies; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life.

(ii) A State must meet all of the following criteria to request a modification under paragraph (c) of this section:

(A) The State must request a modification under paragraph (c)(2) of this section, in the form and manner specified by the Secretaries.

(B) The State must have acted in good faith, and in a diligent, timely, and prudent manner to comply with the monitoring and compliance requirement under the waiver and the terms and conditions of the agreement between the Secretary and the Secretary of the Treasury, as applicable, and the State to implement a section 1332 waiver and to submit and prepare the request for a modification under paragraph (c)(2) of this section.

(C) The State must detail in its request for a modification under paragraph (c)(2) of this section the alternative post award public notice procedures it proposes to implement at the State level, including public hearings, that are designed to provide the greatest opportunity and level of meaningful public input from impacted stakeholders that is practicable given the emergency circumstances underlying the State's request for a modification.

(D) The Secretary and the Secretary of the Treasury will evaluate a State's request for a modification under paragraph (c)(2) of this section and issue their modification determination within approximately 15 calendar days after the request is received.

(E) The State must publish on its website any modification requests and determinations within 15 calendar days of receipt of the determination, as well as information on the approved revised timeline for the State's post award public notice procedures, as applicable.

(F) The State must explain in its request for a modification under paragraph (c)(2) of this section how the emergent circumstances underlying its request results from a natural disaster; public health emergency; or other emergent situations that threaten consumers' access to comprehensive coverage, consumers' access to health care, or human life and could not reasonably have been foreseen and how the application of the post award public notice requirements would be contrary to the interests of consumers.

(iii) The Secretary and the Secretary of the Treasury will consider circumstances to be emergent when they could not have been reasonably foreseen. The Secretary and the Secretary of the Treasury will assess ''reasonable foreseeability'' based on the specific issues that a section 1332 waiver proposes to address and other relevant factors, and will not make this assessment based solely on the number of days a State may have been aware of such issues.

(d) *Terminations and suspensions.* The Secretary and the Secretary of the Treasury, as applicable, reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretary or the Secretary of the Treasury, as applicable, determines that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of the Treasury, as applicable, or an independent evaluator selected by the Secretary or the

Secretary of the Treasury, as applicable, to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of the Treasury, as applicable, or the independent evaluator.

[77 FR 11718, Feb. 27, 2012, as amended at 85 FR 71203, Nov. 6, 2020; 86 FR 6178, Jan. 19, 2021; 86 FR 53505, Sept. 27, 2021; 89 FR 26424, Apr. 15, 2024]

§ 155.1322 Pass-through funding for approved waivers.

(a) *Pass-through funding.* With respect to a State's approved section 1332 waiver, under which, due to the structure of the approved State waiver plan, individuals and small employers in the State would not qualify for or would qualify for a reduced amount of premium tax credit under section 36B of the Internal Revenue Code, small business tax credit under section 45R of the Internal Revenue Code, or cost-sharing reductions under ACA part I of subtitle E for which they would otherwise be eligible, the Secretary and the Secretary of the Treasury shall provide for an alternative means by which the aggregate amount of such credits or reductions that would have been paid on behalf of participants in the Exchanges had the State not received such waiver shall be paid to the State for purposes of implementing the approved State waiver plan. Such amount shall be determined annually by the Secretary and the Secretary of the Treasury, taking into consideration the experience of other States with respect to participation in an Exchange and credits and reductions provided under such provisions to residents of the other States. This amount can be updated to reflect applicable changes in Federal or State law.

(b) [Reserved]

[86 FR 53505, Sept. 27, 2021]

§ 155.1324 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with §155.1320(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent with the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary, a State must submit to the Secretary the final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public web site within 30 days of submission to and approval by the Secretary, respectively.

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with §155.1308(f)(3)(iv) and any terms and conditions governing the section 1332 waiver.

(b) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with §155.1324 that relate to the period of time covered by the evaluation.

[77 FR 11718, Feb. 27, 2012, as amended at 86 FR 53505, Sept. 27, 2021]

§ 155.1330 Waiver amendment.

(a) *Amendment to an approved section 1332 waiver.* A State may request an

amendment to an approved section 1332 waiver from the Secretary and the Secretary of the Treasury. A section 1332 waiver amendment is considered a change to a section 1332 waiver plan that is not otherwise allowable under the terms and conditions of an approved waiver, a change that could impact any of the section 1332 statutory guardrails or a change to the program design for an approved waiver. A State is not authorized to implement any aspect of the proposed amendment without prior approval by the Secretary and the Secretary of the Treasury.

(b) [Reserved]

[86 FR 53505, Sept. 27, 2021]

§ 155.1332 Waiver extension.

(a) *Extension.* A State may request continuation of an approved section 1332 waiver, and such request shall be deemed granted unless the Secretary and the Secretary of the Treasury, within 90 days after the date of submission of a complete waiver extension request to the Secretary and the Secretary of the Treasury, either denies such request in writing or informs the State in writing with respect to any additional information that is needed in order to make a final determination with respect to the request.

(b) [Reserved]

[86 FR 53505, Sept. 27, 2021]

Subpart O—Quality Reporting Standards for Exchanges

SOURCE: 79 FR 30350, May 27, 2014, unless otherwise noted.

§ 155.1400 Quality rating system.

The Exchange must prominently display quality rating information for each QHP on its website, in accordance with §155.205(b)(1)(v), in a form and manner specified by HHS.

[85 FR 29261, May 14, 2020]

§ 155.1405 Enrollee satisfaction survey system.

The Exchange must prominently display results from the Enrollee Satisfaction Survey for each QHP on its website, in accordance with §155.205(b)(1)(iv), in a form and manner specified by HHS.

[85 FR 29261, May 14, 2020]

Subpart P—Improper Payment Pre-Testing and Assessment (IPPTA) for State-based Exchanges

SOURCE: 88 FR 25920, Apr. 27, 2023, unless otherwise noted.

§ 155.1500 Purpose and scope.

(a) This subpart sets forth the requirements of the IPPTA. The IPPTA is an initiative between HHS and the State-based Exchanges. These requirements are intended to:

(1) Prepare State-based Exchanges for the planned measurement of improper payments.

(2) Test processes and procedures that support HHS's review of determinations of advance payments of the premium tax credit (APTC) made by State-based Exchanges.

(3) Provide a mechanism for HHS and State-based Exchanges to share information that will aid in developing an efficient measurement process.

(b) [Reserved]

§ 155.1505 Definitions.

As used in this subpart–

Business rules means the State-based Exchange's internal directives defining, guiding, or constraining the State-based Exchange's actions when making eligibility determinations and related APTC calculations.

Entity relationship diagram means a graphical representation illustrating the organization and relationship of the data elements that are pertinent to applications for QHP and associated APTC payments.

Pre-testing and assessment means the process that uses the procedures specified in §155.1515 to prepare State-based Exchanges for the planned measurement of improper payments of APTC.

Pre-testing and assessment checklist means the document that contains criteria that HHS will use to review a State-based Exchange's ability to accomplish the requirements of the IPPTA.

Pre-testing and assessment data request form means the document that specifies the structure for the data elements that HHS will require each State-based Exchange to submit.

Pre-testing and assessment period means the two calendar year timespan during which HHS will engage in pre-testing and assessment procedures with a State-based Exchange.

Pre-testing and assessment plan means the template developed by HHS in collaboration with each State-based Exchange enumerating the procedures, sequence, and schedule to accomplish pre-testing and assessment.

Pre-testing and assessment report means the summary report provided by HHS to each State-based Exchange at the end of the State-based Exchange's pre-testing and assessment period that will include, but not be limited to, the State-based Exchange's status regarding completion of each of the pre-testing and assessment procedures specified in §155.1515, as well as observations and recommendations that result from processing and reviewing the data submitted by the State-based Exchange to HHS.

§155.1510 Data submission.

(a) *Requirements*. For purposes of the IPPTA, a State-based Exchange must submit the following information in a form and manner specified by HHS:

(1) *Data documentation*. The State-based Exchange must provide to HHS the following data documentation:

(i) The State-based Exchange's data dictionary including attribute name, data type, allowable values, and description;

(ii) An entity relationship diagram, which shall include the structure of the data tables and the residing data elements that identify the relationships between the data tables; and

(iii) Business rules and related calculations.

(2) *Data for processing and testing*. The State-based Exchange must use the pre-testing and assessment data request form, or other method as specified by HHS, to submit to HHS the application data associated with no fewer than 10 tax household identification numbers and the associated policy identification numbers that address scenarios specified by HHS to allow HHS to test all of the pre-testing and assessment processes and procedures.

(b) *Timing*. The State-based Exchange must submit the information specified in paragraph (a) of this section within the timelines in the pre-testing and assessment plan specified in §155.1515.

§155.1515 Pre-testing and assessment procedures.

(a) *General requirement*. The State-based Exchanges are required to participate in the IPPTA for a period of two calendar years. The State-based Exchange and HHS will execute the pre-testing and assessment procedures in this section within the timelines in the pre-testing and assessment plan.

(b) *Orientation and planning processes*. (1) As a part of the orientation process, HHS will provide State-based Exchanges with an overview of the pre-testing and assessment procedures and identify documentation that a State-based Exchange must provide to HHS for pre-testing and assessment.

(2) As a part of the planning process, HHS, in collaboration with each State-based Exchange, will develop a pre-testing and assessment plan that takes into consideration relevant activities, if any, that were completed during a prior, voluntary State engagement. The pre-testing and assessment plan will include the pre-testing and assessment checklist.

(3) At the conclusion of the pre-testing and assessment planning process, HHS will issue the pre-testing and assessment plan specific to that State-based Exchange. The pre-testing and assessment plan will be for HHS and State-based Exchange internal use only and will not be made available to the public by HHS unless otherwise required by law.

(c) *Notifications and updates*—(1) *Notifications*. As needed throughout the pre-testing and assessment period, HHS will issue notifications to State-based Exchanges concerning information related to the pre-testing and assessment processes and procedures.

(2) *Updates regarding changes*. Throughout the pre-testing and assessment period, the State-based Exchange

must provide HHS with information regarding any operational, policy, business rules, information technology, or other changes that may impact the ability of the State-based Exchange to satisfy the requirements of the pre-testing and assessment.

(d) *Submission of required data and data documentation.* As specified in §155.1510, HHS will inform State-based Exchanges about the form and manner for State-based Exchanges to submit required data and data documentation to HHS in accordance with the pre-testing and assessment plan.

(e) *Data processing.* (1) HHS will coordinate with each State-based Exchange to track and manage the data and data documentation submitted by a State-based Exchange as specified in §155.1510(a)(1) and (2).

(2) HHS will coordinate with each State-based Exchange to provide assistance in aligning the data specified in §155.1510(a)(2) from the State-based Exchange's existing data structure to the standardized set of data elements.

(3) HHS will coordinate with each State-based Exchange to interpret and validate the data specified in §155.1510(a)(2).

(4) HHS will use the data and data documentation submitted by the State-based Exchange to execute the pre-testing and assessment procedures.

(f) *Pre-testing and assessment checklist.* HHS will issue the pre-testing and assessment checklist as part of the pre-testing and assessment plan. The pre-testing and assessment checklist criteria will include but are not limited to:

(1) A State-based Exchange's submission of the data documentation as specified in §155.1510(a)(1).

(2) A State-based Exchange's submission of the data for processing and testing as specified in §155.1510(a)(2); and

(3) A State-based Exchange's completion of the pre-testing and assessment processes and procedures related to the IPPTA program.

(g) *Pre-testing and assessment report.* Subsequent to the completion of a State-based Exchange's pre-testing and assessment period, HHS will issue a pre-testing and assessment report specific to that State-based Exchange. The pre-testing and assessment report will be for HHS and State-based Exchange internal use only and will not be made available to the public by HHS unless otherwise required by law.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

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156.1255 Renewal and re-enrollment notices.
156.1256 Other notices.

AUTHORITY: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

SOURCE: 76 FR 77411, Dec. 13, 2011, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 77 FR 18468, Mar. 27, 2012, unless otherwise noted.

§ 156.10 Basis and scope.

(a) *Basis.* (1) This part is based on the following sections of title I of the Affordable Care Act:

(i) 1301. QHP defined.

(ii) 1302. Essential health benefits requirements.

(iii) 1303. Special rules.

(iv) 1304. Related definitions.

(v) 1311. Affordable choices of health benefit plans.

(vi) 1312. Consumer choice.

(vii) 1313. Financial integrity.

(viii) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(ix) 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

(x) 1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.

(xi) 1334. Multi-State plans.

(xii) 1402. Reduced cost-sharing for individuals enrolling in QHPs.

(xiii) 1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.

(xiv) 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

(xv) 1413. Streamlining of procedures for enrollment through an Exchange and State, Medicaid, CHIP, and health subsidy programs.

(2) This part is based on section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title I of the Act:

(b) *Scope.* This part establishes standards for QHPs under Exchanges, and addresses other health insurance issuer requirements.

§ 156.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial value (AV) means the percentage paid by a health plan of the

percentage of the total allowed costs of benefits.

Applicant has the meaning given to the term in §155.20 of this subchapter.

Base-benchmark plan means the plan that is selected by a State from the options described in §156.100(a) of this subchapter, or a default benchmark plan, as described in §156.100(c) of this subchapter, prior to any adjustments made pursuant to the benchmark standards described in §156.110 of this subchapter.

Benefit design standards means coverage that provides for all of the following:

(1) The essential health benefits as described in section 1302(b) of the Affordable Care Act;

(2) Cost-sharing limits as described in section 1302(c) of the Affordable Care Act; and

(3) A bronze, silver, gold, or platinum level of coverage as described in section 1302(d) of the Affordable Care Act, or is a catastrophic plan as described in section 1302(e) of the Affordable Care Act.

Benefit year has the meaning given to the term in §155.20 of this subtitle.

Cost-sharing has the meaning given to the term in §155.20 of this subtitle.

Cost-sharing reductions has the meaning given to the term in §155.20 of this subtitle.

Delegated entity means any party, including an agent or broker, that enters into an agreement with a QHP issuer to provide administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

Downstream entity means any party, including an agent or broker, that enters into an agreement with a delegated entity or with another downstream entity for purposes of providing administrative or health care services related to the agreement between the delegated entity and the QHP issuer. The term ''downstream entity'' is intended to reach the entity that directly provides administrative services or health care services to qualified individuals, qualified employers, or qualified employees and their dependents.

EHB-benchmark plan means the standardized set of essential health benefits that must be met by a QHP, as defined in §155.20 of this section, or other issuer as required by §147.150 of this subchapter.

Enrollee satisfaction survey vendor means an organization that has relevant survey administration experience (for example, CAHPS® surveys), organizational survey capacity, and quality control procedures for survey administration.

Essential health benefits package or EHB package means the scope of covered benefits and associated limits of a health plan offered by an issuer that provides at least the ten statutory categories of benefits, as described in §156.110(a) of this subchapter; provides the benefits in the manner described in §156.115 of this subchapter; limits cost sharing for such coverage as described in §156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in §156.140 of this subchapter.

Federally-facilitated SHOP has the meaning given to the term in §155.20 of this subchapter.

Group health plan has the meaning given to the term in §144.103 of this subtitle.

Health insurance coverage has the meaning given to the term in §144.103 of this subtitle.

Health insurance issuer or issuer has the meaning given to the term in §144.103 of this subtitle.

Issuer group means all entities treated under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark.

Level of coverage means one of four standardized actuarial values as defined by section 1302(d)(1) of the Affordable Care Act of plan coverage.

Percentage of the total allowed costs of benefits means the anticipated covered medical spending for EHB coverage (as defined in §156.110(a) of this subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing,

divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

Plan has the meaning given the term in § 144.103 of this subchapter.

Plan year has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

Registered user of the enrollee satisfaction survey data warehouse means enrollee satisfaction survey vendors, QHP issuers, and Exchanges authorized to access CMS's secure data warehouse to submit survey data and to preview survey results prior to public reporting.

[77 FR 18468, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012; 78 FR 12865, Feb. 25, 2013; 78 FR 15535, Mar. 11, 2013; 78 FR 54142, Aug. 30, 2013; 78 FR 65096, Oct. 30, 2013; 80 FR 10871, Feb. 27, 2015; 84 FR 17567, Apr. 25, 2019; 85 FR 29261, May 14, 2020]

§ 156.50 Financial support.

(a) *Definitions.* The following definitions apply for the purposes of this section:

Participating issuer means any issuer offering a plan that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in § 155.1000(a) of this subchapter), issuers of stand-alone dental plans (as described in § 155.1065 of this subtitle), or other issuers identified by an Exchange.

(b) *Requirement for State-based Exchange user fees.* A participating issuer must remit user fee payments, or any other payments, charges, or fees, if assessed by a State-based Exchange under § 155.160 of this subchapter.

(c) *Requirement for Exchange user fees.* (1) To support the functions of Federally-facilitated Exchanges, a participating issuer offering a plan through a Federally-facilitated Exchange must remit a user fee to HHS each month, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for Federally-facilitated Exchanges for the applicable benefit year and the monthly premium charged by the issuer for each policy under the plan where enrollment is through a Federally-facilitated Exchange.

(2) To support the functions of State Exchanges on the Federal platform, unless the State Exchange and HHS agree on an alternative mechanism to collect the funds, a participating issuer offering a plan through a State Exchange on the Federal Exchange platform for certain Exchange functions described in § 155.200 of this subchapter, as specified in a Federal platform agreement, must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the sum of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for State Exchanges on the Federal platform for the applicable benefit year, multiplied by the monthly premium charged by the issuer for each policy under the plan where enrollment is through the State-based Exchange on the Federal platform.

(d) *Adjustment of Exchange user fees.* (1) A participating issuer offering a plan through a Federally-facilitated Exchange or State Exchange on the Federal platform may qualify for an adjustment of the Federally-facilitated Exchange user fee specified in paragraph (c)(1) of this section or the State Exchange on the Federal platform user fee specified in paragraph (c)(2) of this section, to the extent that the participating issuer—

(i) Made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815–2713A(b)(2)(ii) or 29 CFR 2590.715–2713A(b)(2)(ii); or

(ii) Seeks an adjustment in the Federally-facilitated Exchange user fee with respect to a third party administrator that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR

2590.715–2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815–2713A(b)(2)(i) or (ii) or 29 CFR 2590.715–2713A(b)(2)(i) or (ii).

(2) For a participating issuer described in paragraph (d)(1) of this section to receive an adjustment of a user fee under this section—

(i) The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided —

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) or with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable; and

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator.

(ii) Each third party administrator that intends to seek an adjustment on behalf of a participating issuer of the Federally-facilitated Exchange user fee or the State-based Exchange on the Federal platform user fee based on payments for contraceptive services, must submit to HHS a notification of such intent, in a manner specified by HHS, by the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) Each third party administrator identified in paragraph (d)(2)(i)(A) of this section must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided—

(A) Identifying information for the third party administrator and the participating issuer;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section, as applicable;

(C) The total number of participants and beneficiaries in each such self-insured group health plan during the applicable calendar year;

(D) For each such self-insured group health plan with respect to which the third party administrator made payments pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the

amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator; and

(E) An attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(3) If the requirements set forth in paragraph (d)(2) of this section are met, the participating issuer will be provided a reduction in its obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third-party administrators, as described in paragraph (d)(2)(iii)(D) of this section; and

(ii) An allowance for administrative costs and margin. The allowance will be no less than 10 percent of the total dollar amount of the payments for contraceptive services specified in paragraph (d)(3)(i) of this section. HHS will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

(4) If the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer's obligation to pay the user fee specified in paragraph (c)(1) or (2) of this section, as applicable, in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment of a user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount that is no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer that receives an adjustment in the user fee specified in paragraph (c)(1) or (2) of this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator of a plan with respect to which an adjustment of the user fee specified in paragraph (c)(1) or (2) of this section is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) A copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) for each self-insured plan with respect to which an adjustment is received.

(ii) Documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(iii) Documentation supporting the total dollar amount of the payments for contraceptive services submitted by

the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section.

[77 FR 18468, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 78 FR 39897, July 2, 2013; 81 FR 12348, Mar. 8, 2016; 83 FR 62498, Dec. 4, 2018; 86 FR 24290, May 5, 2021; 87 FR 27389, May 6, 2022]

§ 156.80 Single risk pool.

(a) *Individual market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the individual market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(b) *Small group market.* A health insurance issuer must consider the claims experience of all enrollees in all health plans (other than grandfathered health plans) subject to section 2701 of the Public Health Service Act and offered by such issuer in the small group market in a state, including those enrollees who do not enroll in such plans through the Exchange, to be members of a single risk pool.

(c) *Merger of the individual and small group markets.* A state may require the individual and small group insurance markets within a state to be merged into a single risk pool if the state determines appropriate. A state that requires such merger must submit to CMS information on its election in accordance with the procedures described in §147.103 of this subchapter.

(d) *Index rate*—(1) *In general.* A health insurance issuer must establish an index rate that is effective January 1 of each calendar year for a State market described in paragraphs (a) through (c) of this section.

(i) The index rate must be based on the total combined claims costs for providing essential health benefits within the single risk pool of that State market.

(ii) The index rate must be adjusted on a market-wide basis for the State based on the total expected market-wide payments and charges under the risk adjustment program and Exchange user fees (expected to be remitted under §156.50(b) or (c) and (d) as applicable, plus the dollar amount under §156.50(d)(3)(i) and (ii) expected to be credited against user fees payable for that State market).

(iii) The premium rate for all of the health insurance issuer's plans in the relevant State market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

(2) *Permitted plan-level adjustments to the index rate.* For plan years or policy years beginning on or after January 1, 2014, a health insurance issuer may vary premium rates for a particular plan from its market-wide index rate for a relevant state market based only on the following actuarially justified plan-specific factors:

(i) The actuarial value and cost-sharing design of the plan.

(ii) The plan's provider network, delivery system characteristics, and utilization management practices.

(iii) The benefits provided under the plan that are in addition to the essential health benefits. These additional benefits must be pooled with similar benefits within the single risk pool and the claims experience from those benefits must be utilized to determine rate variations for plans that offer those benefits in addition to essential health benefits.

(iv) Administrative costs, excluding Exchange user fees.

(v) With respect to catastrophic plans, the expected impact of the specific eligibility categories for those plans.

(3) *Calibration.* The issuer must calibrate the plan-adjusted index rate for its plans within the single risk pool to correspond to an age rating factor of 1.0, a geographic rating factor of 1.0, and a tobacco use rating factor of 1.0, in a manner specified by the Secretary in guidance, to ensure that any rating variation under §147.102 of this subchapter may be accurately applied with respect to a particular plan or coverage. The calibration must be applied uniformly to all plans within the single risk pool of the State market and cannot vary by plan.

(4) *Frequency of index rate and plan-level adjustments.* (i) A health insurance

issuer may not establish an index rate and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, make the plan-level adjustments pursuant to paragraph (d)(2) of this section, or calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) of this section more or less frequently than annually, except as provided in paragraph (d)(4)(ii) of this section.

(ii) A health insurance issuer in the small group market (not including a merged market) may establish index rates and make the marketwide adjustments under paragraph (d)(1) of this section, make the plan-level adjustments under paragraph (d)(2) of this section, and calibrate the plan-adjusted index rate for its plans pursuant to paragraph (d)(3) of this section, no more frequently than quarterly. Any changes to rates must have effective dates of January 1, April 1, July 1, or October 1. Such rates may only apply to coverage issued or renewed on or after the rate effective date and will apply for the entire plan year of the group health plan.

(e) *Grandfathered health plans in the individual and small group market.* A state law requiring grandfathered health plans described in §147.140 of this subchapter to be included in a single risk pool described in paragraphs (a) through (c) of this section does not apply.

(f) *Applicability date.* The provisions of this section apply for plan years (as that term is defined in §144.103 of this subchapter) in the group market, and for policy years (as that term is defined in §144.103 of this subchapter) in the individual market, beginning on or after January 1, 2014.

[78 FR 13441, Feb. 27, 2013, as amended at 78 FR 39898, July 2, 2013; 78 FR 65096, Oct. 30, 2013; 81 FR 12349, Mar. 8, 2016; 81 FR 94180, Dec. 22, 2016]

Subpart B—Essential Health Benefits Package

SOURCE: 78 FR 12866, Feb. 25, 2013, unless otherwise noted.

§ 156.100 State selection of benchmark plan for plan years beginning prior to January 1, 2020.

For plan years beginning before January 1, 2020, each State may identify a base-benchmark plan according to the selection criteria described below:

(a) *State selection of base-benchmark plan.* The options from which a base-benchmark plan may be selected by the State are the following:

(1) *Small group market health plan.* The largest health plan by enrollment in any of the three largest small group insurance products by enrollment, as defined in §159.110 of this subpart, in the State's small group market as defined in §155.20 of this subchapter.

(2) *State employee health benefit plan.* Any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State involved.

(3) *FEHBP plan.* Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees under 5 USC 8903.

(4) *HMO.* The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

(b) *EHB-benchmark selection standards.* In order to become an EHB-benchmark plan as defined in §156.20 of this subchapter, a state-selected base-benchmark plan must meet the requirements for coverage of benefits and limits described in §156.110 of this subpart; and

(c) *Default base-benchmark plan.* If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market.

(d) *Applicability date:* For plan years beginning on or after January 1, 2020, §156.111 applies in place of this section.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015; 83 FR 17068, Apr. 17, 2018]

§ 156.105 Determination of EHB for multi-state plans.

A multi-state plan must meet benchmark standards set by the U.S. Office of Personnel Management.

§ 156.110 EHB-benchmark plan standards.

An EHB-benchmark plan must meet the following standards:

(a) *EHB coverage.* Provide coverage of at least the following categories of benefits:

(1) Ambulatory patient services.

(2) Emergency services.

(3) Hospitalization.

(4) Maternity and newborn care.

(5) Mental health and substance use disorder services, including behavioral health treatment.

(6) Prescription drugs.

(7) Rehabilitative and habilitative services and devices.

(8) Laboratory services.

(9) Preventive and wellness services and chronic disease management.

(10) Pediatric services, including oral and vision care.

(b) *Coverage in each benefit category.* A base-benchmark plan not providing any coverage in one or more of the categories described in paragraph (a) of this section, must be supplemented as follows:

(1) *General supplementation methodology.* A base-benchmark plan that does not include items or services within one or more of the categories described in paragraph (a) of this section must be supplemented by the addition of the entire category of such benefits offered under any other benchmark plan option described in §156.100(a) of this subpart unless otherwise described in this subsection.

(2) *Supplementing pediatric oral services.* A base-benchmark plan lacking the category of pediatric oral services must be supplemented by the addition of the entire category of pediatric oral benefits from one of the following:

(i) The FEDVIP dental plan with the largest national enrollment that is described in and offered to federal employees under 5 U.S.C. 8952; or

(ii) The benefits available under that State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(3) *Supplementing pediatric vision services.* A base-benchmark plan lacking the category of pediatric vision services must be supplemented by the addition of the entire category of pediatric vision benefits from one of the following:

(i) The FEDVIP vision plan with the largest national enrollment that is offered to federal employees under 5 USC 8982; or

(ii) The benefits available under the State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(c) *Supplementing the default base-benchmark plan.* A default base-benchmark plan as defined in §156.100(c) of this subpart that lacks any categories of essential health benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

(1) The largest plan by enrollment in the second largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(2) The largest plan by enrollment in the third largest product by enrollment in the State's small group market, as defined in §155.20 of this subchapter (except for pediatric oral and vision benefits);

(3) The largest national FEHBP plan by enrollment across States that is offered to federal employees under 5 USC 8903 (except for pediatric oral and vision benefits);

(4) The plan described in paragraph (b)(2)(i) of this section for pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section for pediatric vision care benefits.

(d) *Non-discrimination.* Not include discriminatory benefit designs that contravene the non-discrimination standards defined in §156.125 of this subpart.

(e) *Balance.* Ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category.

(f) *Determining habilitative services.* If the base-benchmark plan does not include coverage for habilitative services, the State may determine which services are included in that category.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015]

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020.

(a)(1) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2020, through December 31, 2025, a State may change its EHB-benchmark plan by:

(i) Selecting the EHB-benchmark plan that another State used for the 2017 plan year under §§ 156.100 and 156.110;

(ii) Replacing one or more categories of EHBs established at § 156.110(a) in the State's EHB-benchmark plan used for the 2017 plan year with the same category or categories of EHB from the EHB-benchmark plan that another State used for the 2017 plan year under §§ 156.100 and 156.110; or

(iii) Otherwise selecting a set of benefits that would become the State's EHB-benchmark plan.

(2) Subject to paragraphs (b) through (e) of this section, for plan years beginning on or after January 1, 2026, a State may change its EHB-benchmark plan by selecting a set of benefits that would become the State's EHB-benchmark plan.

(b) A State's EHB-benchmark plan must:

(1) *EHB coverage.* Provide coverage of items and services for at least the categories of benefits at § 156.110(a), including an appropriate balance of coverage for these categories of benefits.

(2) *Scope of benefits.* (i) For plan years beginning on or after January 1, 2020, through December 31, 2025:

(A) Provide a scope of benefits equal to the scope of benefits provided under a typical employer plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), defined as either:

(*1*) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(*2*) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(*i*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*ii*) The plan provides minimum value, as defined under § 156.145;

(*iii*) The benefits are not excepted benefits, as established under §§ 146.145(b), and 148.220 of this subchapter; and

(*iv*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(B) Not exceed the generosity of the most generous among a set of comparison plans, including:

(*1*) The State's EHB-benchmark plan used for the 2017 plan year, and

(*2*) Any of the State's base-benchmark plan options for the 2017 plan year described in § 156.100(a)(1), supplemented as necessary under § 156.110.

(ii) For plan years beginning on or after January 1, 2026, provide a scope of benefits that is equal to the scope benefits of a typical employer plan in the State. The scope of benefits in a typical employer plan in a State is any scope of benefits that is as or more generous than the scope of benefits in the least generous plan (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), and as or less generous than the scope of benefits in the most generous plan in the State (supplemented by the State as necessary to provide coverage within each EHB category at § 156.110(a)), among the following:

(A) One of the selecting State's 10 base-benchmark plan options established at § 156.100, and available for the selecting State's selection for the 2017 plan year; or

(B) The largest health insurance plan by enrollment within one of the five largest large group health insurance products by enrollment in the State, as product and plan are defined at § 144.103 of this subchapter, provided that:

(*1*) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products in the State;

(*2*) The plan provides minimum value, as defined under §156.145;

(*3*) The benefits are not excepted benefits, as established under §146.145(b), and §148.220 of this subchapter; and

(*4*) The benefits in the plan are from a plan year beginning after December 31, 2013.

(c) The State must provide reasonable public notice and an opportunity for public comment on the State's selection of an EHB-benchmark plan that includes posting a notice on its opportunity for public comment with associated information on a relevant State website.

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan.

(1) If the State does not make a selection by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan, or its benchmark plan selection does not meet the requirements of this section and section 1302 of the ACA, the State's EHB-benchmark plan for the applicable plan year will be that State's EHB-benchmark plan applicable for the prior year.

(2) [Reserved]

(e) A State changing its EHB-benchmark plan under this section must submit documents in a format and manner specified by HHS by the first Wednesday in May of the year that is 2 years before the effective date of the new EHB-benchmark plan. These must include:

(1) A document confirming that the State's EHB-benchmark plan definition complies with the requirements under paragraphs (a), (b) and (c) of this section, including information on which selection option under paragraph (a) of this section the State is using, and whether the State is using another State's EHB-benchmark plan;

(2) An actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms that the State's EHB-benchmark plan complies with the applicable scope of benefits requirements at paragraph (b)(2) of this section.

(3) The State's EHB-benchmark plan document that reflects the benefits and limitations, including medical management requirements, a schedule of benefits and, if the State is changing the number of prescription drugs pursuant to §156.122(a)(1)(ii), a formulary drug list in a format and manner specified by HHS; and

(4) Other documentation specified by HHS, which is necessary to operationalize the State's EHB-benchmark plan.

[83 FR 17068, Apr. 17, 2018, as amended at 85 FR 29261, May 14, 2020; 87 FR 27390, May 6, 2022; 89 FR 26424, Apr. 15, 2024]

§156.115 Provision of EHB.

(a) Provision of EHB means that a health plan provides benefits that—

(1) Are substantially equal to the EHB-benchmark plan including:

(i) Covered benefits;

(ii) Limitations on coverage including coverage of benefit amount, duration, and scope; and

(iii) Prescription drug benefits that meet the requirements of §156.122 of this subpart;

(2) With the exception of the EHB category of coverage for pediatric services, do not exclude an enrollee from coverage in an EHB category.

(3) With respect to the mental health and substance use disorder services, including behavioral health treatment services, required under §156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations.

(4) Include preventive health services described in §147.130 of this subchapter.

(5) With respect to habilitative services and devices—

(i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy,

speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings;

(ii) Do not impose limits on coverage of habilitative services and devices that are less favorable than any such limits imposed on coverage of rehabilitative services and devices; and

(iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.

(6) For plan years beginning on or after January 1, 2016, for pediatric services that are required under §156.110(a)(10), provide coverage for enrollees until at least the end of the month in which the enrollee turns 19 years of age.

(b) An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan under the following conditions—

(1) The issuer substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(4) of this section; and

(ii) Is not a prescription drug benefit.

(2) An issuer may substitute a benefit within the same EHB category, unless prohibited by applicable State requirements. Substitution of benefits between EHB categories is not permitted.

(3) The plan that includes substituted benefits must:

(i) Continue to comply with the requirements of paragraph (a) of this section, including by providing benefits that are substantially equal to the EHB-benchmark plan;

(ii) Provide an appropriate balance among the EHB categories such that benefits are not unduly weighted toward any category; and

(iii) Provide benefits for diverse segments of the population.

(4) The issuer submits to the State evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined without taking cost-sharing into account.

(c) A health plan does not fail to provide EHB solely because it does not offer the services described in §156.280(d) of this subchapter.

(d) For plan years beginning on or before January 1, 2026, an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB. For plan years beginning on or after January 1, 2027, an issuer of a plan offering EHB may not include routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018; 86 FR 53506, Sept. 27, 2021; 87 FR 27390, May 6, 2022; 89 FR 26425, Apr. 15, 2024]

§156.120 Collection of data to define essential health benefits.

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at §144.103 of this subchapter, which may be delivered through the purchase of insurance or otherwise.

Health plan has the meaning given to the term ''Portal Plan'' in §159.110 of this subchapter.

State has the meaning given to that term in §155.20 of this subchapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation.

(b) *Reporting requirement.* A State that selects a base-benchmark plan or an issuer that offers a default base-benchmark plan in accordance with §156.100 must submit to HHS the following information in a form and manner, and by a date, determined by HHS:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Exclusions.

[80 FR 10871, Feb. 27, 2015]

§ 156.122 Prescription drug benefits.

(a) A health plan does not provide essential health benefits unless it:

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan;

(2) Submits its formulary drug list to the Exchange, the State or OPM; and

(3) For plans years beginning on or after January 1, 2017, uses a pharmacy and therapeutics (P&T) committee that meets the following standards.

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(E) For plan years beginning on or after January 1, 2026, include at minimum one patient representative who must:

(*1*) Represent the patient perspective as a member of the P&T committee.

(*2*) Have relevant experience or participation in patient or community-based organizations.

(*3*) Be able to demonstrate the ability to integrate data interpretations with practical patient considerations.

(*4*) Have no fiduciary obligation to a health facility or other health agency and have no material financial interest in the rendering of health services.

(*5*) Have a broad understanding of one or more conditions or diseases, associated treatment options, and research.

(*6*) Disclose financial interests on their conflict-of-interest statements. Disclosed financial interests must include all interests with any entity that would benefit from decisions regarding plan formularies as well as specific information about their financial interests, such as the nature of the relationship and the value of the financial interest.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

(E) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.

(F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.

(G) Review new FDA-approved drugs and new uses for existing drugs.

(H) Ensure the issuer's formulary drug list:

(*1*) Covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and does not discourage enrollment by any group of enrollees; and

(*2*) Provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(b) A health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs approved by the Food and Drug Administration as a service described in § 156.280(d) of this subchapter.

(c) A health plan providing essential health benefits must have the following processes in place that allow an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (a request for exception). In the event that an exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan's annual limitation on cost-sharing under § 156.130 and when calculating the plan's actuarial value under § 156.135.

(1) *Standard exception request.* For plans years beginning on or after January 1, 2016:

(i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request a standard review of a decision that a drug is not covered by the plan.

(ii) A health plan must make its determination on a standard exception and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following receipt of the request.

(iii) A health plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

(2) *Expedited exception request.* (i) A health plan must have a process for an enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request an expedited review based on exigent circumstances.

(ii) Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.

(iii) A health plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 24 hours following receipt of the request.

(iv) A health plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

(3) *External exception request review.* For plans years beginning on or after January 1, 2016:

(i) If the health plan denies a request for a standard exception under paragraph (c)(1) of this section or for an expedited exception under paragraph (c)(2) of this section, the health plan must have a process for the enrollee, the enrollee's designee, or the enrollee's prescribing physician (or other prescriber) to request that the original exception request and subsequent denial of such request be reviewed by an independent review organization.

(ii) A health plan must make its determination on the external exception request and notify the enrollee or the enrollee's designee and the prescribing physician (or other prescriber, as appropriate) of its coverage determination no later than 72 hours following its receipt of the request, if the original request was a standard exception request under paragraph (c)(1) of this section, and no later than 24 hours following its receipt of the request, if the original request was an expedited exception request under paragraph (c)(2) of this section.

(iii) If a health plan grants an external exception review of a standard exception request, the health plan must provide coverage of the non-formulary drug for the duration of the prescription. If a health plan grants an external exception review of an expedited exception request, the health plan must provide coverage of the non-formulary drug for the duration of the exigency.

(4) *Application of coverage appeals laws.* (i) A State may determine that a health plan in the State satisfies the requirements of this paragraph (c) if the health plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the health plan that is compliant with the State's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of this paragraph (c) and include:

(A) An internal review;

(B) An external review;

(C) The ability to expedite the reviews; and

(D) Timeframes that are the same or shorter than the timeframes under paragraphs (c)(1)(ii), (c)(2)(iii), and (c)(3)(ii) of this section.

(ii) [Reserved]

(d)(1) For plan years beginning on or after January 1, 2016, a health plan must publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:

(i) It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and

(ii) If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

(2) A QHP in the Federally-facilitated Exchange must make available the information described in paragraph (d)(1) of this section on its Web site in an HHS-specified format and also submit this information to HHS, in a format and at times determined by HHS.

(e) For plan years beginning on or after January 1, 2017, a health plan providing essential health benefits must have the following access procedures:

(1) A health plan must allow enrollees to access prescription drug benefits at in-network retail pharmacies, unless:

(i) The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or

(ii) The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(2) A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing under §156.130 and must be accounted for in the plan's actuarial value calculated under §156.135.

(f) If a health plan covers prescription drugs in excess of the prescription drugs required to be covered under paragraph (a)(1) of this section, the additional prescription drugs are considered an essential health benefit and subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits, unless coverage of the drug is mandated by State action and is in addition to an essential health benefit pursuant to §155.170, in which case the drug would not be considered an essential health benefit.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10871, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016; 89 FR 26425, Apr. 15, 2024]

§156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Beginning on the earlier of January 1, 2023 (the start of the 2023 plan

year) or upon renewal of any plan subject to this rule, a non-discriminatory benefit design that provides EHB is one that is clinically-based.

(b) An issuer providing EHB must comply with the requirements of §156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

[78 FR 12866, Feb. 25, 2013, as amended at 87 FR 27390, May 6, 2022]

§ 156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.* (1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) [Reserved]

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network is not required to count toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraph (a) of this section that does not result in a multiple of 50 dollars will be rounded down, to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS may publish the annual premium adjustment percentage in guidance in January of the calendar year preceding the benefit year for which the premium adjustment percentage is applicable, unless HHS proposes changes to the methodology, in which case, HHS will publish the annual premium adjustment percentage in an annual HHS notice of benefit and payment parameters or another appropriate rulemaking.

(f) *Coordination with preventive limits.* Nothing in this subpart is in derogation of the requirements of §147.130 of this subchapter.

(g) *Coverage of emergency department services.* Emergency department services must be provided as follows:

(1) Without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services is out of network that is more restrictive than the requirements or limitations that apply to emergency department services received in network; and

(2) If such services are provided out-of-network, cost-sharing must be limited as provided in §147.138(b)(3) of this subchapter.

(h) *Use of direct support offered by drug manufacturers.* Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10872, Feb. 27, 2015; 84 FR 17567, Apr. 25, 2019; 85 FR 29261, May 14, 2020; 86 FR 24291, May 5, 2021]

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraphs (b) and (d) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS for the given benefit year.

(b) *Exception to the use of the AV Calculator.* If a health plan's design is not compatible with the AV Calculator, the issuer must meet the following:

(1) Submit the actuarial certification from an actuary, who is a member of the American Academy of Actuaries, on the chosen methodology identified in paragraphs (b)(2) and (b)(3) of this section:

(2) Calculate the plan's AV by:

(i) Estimating a fit of its plan design into the parameters of the AV Calculator; and

(ii) Having an actuary, who is a member of the American Academy of Actuaries, certify that the plan design was fit appropriately in accordance with generally accepted actuarial principles and methodologies; or

(3) Use the AV Calculator to determine the AV for the plan provisions that fit within the calculator parameters and have an actuary, who is a member of the American Academy of Actuaries calculate and certify, in accordance with generally accepted actuarial principles and methodologies, appropriate adjustments to the AV identified by the calculator, for plan design features that deviate substantially from the parameters of the AV Calculator.

(4) The calculation methods described in paragraphs (b)(2) and (3) of this section may include only in-network cost-sharing, including multi-tier networks.

(c) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For plans other than those in the individual market that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

(d) *Use of state-specific standard population for the calculation of AV.* Beginning in 2015, if submitted by the State and approved by HHS, a state-specific data set will be used as the standard population to calculate AV in accordance with paragraph (a) of this section. The data set may be approved by HHS if it is submitted in accordance with paragraph (e) of this section and:

(1) Supports the calculation of AVs for the full range of health plans available in the market;

(2) Is derived from a non-elderly population and estimates those likely to be covered by private health plans on or after January 1, 2014;

(3) Is large enough that: (i) The demographic and spending patterns are stable over time; and (ii) Includes a substantial majority of the State's insured population, subject to the requirement in paragraph (d)(2) of this section;

(4) Is a statistically reliable and stable basis for area-specific calculations; and (5) Contains claims data on health care services typically offered in the then-current market.

(e) *Submission of state-specific data.* AV will be calculated using the default standard population described in paragraph (f) of this section, unless a data set in a format specified by HHS that can support the use of the AV Calculator as described in paragraph (a) of this section is submitted by a State and approved by HHS consistent with paragraph (d) of this section by a date specified by HHS.

(f) *Default standard population.* The default standard population for AV calculation will be developed and summary statistics, such as in continuance tables, will be provided by HHS in a format that supports the calculation of

AV as described in paragraph (a) of this section.

(g) *Updates to the AV Calculator.* HHS will update the AV Calculator annually for material changes that may include costs, plan designs, the standard population, developments in the function and operation of the AV Calculator and other actuarially relevant factors.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13839, Mar. 11, 2014; 81 FR 12349, Mar. 8, 2016]

§ 156.140 Levels of coverage.

(a) *General requirement for levels of coverage.* AV, calculated as described in § 156.135 of this subpart, and within a de minimis variation as defined in paragraph (c) of this section, determines whether a health plan offers a bronze, silver, gold, or platinum level of coverage.

(b) *The levels of coverage* are:

(1) *A bronze health plan* is a health plan that has an AV of 60 percent.

(2) *A silver health plan* is a health plan that has an AV of 70 percent.

(3) *A gold health plan* is a health plan that has an AV of 80 percent.

(4) *A platinum health plan* is a health plan that has as an AV of 90 percent.

(c) *De minimis variation.* (1) For plan years beginning on or after January 1, 2018 through December 31, 2022, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −4 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −4 percentage points and +5 percentage points.

(2) For plan years beginning on or after January 1, 2023, the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is −2 percentage points and +2 percentage points, except if a health plan under paragraph (b)(1) of this section (a bronze health plan) either covers and pays for at least one major service, other than preventive services, before the deductible or meets the requirements to be a high deductible health plan within the meaning of section 223(c)(2) of the Internal Revenue Code, in which case the allowable variation in AV for such plan is −2 percentage points and +5 percentage points.

[78 FR 12866, Feb. 25, 2013, as amended at 81 FR 94180, Dec. 22, 2016; 82 FR 18382, Apr. 18, 2017; 87 FR 27390, May 6, 2022]

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

(1) The MV Calculator to be made available by HHS and the Internal Revenue Service. The result derived from the calculator may be modified under the rules in paragraph (b) of this section.

(2) Any safe harbor established by HHS and the Internal Revenue Service.

(3) A group health plan may seek certification by an actuary to determine MV if the plan contains non-standard features that are not suitable for either of the methods described in paragraphs (a)(1) or (2) of this section. The determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies.

(4) Any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

(b) *Benefits that may be counted towards the determination of MV.* (1) In the event that a group health plan uses the

MV Calculator and offers an EHB outside of the parameters of the MV Calculator, the plan may seek an actuary, who is a member of the American Academy of Actuaries, to determine the value of that benefit and adjust the result derived from the MV Calculator to reflect that value.

(2) For the purposes of applying the options described in paragraph (a) of this section in determining MV, a group health plan will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

(c) *Standard population.* The standard population for MV determinations described in paragraph (a) of this section is the standard population developed by HHS for such use and described through summary statistics issued by HHS. The standard population for MV must reflect the population covered by self-insured group health plans.

(d) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For employer-sponsored self-insured group health plans and insured group health plans that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10872, Feb. 27, 2015]

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* For a stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter in any Exchange, cost sharing may not exceed $350 for one covered child and $700 for two or more covered children.

(1) For plan years beginning after 2017, for one covered child—the dollar limit applicable to a stand-alone dental plan for one covered child specified in this paragraph (a) increased by the percent increase of the consumer price index for dental services for the year 2 years prior to the applicable plan year over the consumer price index for dental services for 2016.

(2) For plan years after 2017, for two or more covered children—twice the dollar limit for one child described in paragraph (a)(1) of this section.

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135; and

(2) Must have the plan's actuarial value of coverage for pediatric dental essential health benefits certified by a member of the American Academy of Actuaries using generally accepted actuarial principles and reported to the Exchange.

(c) *Consumer price index for dental services defined.* The consumer price index for dental services is a sub-component of the U.S. Department of Labor's Bureau of Labor Statistics Consumer Price Index specific to dental services.

(d) *Increments of cost sharing increases.* Any increase in the annual dollar limits described in paragraph (a)(1) of this section that does not result in a multiple of 25 dollars will be rounded down, to the next lowest multiple of 25 dollars.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13840, Mar. 11, 2014; 81 FR 12349, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018]

§ 156.155 Enrollment in catastrophic plans.

(a) *General rule.* A health plan is a catastrophic plan if it meets the following conditions:

(1) Meets all applicable requirements for health insurance coverage in the individual market (including but not limited to those requirements described in parts 147 and 148 of this subchapter), and is offered only in the individual market.

(2) Does not provide a bronze, silver, gold, or platinum level of coverage described in section 1302(d) of the Affordable Care Act.

(3) Provides coverage of the essential health benefits under section 1302(b) of the Affordable Care Act, except that the plan provides no benefits for any plan year (except as provided in paragraphs (a)(4), (b), and (c) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the Affordable Care Act is reached.

(4) Provides coverage for at least three primary care visits per year before reaching the deductible.

(5) Covers only individuals who meet either of the following conditions:

(i) Have not attained the age of 30 prior to the first day of the plan or policy year.

(ii) Have received a certificate of exemption for the reasons identified in section 1302(e)(2)(B)(i) or (ii) of the Affordable Care Act.

(b) *Coverage of preventive health services.* A catastrophic plan may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) for preventive services, in accordance with section 2713 of the Public Health Service Act.

(c) *Coverage to prevent surprise medical bills.* A catastrophic plan must provide benefits as required under sections 2799A–1 and 2799A–2 of the Public Health Service Act and their implementing regulations in §§149.110, 149.120, and 149.130 or any applicable State law providing similar protections to individuals, and will not violate paragraph (a)(3) of this section solely because of the provision of such benefits before the annual limitation on cost sharing is reached.

(d) *Application for family coverage.* For other than self-only coverage, each individual enrolled must meet the requirements of paragraph (a)(5) of this section.

[78 FR 13442, Feb. 27, 2013, as amended at 78 FR 65096, Oct. 30, 2013; 86 FR 36985, July 13, 2021]

Subpart C—Qualified Health Plan Minimum Certification Standards

SOURCE: 77 FR 18469, Mar. 27, 2012, unless otherwise noted.

§ 156.200 QHP issuer participation standards.

(a) *General requirement.* In order to participate in an Exchange, a health insurance issuer must have in effect a certification issued or recognized by the Exchange to demonstrate that each health plan it offers in the Exchange is a QHP.

(b) *QHP issuer requirement.* A QHP issuer must—

(1) Comply with the requirements of this subpart with respect to each of its QHPs on an ongoing basis;

(2) Comply with Exchange processes, procedures, and requirements set forth in accordance with subpart K of part 155 of this subchapter and, in the small group market, §§155.705 and 155.706 of this subchapter;

(3) Ensure that each QHP complies with benefit design standards, as defined in §156.20, except that individual market silver QHPs must have an AV of 70 percent, with a *de minimis* allowable AV variation of −0 percentage points and +2 percentage points;

(4) Be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage;

(5) Implement and report on a quality improvement strategy or strategies described in section 1311(c)(1)(E) of the Affordable Care Act consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H), (c)(1)(I), and (c)(3) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act

(6) Pay any applicable user fees assessed under §156.50; and

(7) Comply with the standards under 45 CFR part 153.

(c) *Offering requirements.* A QHP issuer must offer through the Exchange:

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in §156.140 throughout each service area in which it offers coverage through the Exchange; and,

(2) A child-only plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, as any QHP offered through the Exchange to individuals who, as of the beginning of the plan year, have not attained the age of 21.

(d) *State requirements.* A QHP issuer certified by an Exchange must adhere to the requirements of this subpart and any provisions imposed by the Exchange, or a State in connection with its Exchange, that are conditions of participation or certification with respect to each of its QHPs.

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

(f) *Broker compensation in a Federally-facilitated Exchange.* A QHP issuer must pay the same broker compensation for QHPs offered through a Federally-facilitated Exchange that the QHP issuer pays for similar health plans offered in the State outside a Federally-facilitated Exchange.

(g) *Certification standard specific to a Federally-facilitated Exchange for plan years beginning before January 1, 2018.* A Federally-facilitated Exchange may certify a QHP in the individual market of a Federally-facilitated Exchange only if the QHP issuer meets one of the conditions below:

(1) The QHP issuer also offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage as described in section 1302(d) of the Affordable Care Act;

(2) The QHP issuer does not offer small group market products in that State, but another issuer in the same issuer group offers through a Federally-facilitated SHOP serving that State at least one small group market QHP at the silver level of coverage and one at the gold level of coverage; or

(3) Neither the issuer nor any other issuer in the same issuer group has a share of the small group market, as determined by HHS, greater than 20 percent, based on the earned premiums submitted by all issuers in the State's small group market, under §158.110 of this subchapter, on the reporting date immediately preceding the due date of the application for QHP certification.

(h) *Operational requirements.* As a condition of certification of a QHP, an issuer must attest that it will comply with all QHP operational requirements described in subparts D, E, H, K, L, and M of this part.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 79 FR 30351, May 27, 2014; 80 FR 10873, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016; 83 FR 17069, Apr. 17, 2018; 85 FR 37248, June 19, 2020; 87 FR 27391, May 6, 2022; 89 FR 37703, May 6, 2024]

§ 156.201 Standardized plan options.

A qualified health plan (QHP) issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform, other than an issuer that is already required to offer standardized plan options under State action taking place on or before January 1, 2020, must:

(a) For the plan year 2023, offer in the individual market at least one standardized QHP option, defined at §155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, at every metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at §156.420(a); and

(b) For plan year 2024 and subsequent plan years, offer in the individual market at least one standardized QHP option, defined at §155.20 of this subchapter, at every product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, at every metal level except the non-expanded bronze metal level, and throughout every service area that it also offers non-standardized QHP options, including, for silver plans, for the income-based cost-sharing reduction plan variations, as provided for at §156.420(a).

[88 FR 25921, Apr. 27, 2023]

§ 156.202 Non-standardized plan option limits.

A QHP issuer in a Federally-facilitated Exchange or a State-based Exchange on the Federal platform:

(a) For plan year 2024, is limited to offering four non-standardized plan options per product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of dental and/or vision benefit coverage (as defined in paragraph (c) of this section), in any service area.

(b) For plan year 2025 and subsequent plan years, is limited to offering two non-standardized plan options per product network type, as the term is described in the definition of ''product'' at §144.103 of this subchapter, metal level (excluding catastrophic plans), and inclusion of dental and/or vision benefit coverage (as defined in paragraph (c) of this section), in any service area.

(c) For purposes of paragraphs (a) and (b) of this section, the inclusion of dental and/or vision benefit coverage is defined as coverage of any or all of the following:

(1) Adult dental benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template:

(i) Routine Dental Services (Adult);

(ii) Basic Dental Care—Adult; or

(iii) Major Dental Care—Adult.

(2) Pediatric dental benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template:

(i) Dental Check-Up for Children;

(ii) Basic Dental Care—Child; or

(iii) Major Dental Care—Child.

(3) Adult vision benefit coverage as defined by the following in the ''Benefits'' column in the Plans and Benefits Template: Routine Eye Exam (Adult).

(d) For plan year 2025 and subsequent years, an issuer may offer additional non-standardized plan options for each product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area if it demonstrates that these additional plans' cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions (including benefits in the form of prescription drugs, if pertaining to the treatment of the condition(s)) is at least 25 percent lower, as applied without restriction in scope throughout the plan year, than the cost sharing for the same corresponding benefits in an issuer's other non-standardized plan option offerings in the same product network type, metal level, and service area.

(1) The 25 percent reduction in cost sharing for benefits pertaining to the treatment of chronic and high-cost conditions will be evaluated at the level of total out-of-pocket costs for the treatment of the chronic and high-cost condition for a population of enrollees with the relevant chronic and high-cost condition.

(2) The reduction in cost sharing must not be limited to a part of the year, or an otherwise limited scope of benefits.

(3) The reduction in cost sharing for these benefits cannot be conditioned on a consumer having a particular diagnosis.

(4) The required reduction in cost sharing only applies to the standard variant of the plan for which an issuer seeks an exception, and not to the income-based cost-sharing reduction plan variations required by §156.420(a), nor to the zero and limited cost-sharing plan variations required by §156.420(b).

(5) Issuers are limited to one exception per product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area, for each chronic and high-cost condition.

(6) Chronic and high-cost conditions that may qualify an issuer for this exception will be determined by HHS.

(e) An issuer that seeks to utilize this exceptions process is required to submit a written justification in a form and manner and at a time prescribed by HHS that:

(1) Identifies the specific chronic and high-cost condition that its additional non-standardized plan option offers substantially reduced cost sharing for, in accordance with the definition of ''cost sharing'' at §156.20;

(2) Identifies which benefits in the Plans and Benefits Template are discounted to provide reduced treatment-specific cost sharing for individuals with the specified chronic and high-

cost condition. These discounts must be relative to the treatment-specific cost sharing for the same corresponding benefits in the issuer's other non-standardized plan offerings in the same product network type, metal level, inclusion of dental and/or vision benefit coverage, and service area. For the purposes of this standard, treatment specific cost sharing consists of the costs for obtaining services that pertain to the treatment of a particular chronic and high-cost condition—but not the costs for obtaining services that do not pertain to the treatment of the relevant condition. The issuer must identify all services for which the benefits substantially reduce cost sharing in the Plans and Benefits Template. These benefits must encompass a complete list of relevant services pertaining to the treatment of the relevant condition;

(3) Explains how the reduced cost sharing for these services pertains to clinically indicated guidelines and a representative treatment scenario for treatment of the specified chronic and high-cost condition (and include any relevant studies, guidelines, or supplementary documents to support the application, as applicable). For the purposes of this standard, a representative treatment scenario is an annual course of treatment for a chronic and high-cost condition; and

(4) Includes a corresponding actuarial memorandum that explains the underlying actuarial assumptions made in the design of the plan the issuer is requesting to except. In this memorandum, an issuer must demonstrate how the benefits that are discounted to provide reduced treatment-specific cost sharing of at least 25 percent identified at §156.202(e)(2) for the treatment of the condition identified at §156.202(e)(1) under the excepted plan compare to the identified in-limit offering in the same product network type, metal level, inclusion of dental and/or vision coverage, and service area. This demonstration must specifically be in reference to the specific population that would be seeking treatment for the relevant condition and not the general population. This memorandum must also include an actuarial opinion confirming that this analysis was prepared in accordance with the appropriate Actuarial Standards of Practice and the profession's Code of Professional Conduct.

[88 FR 25922, Apr. 27, 2023, as amended at 89 FR 26425, Apr. 15, 2024]

§156.210 QHP rate and benefit information.

(a) *General rate requirement.* A QHP issuer must set rates for an entire benefit year, or for the SHOP, plan year.

(b) *Rate and benefit submission.* A QHP issuer must submit rate and benefit information to the Exchange.

(c) *Rate justification.* A QHP issuer must submit to the Exchange a justification for a rate increase prior to the implementation of the increase. A QHP issuer must prominently post the justification on its Web site.

(d) *Rate requirements* for *stand-alone dental plans.* For benefit and plan years beginning on or after January 1, 2024:

(1) *Age on effective date.* The premium rate charged by an issuer of stand-alone dental plans may vary with respect to the particular plan or coverage involved by determining the enrollee's age. Any age calculation for rating and eligibility purposes must be based on the age as of the time of policy issuance or renewal.

(2) *Guaranteed rates.* An issuer of stand-alone dental plans must set guaranteed rates.

[77 FR 18469, Mar. 27, 2012, as amended at 88 FR 25922, Apr. 27, 2023]

§156.215 Advance payments of the premium tax credit and cost-sharing reduction standards.

(a) *Standards relative to advance payments of the premium tax credit and cost-sharing reductions.* In order for a health plan to be certified as a QHP initially and to maintain certification to be offered in the individual market on the Exchange, the issuer must meet the requirements related to the administration of cost-sharing reductions and advance payments of the premium tax credit set forth in subpart E of this part.

(b) [Reserved]

[78 FR 15535, Mar. 11, 2013]

§ 156.220 Transparency in coverage.

(a) *Required information.* A QHP issuer must provide the following information in accordance with the standards in paragraph (b) of this section:

(1) Claims payment policies and practices;

(2) Periodic financial disclosures;

(3) Data on enrollment;

(4) Data on disenrollment;

(5) Data on the number of claims that are denied;

(6) Data on rating practices;

(7) Information on cost-sharing and payments with respect to any out-of-network coverage; and

(8) Information on enrollee rights under title I of the Affordable Care Act.

(b) *Reporting requirement.* A QHP issuer must submit, in an accurate and timely manner, to be determined by HHS, the information described in paragraph (a) of this section to the Exchange, HHS and the State insurance commissioner, and make the information described in paragraph (a) of this section available to the public.

(c) *Use of plain language.* A QHP issuer must make sure that the information submitted under paragraph (b) is provided in plain language as defined under § 155.20 of this subtitle.

(d) *Enrollee cost sharing transparency.* A QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. At a minimum, such information must be made available to such individual through an Internet Web site and such other means for individuals without access to the Internet.

§ 156.221 Access to and exchange of health data and plan information.

(a) *Application Programming Interface to support enrollees.* Subject to paragraph (h) of this section, a QHP issuer on a Federally-Facilitated Exchange must implement and maintain a standards-based Application Programming Interface (API) that permits third-party applications to retrieve, with the approval and at the direction of a current individual enrollee or the enrollee's personal representative, data specified in paragraph (b) of this section through the use of common technologies and without special effort from the enrollee.

(b) *Accessible content.* (1) A QHP issuer on a Federally-facilitate Exchange must make the following information accessible to its current enrollees or the enrollee's personal representative through the API described in paragraph (a) of this section:

(i) Data concerning adjudicated claims, including claims data for payment decisions that may be appealed, were appealed, or are in the process of appeal, and provider remittances and enrollee cost-sharing pertaining to such claims, no later than one (1) business day after a claim is processed;

(ii) Encounter data from capitated providers, no later than one (1) business day after data concerning the encounter is received by the QHP issuer;

(iii) All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the Qualified Health Plan (QHP) issuer no later than 1 business day after the QHP issuer receives the data; and

(iv) For plan years beginning on or after January 1, 2027, the information in paragraph (b)(1)(iv)(A) of this section about prior authorizations for items and services (excluding drugs, as defined in paragraph (b)(1)(v) of this section), according to the timelines in paragraph (b)(1)(iv)(B) of this section.

(A) The prior authorization request and decision, including all of the following, as applicable:

(*1*) The prior authorization status.

(*2*) The date the prior authorization was approved or denied.

(*3*) The date or circumstance under which the prior authorization ends.

(*4*) The items and services approved.

(*5*) If denied, a specific reason why the request was denied.

(*6*) Related structured administrative and clinical documentation submitted by a provider.

(B) The information in paragraph (b)(1)(iv)(A) of this section must—

(*1*) Be accessible no later than 1 business day after the QHP issuer receives a prior authorization request;

(*2*) Be updated no later than 1 business day after any status change; and

(*3*) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

(v) Drugs are defined for the purposes of paragraph (b)(1)(iv) of this section as any and all drugs covered by the QHP issuer.

(2) [Reserved]

(c) *Technical requirements.* A QHP issuer on a Federally-facilitated Exchange implementing an API under paragraph (a) of this section:

(1) Must implement and maintain API technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1);

(2) Must conduct routine testing and monitoring, and update as appropriate, to ensure the API functions properly, including assessments to verify the API is fully and successfully implementing privacy and security features such as, but not limited to, those required to comply with HIPAA privacy and security requirements in parts 160 and 164, 42 CFR parts 2 and 3, and other applicable law protecting privacy and security of individually identifiable data;

(3) Must comply with the content and vocabulary standard requirements in paragraphs (c)(3)(i) and (ii) of this section, as applicable, to the data type or data element, unless alternate standards are required by other applicable law:

(i) Content and vocabulary standards at 45 CFR 170.213 where such are applicable to the data type or element, as appropriate; and

(ii) Content and vocabulary standards at part 162 of this subchapter and 42 CFR 423.160 where required by law, or where such standards are applicable to the data type or element, as appropriate.

(4) May use an updated version of any standard or all standards required under paragraphs (c)(1) or (3) of this section, where:

(i) Use of the updated version of the standard is required by other applicable law, or

(ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:

(A) For content and vocabulary standards other than those at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of this section or part 170 of this subchapter;

(B) For standards at 45 CFR 170.213 and 45 CFR 170.215, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program; and

(C) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user's ability to access the data specified in paragraph (b) of this section or §§ 156.221, 156.222, and 156.223 through the required APIs.

(d) *Documentation requirements for APIs.* For each API implemented in accordance with paragraph (a) of this section, a QHP issuer on a Federally-Facilitated Exchange must make publicly accessible, by posting directly on its website and/or via publicly accessible hyperlink(s), complete accompanying documentation that contains, at a minimum the information listed in this paragraph. For the purposes of this section, ''publicly accessible'' means that any person using commonly available technology to browse the internet could access the information without any preconditions or additional steps, such as a fee for access to the documentation; a requirement to receive a copy of the material via email; a requirement to register or create an account to receive the documentation; or a requirement to read promotional material or agree to receive future communications from the organization making the documentation available;

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

(2) The software components and configurations an application must use in order to successfully interact with the API and process its response(s); and

(3) All applicable technical requirements and attributes necessary for an application to be registered with any authorization server(s) deployed in conjunction with the API.

(e) *Denial or discontinuation of access to the API.* A QHP issuer on a Federally-Facilitated Exchange may deny or discontinue any third party application's connection to the API required under paragraph (a) of this section if the QHP issuer:

(1) Reasonably determines, consistent with its security risk analysis under 45 CFR part 164 subpart C, that allowing an application to connect or remain connected to the API would present an unacceptable level of risk to the security of personally identifiable information, including protected health information, on the QHP issuer's systems; and

(2) Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to criteria that rely on automated monitoring and risk mitigation tools.

(f) *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 following any calendar year that it offers a QHP on a Federally-facilitated Exchange, a QHP issuer must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the issuer level in the form and manner specified by the Secretary:

(1) The total number of unique enrollees whose data are transferred via the Patient Access API to a health app designated by the enrollee.

(2) The total number of unique enrollees whose data are transferred more than once via the Patient Access API to a health app designated by the enrollee.

(g) *Enrollee resources regarding privacy and security.* A QHP issuer on a Federally-facilitated Exchange must provide in an easily accessible location on its public website and through other appropriate mechanisms through which it ordinarily communicates with current and former enrollees seeking to access their health information held by the QHP issuer, educational resources in non-technical, simple and easy-to-understand language explaining at a minimum:

(1) General information on steps the individual may consider taking to help protect the privacy and security of their health information, including factors to consider in selecting an application including secondary uses of data, and the importance of understanding the security and privacy practices of any application to which they will entrust their health information; and

(2) An overview of which types of organizations or individuals are and are not likely to be HIPAA covered entities, the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to:

(i) The HHS Office for Civil Rights (OCR); and

(ii) The Federal Trade Commission (FTC).

(h) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraphs (a) through (g) of this section, the issuer must include as part of its QHP application a narrative justification describing the reasons why the plan cannot reasonably satisfy the requirements for the applicable plan year, the impact of non-compliance upon enrollees, the current or proposed means of providing health information to enrollees, and solutions and a timeline to achieve compliance with the requirements of this section.

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a) through (g) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

(i) *Applicability.* A QHP issuer on an individual market Federally-facilitated Exchange, not including QHP issuers offering only stand-alone dental plans, must comply with the requirements in paragraphs (a) through (e) and (g) of this section beginning with plan years beginning on or after January 1, 2021, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:

(1) With a date of service on or after January 1, 2016; and

(2) That are maintained by the QHP issuer for enrollees in QHPs.

[85 FR 25638, May 1, 2020, as amended at 89 FR 8986, Feb. 8, 2024]

§ 156.222 Access to and exchange of health data for providers and payers.

(a) *Application programming interface to support data exchange from payers to providers—Provider Access API.* Unless granted an exception under paragraph (c) of this section, for plan years beginning on or after January 1, 2027, QHP issuers on a Federally-facilitated Exchange must do the following:

(1) *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:

(i) Section 156.221(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).

(2) *Provider access.* Make the data specified in §156.221(b) with a date of service on or after January 1, 2016, excluding provider remittances and enrollee cost-sharing information, that are maintained by the QHP issuer to available in-network providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:

(i) The QHP issuer authenticates the identity of the provider that requests access and attributes the enrollee to the provider under the attribution process described in paragraph (a)(3) of this section.

(ii) The enrollee does not opt out as described in paragraph (a)(4) of this section.

(iii) Disclosure of the data is not prohibited by other applicable law.

(3) *Attribution.* Establish and maintain a process to associate enrollees with their in-network providers to enable data exchange via the Provider Access API.

(4) *Opt out and patient educational resources.* (i) Establish and maintain a process to allow an enrollee or the enrollee's personal representative to opt out of data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the QHP issuer makes enrollee information available via the Provider Access API and at any time while the enrollee is enrolled with the QHP issuer.

(ii) Provide information to enrollees in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:

(A) Before the first date on which the QHP issuer makes enrollee information available through the Provider Access API.

(B) No later than 1 week after the after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(C) At least annually.

(D) In an easily accessible location on its public website.

(5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting enrollee data using the Provider Access API required in paragraph (a)(1) of this section. The resources must include information about how to use the QHP issuer's attribution process to associate enrollees with their providers.

(b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Unless granted an exception under paragraph (c) of this section, for plan years beginning on or after January 1, 2027, QHP issuers on a Federally-facilitated Exchange must do the following:

(1) *API requirements.* Implement and maintain an API conformant with all of the following:

(i) Section 156.221(c)(2) through (4), (d), and (e).

(ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).

(2) *Opt in.* Establish and maintain a process to allow enrollees or their personal representatives to opt into the QHP issuer's payer to payer data exchange with the enrollee's previous payer(s), described in paragraphs (b)(4)

and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.

(i) The opt in process must be offered as follows:

(A) To current enrollees, no later than the compliance date.

(B) To new enrollees, no later than 1 week after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(ii) If an enrollee does not respond or additional information is necessary, the QHP issuer must make reasonable efforts to engage with the enrollee to collect this information.

(3) *Identify previous and concurrent payers.* Establish and maintain a process to identify a new enrollee's previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:

(i) For current enrollees, no later than the compliance date.

(ii) For new enrollees, no later than 1 week after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

(iii) If an enrollee does not respond or additional information is necessary, the QHP issuer must make reasonable efforts to engage with the enrollee to collect this information.

(4) *Exchange request requirements.* Exchange enrollee data with other payers, consistent with the following requirements:

(i) The QHP issuer must request the data specified in paragraph (b)(4)(ii) of this section through the enrollee's previous payers' API, if all the following conditions are met:

(A) The enrollee has opted in, as described in paragraph (b)(2) of this section.

(B) The exchange is not prohibited by other applicable law.

(ii) The data to be requested are all of the following with a date of service within 5 years before the request:

(A) Data specified in §156.221(b) excluding the following:

(*1*) Provider remittances and enrollee cost-sharing information.

(*2*) Denied prior authorizations.

(B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.

(iii) The QHP issuer must include an attestation with this request affirming that the enrollee is enrolled with the QHP issuer and has opted into the data exchange.

(iv) The QHP issuer must complete this request as follows:

(A) No later than 1 week after the payer has sufficient identifying information about previous payers and the enrollee has opted in.

(B) At an enrollee's request, within 1 week of the request.

(v) The QHP issuer must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the enrollee, any data made available by other payers in response to the request.

(5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the QHP issuer to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:

(i) The payer that requests access has its identity authenticated and includes an attestation with the request that the patient is enrolled with the payer and has opted into the data exchange.

(ii) Disclosure of the data is not prohibited by other applicable law.

(6) *Concurrent coverage data exchange requirements.* When an enrollee has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, a QHP issuer on a Federally-facilitated Exchange must do the following, through the API required in paragraph (b)(1) of this section:

(i) Request the enrollee's data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the enrollee is enrolled with both payers.

(ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the QHP issuer may exclude any data that were previously

sent to or originally received from the concurrent payer.

(7) *Patient educational resources.* Provide information to enrollees in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The QHP issuer must provide the following resources:

(i) When requesting an enrollee's permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.

(ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current enrollees.

(iii) In an easily accessible location on its public website.

(c) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraph (a) or (b) (or paragraphs (a) and (b)) of this section, the issuer must include a narrative justification in its QHP application that describes all of the following:

(i) The reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year.

(ii) The impact of non-compliance upon providers and enrollees.

(iii) The current or proposed means of providing health information to payers.

(iv) Solutions and a timeline to achieve compliance with the requirements in paragraph (a) or (b) of this section (or paragraphs (a) and (b)).

(2) The Federally-facilitated Exchange may grant an exception to the requirements in paragraph (a) or (b) (or paragraphs (a) and (b)) of this section if the Exchange determines that making QHPs of such issuer available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates, and an exception is warranted to permit the issuer to offer QHPs through the FFE.

[89 FR 8986, Feb. 8, 2024]

§ 156.223 Prior authorization requirements.

(a) *Communicating a reason for denial.* Beginning January 1, 2026, if the QHP issuer denies a prior authorization request (excluding a request for coverage of drugs as defined in §156.221(b)(1)(v)), the response to the provider must include a specific reason for the denial, regardless of the method used to communicate that information.

(b) *Prior Authorization Application Programming Interface (API).* Unless granted an exception under paragraph (d) of this section, for plan years beginning on or after January 1, 2027, a QHP issuer on a Federally-facilitated Exchange must implement and maintain an API conformant with §156.221(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—

(1) Is populated with the QHP issuer's list of covered items and services (excluding drugs as defined in §156.221(b)(1)(v)) that require prior authorization;

(2) Can identify all documentation required by the QHP issuer for approval of any items or services that require prior authorization;

(3) Supports a HIPAA-compliant prior authorization request and response, as described in 45 CFR part 162; and

(4) Communicates the following information about prior authorization requests:

(i) Whether the QHP issuer—

(A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);

(B) Denies the prior authorization request; or

(C) Requests more information.

(ii) If the QHP issuer denies the prior authorization request, it must include a specific reason for the denial.

(c) *Publicly reporting prior authorization metrics.* Beginning in 2026, following each year it offers a QHP on a Federally-facilitated Exchange, a QHP issuer must report prior authorization data, excluding data on drugs as defined in §156.221(b)(1)(v), at the issuer level by March 31. The QHP issuer must make the following data from the previous calendar year publicly accessible by posting them on its website:

(1) A list of all items and services that require prior authorization.

(2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(8) The average and median time that elapsed between the submission of a request and a determination by the QHP issuer, for standard prior authorizations, aggregated for all items and services.

(9) The average and median time that elapsed between the submission of a request and a decision by the QHP issuer for expedited prior authorizations, aggregated for all items and services.

(d) *Exception.* (1) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange believes it cannot satisfy the requirements in paragraph (b) of this section, the issuer must include a narrative justification in its QHP application that describes all of the following:

(i) The reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year.

(ii) The impact of non-compliance upon providers and enrollees.

(iii) The current or proposed means of providing health information to providers.

(iv) Solutions and a timeline to achieve compliance with the requirements in paragraph (b) of this section.

(2) The Federally-facilitated Exchange (FFE) may grant an exception to the requirements in paragraph (b) of this section if the Exchange determines that making QHPs of such issuer available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates and an exception is warranted to permit the issuer to offer QHPs through the FFE.

[89 FR 8988, Feb. 8, 2024]

§ 156.225 Marketing and benefit design of QHPs.

A QHP issuer and its officials, employees, agents and representatives must—

(a) *State law applies.* Comply with any applicable State laws and regulations regarding marketing by health insurance issuers;

(b) *Non-discrimination.* Not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs; and

(c) *Plan marketing names.* Offer plans and plan variations with marketing names that include correct information, without omission of material fact, and do not include content that is misleading.

[77 FR 18469, Mar. 27, 2012, as amended at 88 FR 25922, Apr. 27, 2023]

§ 156.230 Network adequacy standards.

(a) *General requirement.* (1) Each QHP issuer must use a provider network and ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards:

(i) Includes essential community providers in accordance with §156.235;

(ii) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to ensure that all services will be accessible without unreasonable delay; and

(iii) Is consistent with the rules for network plans of section 2702(c) of the PHS Act.

(2)(i) *Standards.* A QHP issuer on a Federally-facilitated Exchange must comply with the requirement in paragraph (a)(1)(ii) of this section by:

(A) For plan years beginning on or after January 1, 2023, meeting time and

distance standards established by the Federally-facilitated Exchange. Such time and distance standards will be developed for consistency with industry standards and published in guidance. Quantitative reviews of compliance with time and distance standards will be conducted using issuer-submitted data; and

(B) For plan years beginning on or after January 1, 2025, meeting appointment wait time standards established by the Federally-facilitated Exchange. Such appointment wait time standards will be developed for consistency with industry standards and published in guidance.

(ii) *Written justification.* If a plan applying for QHP certification to be offered through a Federally-facilitated Exchanges does not satisfy the network adequacy standards described in paragraphs (a)(2)(i)(A) and (B) of this section, the issuer must include it as part of its QHP application a justification describing how the plan's provider network provides an adequate level of service for enrollees and how the plan's provider network will be strengthened and brought closer to compliance with the network adequacy standards prior to the start of the plan year. The issuer must provide information as requested by the FFE to support this justification.

(3) The Federally-facilitated Exchange may grant an exception to the requirements in paragraphs (a)(2)(i)(A) and (B) of this section if the Exchange determines that making such health plan available through such Exchange is in the interests of qualified individuals in the State or States in which such Exchange operates.

(4) A limited exception to the requirement described under paragraph (a)(1) of this section that each QHP issuer use a provider network is available to stand-alone dental plans issuers that sell plans in areas where it is prohibitively difficult for the issuer to establish a network of dental providers; this exception is not available to medical QHP issuers. Under this exception, an area is considered ''prohibitively difficult'' for the stand-alone dental plan issuer to establish a network of dental providers based on attestations from State departments of insurance in States with at least 80 percent of counties classified as Counties with Extreme Access Considerations (CEAC) that at least one of the following factors exists in the area of concern: a significant shortage of dental providers, a significant number of dental providers unwilling to contract with Exchange issuers, or significant geographic limitations impacting consumer access to dental providers.

(b) *Access to provider directory.* (1) A QHP issuer must make its provider directory for a QHP available to the Exchange for publication online in accordance with guidance from HHS and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

(2) For plan years beginning on or after January 1, 2016, a QHP issuer must publish an up-to-date, accurate, and complete provider directory, including information on which providers are accepting new patients, the provider's location, contact information, specialty, medical group, and any institutional affiliations, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS and OPM. A provider directory is easily accessible when—

(i) The general public is able to view all of the current providers for a plan in the provider directory on the issuer's public Web site through a clearly identifiable link or tab and without creating or accessing an account or entering a policy number; and

(ii) If a health plan issuer maintains multiple provider networks, the general public is able to easily discern which providers participate in which plans and which provider networks.

(c) *Increasing consumer transparency.* A QHP issuer in a Federally-facilitated Exchange must make available the information described in paragraph (b) of this section on its Web site in an HHS specified format and also submit this information to HHS, in a format and manner and at times determined by HHS.

(d) *Provider transitions.* A QHP issuer in a Federally-facilitated Exchange must—

(1) Make a good faith effort to provide written notice of discontinuation

of a provider 30 days prior to the effective date of the change or otherwise as soon as practicable, to enrollees who are patients seen on a regular basis by the provider or who receive primary care from the provider whose contract is being discontinued, irrespective of whether the contract is being discontinued due to a termination for cause or without cause, or due to a non-renewal;

(2) In cases where a provider is terminated without cause, allow an enrollee in an active course of treatment to continue treatment until the treatment is complete or for 90 days, whichever is shorter, at in-network cost-sharing rates.

(i) For the purposes of paragraph (d)(2) of this section, active course of treatment means:

(A) An ongoing course of treatment for a life-threatening condition, defined as a disease or condition for which likelihood of death is probable unless the course of the disease or condition is interrupted;

(B) An ongoing course of treatment for a serious acute condition, defined as a disease or condition requiring complex ongoing care which the covered person is currently receiving, such as chemotherapy, radiation therapy, or post-operative visits;

(C) The second or third trimester of pregnancy, through the postpartum period; or

(D) An ongoing course of treatment for a health condition for which a treating physician or health care provider attests that discontinuing care by that physician or health care provider would worsen the condition or interfere with anticipated outcomes.

(ii) Any QHP issuer decision made for a request for continuity of care under paragraph (d)(2) of this section must be subject to the health benefit plan's internal and external grievance and appeal processes in accordance with applicable State or Federal law or regulations.

(e) *Out-of-network cost-sharing.* Beginning for the 2018 and later benefit years, for a network to be deemed adequate, each QHP must:

(1) Notwithstanding §156.130(c), count the cost sharing paid by an enrollee for an essential health benefit provided by an out-of-network ancillary provider in an in-network setting towards the enrollee's annual limitation on cost sharing; or

(2) Provide a written notice to the enrollee by the longer of when the issuer would typically respond to a prior authorization request timely submitted, or 48 hours before the provision of the benefit, that additional costs may be incurred for an essential health benefit provided by an out-of- network ancillary provider in an in-network setting, including balance billing charges, unless such costs are prohibited under State law, and that any additional charges may not count toward the in-network annual limitation on cost sharing.

(f) [Reserved]

[77 FR 18469, Mar. 27, 2012, as amended at 80 FR 10873, Feb. 27, 2015; 81 FR 12349, Mar. 8, 2016; 86 FR 6178, Jan. 19, 2021; 87 FR 27391, May 6, 2022; 88 FR 25922, Apr. 27, 2023]

§ 156.235 Essential community providers.

(a) *General ECP standard.* (1) A QHP issuer must include in its provider network a sufficient number and geographic distribution of essential community providers (ECPs), where available, to ensure reasonable and timely access to a broad range of such providers for low-income individuals or individuals residing in Health Professional Shortage Areas within the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of ECPs if it demonstrates in its QHP application that—

(i) The QHP issuer's provider network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area collectively across all ECP categories defined under paragraph (a)(2)(ii)(B) of this section, and at least a minimum percentage of available ECPs in each plan's service area within certain individual ECP categories, as specified by HHS. Multiple providers at a single location will count as a single ECP toward both the

available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with two network tiers (for example, participating providers and preferred providers), such as many preferred provider organizations (PPOs), where cost-sharing is lower for preferred providers, only preferred providers will be counted towards ECP standards; and

(ii) The issuer of the plan offers contracts to—

(A) All available Indian health care providers in the service area, applying the special terms and conditions required by Federal law and regulations as referenced in the recommended model QHP addendum for Indian health care providers developed by HHS; and

(B) At least one ECP in each of the eight (8) ECP categories in each county in the service area, where an ECP in that category is available and provides medical or dental services that are covered by the issuer plan type. The ECP categories are: Federally Qualified Health Centers, Ryan White Program Providers, Family Planning Providers, Indian Health Care Providers, Inpatient Hospitals, Mental Health Facilities, Substance Use Disorder Treatment Centers, and Other ECP Providers. The Other ECP Providers category includes the following types of providers: Rural Health Clinics, Black Lung Clinics, Hemophilia Treatment Centers, Sexually Transmitted Disease Clinics, Tuberculosis Clinics, and Rural Emergency Hospitals.

(3) If a plan applying for QHP certification to be offered through a Federally-facilitated Exchange does not satisfy the ECP standard described in paragraph (a)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider network provides an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(4) Nothing in paragraphs (a)(1) through (3) of this section requires any QHP to provide coverage for any specific medical procedure.

(5) A plan that provides a majority of covered professional services through physicians employed by the issuer or through a single contracted medical group may instead comply with the alternate standard described in paragraph (b) of this section.

(b) *Alternate ECP standard.* (1) A plan described in paragraph (a)(5) of this section must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities, to ensure reasonable and timely access for low-income individuals or individuals residing in Health Professional Shortage Areas within the plan's service area, in accordance with the Exchange's network adequacy standards.

(2) A plan described in paragraph (a)(5) of this section applying for QHP certification to be offered through a Federally-facilitated Exchange has a sufficient number and geographic distribution of employed or contracted providers if it demonstrates in its QHP application that—

(i) The number of its providers that are located in Health Professional Shortage Areas or five-digit zip codes in which 30 percent or more of the population falls below 200 percent of the Federal poverty level satisfies a minimum percentage, specified by HHS, of available ECPs in each plan's service area collectively across all ECP categories defined under paragraph (a)(2)(ii)(B) of this section, and at least a minimum percentage of available ECPs in each plan's service area within certain individual ECP categories, as specified by HHS. Multiple providers at a single location will count as a single ECP toward both the available ECPs in the plan's service area and the issuer's satisfaction of the ECP participation standard. For plans that use tiered networks, to count toward the issuer's satisfaction of the ECP standards, providers must be contracted within the network tier that results in the lowest cost-sharing obligation. For plans with

two network tiers (for example, participating providers and preferred providers), such as many PPOs, where cost sharing is lower for preferred providers, only preferred providers would be counted towards ECP standards; and

(ii) The issuer's integrated delivery system provides all of the categories of services provided by entities in each of the ECP categories in each county in the plan's service area as outlined in the general ECP standard, or otherwise offers a contract to at least one ECP outside of the issuer's integrated delivery system per ECP category in each county in the plan's service area that can provide those services to low-income, medically underserved individuals.

(3) If a plan does not satisfy the alternate ECP standard described in paragraph (b)(2) of this section, the issuer must include as part of its QHP application a narrative justification describing how the plan's provider networks provide an adequate level of service for low-income enrollees or individuals residing in Health Professional Shortage Areas within the plan's service area and how the plan's provider network will be strengthened toward satisfaction of the ECP standard prior to the start of the benefit year.

(c) *Definition.* An essential community provider is a provider that serves predominantly low-income, medically underserved individuals, including a health care provider defined in section 340B(a)(4) of the PHS Act; or described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Pub. L. 111–8; or a State-owned family planning service site, or governmental family planning service site, or not-for-profit family planning service site that does not receive Federal funding under special programs, including under Title X of the PHS Act, or an Indian health care provider, unless any of the above providers has lost its status under either of these sections, 340(B) of the PHS Act or 1927 of the Act as a result of violating Federal law.

(d) *Payment rates.* Nothing in paragraph (a) of this section may be construed to require a QHP issuer to contract with an ECP if such provider refuses to accept the same rates and contract provisions included in contracts accepted by similarly situated providers.

(e) *Payment of Federally qualified health centers.* If an item or service covered by a QHP is provided by a Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Act) to an enrollee of a QHP, the QHP issuer must pay the Federally qualified health center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the Act for such item or service. Nothing in this paragraph (e) precludes a QHP issuer and Federally-qualified health center from agreeing upon payment rates other than those that would have been paid to the center under section 1902(bb) of the Act, as long as that rate is at least equal to the generally applicable payment rate of the issuer described in paragraph (d) of this section.

[80 FR 10873, Feb. 27, 2015, as amended at 88 FR 25922, Apr. 27, 2023]

§ 156.245 Treatment of direct primary care medical homes.

A QHP issuer may provide coverage through a direct primary care medical home that meets criteria established by HHS, so long as the QHP meets all requirements that are otherwise applicable and the services covered by the direct primary care medical home are coordinated with the QHP issuer.

§ 156.250 Meaningful access to qualified health plan information.

A QHP issuer must provide all information that is critical for obtaining health insurance coverage or access to health care services through the QHP, including applications, forms, and notices, to qualified individuals, applicants, qualified employers, qualified employees, and enrollees in accordance with the standards described in § 155.205(c) of this subchapter. Information is deemed to be critical for obtaining health insurance coverage or access to health care services if the issuer is required by law or regulation to provide the document to a qualified individual, applicant, qualified employer, qualified employee, or enrollee.

[80 FR 10874, Feb. 27, 2015]

§ 156.255 Rating variations.

(a) *Rating areas.* A QHP issuer, including an issuer of a multi-State plan, may vary premiums by the geographic rating area established under section 2701(a)(2) of the PHS Act.

(b) *Same premium rates.* A QHP issuer must charge the same premium rate without regard to whether the plan is offered through an Exchange, or whether the plan is offered directly from the issuer or through an agent.

§ 156.260 Enrollment periods for qualified individuals.

(a) *Individual market requirement.* A QHP issuer must:

(1) Enroll a qualified individual during the initial and annual open enrollment periods described in §155.410(b) and (e) of this subchapter, and abide by the effective dates of coverage established by the Exchange in accordance with §155.410(c) and (f) of this subchapter; and

(2) Make available, at a minimum, special enrollment periods described in §155.420(d) of this subchapter, for QHPs and abide by the effective dates of coverage established by the Exchange in accordance with §155.420(b) of this subchapter.

(b) *Notification of effective date.* A QHP issuer must notify a qualified individual of his or her effective date of coverage.

§ 156.265 Enrollment process for qualified individuals.

(a) *General requirement.* A QHP issuer must process enrollment in accordance with this section.

(b) *Enrollment through the Exchange for the individual market.* (1) A QHP issuer must enroll a qualified individual only if the Exchange—

(i) Notifies the QHP issuer that the individual is a qualified individual; and

(ii) Transmits information to the QHP issuer as provided in §155.400(a) of this subchapter.

(2) If an applicant initiates enrollment directly with the QHP issuer for enrollment through the Exchange, the QHP issuer must either—

(i) Direct the individual to file an application with the Exchange in accordance with §155.310, or

(ii) Ensure the applicant's completion of an eligibility verification and enrollment application through the Exchange Internet Web site as described in §155.405, or ensure that the eligibility application information is submitted for an eligibility determination through the Exchange-approved Web service subject to meeting the requirements in paragraph (b)(3) through (5) of this section;

(3) When an Internet Web site of an issuer is used to complete the Exchange eligibility application outlined in this section, at a minimum, the Internet Web site must:

(i) Use exactly the same eligibility application language as appears in the FFE Single Streamlined Application required in §155.405 of this subchapter, unless HHS approves a deviation;

(ii) Ensure that all necessary information for the consumer's applicable eligibility circumstances are submitted through the Exchange-approved Web service;

(iii) Ensure that the process used for consumers to complete the eligibility application complies with all applicable Exchange standards, including §§155.230 and 155.260(b) of this subchapter; and

(iv) Differentially display all standardized options in accordance with the requirements under §155.205(b)(1) in a manner consistent with that adopted by HHS for display on the Federally-facilitated Exchange Web site, unless HHS approves a deviation.

(4) An issuer must obtain HHS approval that the requirements of this section have been met prior to completing an applicant's eligibility application through the issuer's Internet Web site.

(5) HHS or its designee may periodically monitor and audit an agent, broker, or issuer to assess its compliance with the applicable requirements of this section.

(c) *Acceptance of enrollment information.* A QHP issuer must accept enrollment information consistent with the privacy and security requirements established by the Exchange in accordance with §155.260 and in an electronic format that is consistent with §155.270.

(d) *Premium payment.* A QHP issuer must follow the premium payment

process established by the Exchange in accordance with §155.240 of this subchapter and the payment rules established in §155.400(e) of this subchapter.

(e) *Enrollment information package.* A QHP issuer must provide new enrollees an enrollment information package that is compliant with accessibility and readability standards established in §155.230(b).

(f) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) and resolve assigned updates no less than once a month in accordance with §155.400(d) of this subchapter, using the most recent enrollment information that is available and that has been verified to the best of the issuer's knowledge or belief.

(g) *Timely updates to enrollment records.* A QHP issuer offering plans through an Exchange must, in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), either:

(1) Verify to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) that the information in the enrollment reconciliation file received from the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) accurately reflects its enrollment data for the applicable benefit year in its next enrollment reconciliation file submission to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), and update its internal enrollment records accordingly; or

(2) Describe to the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) within one reconciliation cycle any discrepancy it identifies in the enrollment reconciliation files it received from the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform).

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 76218, Dec. 17, 2013; 79 FR 30351, May 27, 2014; 80 FR 10874, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 81 FR 94181, Dec. 22, 2016; 85 FR 29261, May 14, 2020]

§156.270 Termination of coverage or enrollment for qualified individuals.

(a) *General requirement.* A QHP issuer may only terminate enrollment in a QHP through the Exchange as permitted by the Exchange in accordance with §155.430(b) of this subchapter. (See also §147.106 of this subchapter for termination of coverage.)

(b) *Termination of coverage or enrollment notice requirement.* If a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange in accordance with §155.430(b) of this subchapter, the QHP issuer must, promptly and without undue delay:

(1) Provide the enrollee with a notice of termination that includes the termination effective date and reason for termination.

(2) [Reserved]

(c) *Termination of coverage or enrollment due to non-payment of premium.* A QHP issuer must establish a standard policy for the termination of enrollment of enrollees through the Exchange due to non-payment of premium as permitted by the Exchange in §155.430(b)(2)(ii) of this subchapter. This policy for the termination of enrollment:

(1) Must include the grace period for enrollees receiving advance payments of the premium tax credits as described in paragraph (d) of this section; and

(2) Must be applied uniformly to enrollees in similar circumstances.

(d) *Grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of 3 consecutive months for an enrollee, who when failing to timely pay premiums, is receiving advance payments of the premium tax credit. During the grace period, the QHP issuer must:

(1) Pay all appropriate claims for services rendered to the enrollee during the first month of the grace period

and may pend claims for services rendered to the enrollee in the second and third months of the grace period;

(2) Notify HHS of such non-payment; and,

(3) Notify providers of the possibility for denied claims when an enrollee is in the second and third months of the grace period.

(e) *Advance payments of the premium tax credit.* For the 3-month grace period described in paragraph (d) of this section, a QHP issuer must:

(1) Continue to collect advance payments of the premium tax credit on behalf of the enrollee from the Department of the Treasury.

(2) Return advance payments of the premium tax credit paid on the behalf of such enrollee for the second and third months of the grace period if the enrollee exhausts the grace period as described in paragraph (g) of this section.

(f) *Notice of non-payment of premiums.* If an enrollee is delinquent on premium payment, the QHP issuer must provide the enrollee with notice of such payment delinquency. Issuers offering QHPs in Exchanges on the Federal platform must provide such notices promptly and without undue delay, within 10 business days of the date the issuer should have discovered the delinquency.

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, subject to a premium payment threshold implemented under §155.400(g) of this subchapter, if applicable, the QHP issuer must terminate the enrollee's enrollment through the Exchange on the effective date described in §155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

(h) *Records of termination of coverage.* QHP issuers must maintain records in accordance with Exchange standards established in accordance with §155.430(c) of this subchapter.

(i) *Effective date of termination of coverage or enrollment.* QHP issuers must abide by the termination of coverage or enrollment effective dates described in §155.430(d) of this subchapter.

(j) *Operational instructions.* QHP issuers must follow the transaction rules established by the Exchange in accordance with §155.430(e) of this subchapter.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 42322, July 15, 2013; 78 FR 54143, Aug. 30, 2013; 79 FR 30351, May 27, 2014; 80 FR 10874, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 81 FR 53032, Aug. 11, 2016; 85 FR 29261, May 14, 2020; 88 FR 25923, Apr. 27, 2023]

§ 156.272 Issuer participation for the full plan year.

(a) An issuer offering a QHP through an individual market Exchange must make the QHP available for enrollment through the Exchange for the full plan year for which the plan was certified, including to eligible enrollees during limited open enrollment periods, unless a basis for suppression under §156.815 applies.

(b) Unless a basis for suppression under §156.815 applies, an issuer offering a QHP through a SHOP must make the QHP available for enrollment through the SHOP for the full plan year for which the QHP was certified.

(c) An issuer offering a QHP through a Federally-facilitated Exchange or a Federally-facilitated SHOP that does not comply with paragraph (a) or (b) of this section may, at the discretion of HHS, be precluded from offering QHPs in a Federally-facilitated Exchange or Federally-facilitated SHOP for up to the two succeeding plan years.

[81 FR 94181, Dec. 22, 2016]

§ 156.275 Accreditation of QHP issuers.

(a) *General requirement.* A QHP issuer must:

(1) Be accredited on the basis of local performance of its QHPs in the following categories by an accrediting entity recognized by HHS:

(i) Clinical quality measures, such as the Healthcare Effectiveness Data and Information Set;

(ii) Patient experience ratings on a standardized CAHPS survey;

(iii) Consumer access;

(iv) Utilization management;

(v) Quality assurance;

(vi) Provider credentialing;

(vii) Complaints and appeals;

(viii) Network adequacy and access; and

(ix) Patient information programs, and

(2) Authorize the accrediting entity that accredits the QHP issuer to release to the Exchange and HHS a copy of its most recent accreditation survey, together with any survey-related information that HHS may require, such as corrective action plans and summaries of findings.

(b) *Timeframe for accreditation.* A QHP issuer must be accredited within the timeframe established by the Exchange in accordance with §155.1045 of this subchapter. The QHP issuer must maintain accreditation so long as the QHP issuer offers QHPs.

(c) *Accreditation*—(1) *Recognition of accrediting entity by HHS*—(i) *Application.* An accrediting entity may apply to HHS for recognition. An application must include the documentation described in paragraph (c)(4) of this section and demonstrate, in a concise and organized fashion how the accrediting entity meets the requirements of paragraphs (c)(2) and (3) of this section.

(ii) *Proposed notice.* Within 60 days of receiving a complete application as described in paragraph (c)(1)(i) of this section, HHS will publish a notice in the FEDERAL REGISTER identifying the accrediting entity making the request, summarizing HHS's analysis of whether the accrediting entity meets the criteria described in paragraphs (c)(2) and (3) of this section, and providing no less than a 30-day public comment period about whether HHS should recognize the accrediting entity.

(iii) *Final notice.* After the close of the comment period described in paragraph (c)(1)(ii) of this section, HHS will notify the public in the FEDERAL REGISTER of the names of the accrediting entities recognized and those not recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs.

(iv) *Other recognition.* Upon completion of conditions listed in paragraphs (c)(2), (3), and (4) of this section, HHS recognized, and provided notice to the public in the FEDERAL REGISTER, the National Committee for Quality Assurance (NCQA) and URAC as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

(2)(i) *Scope of accreditation.* Subject to paragraphs (c)(2)(ii), (iii), and (iv) of this section, recognized accrediting entities must provide accreditation within the categories identified in paragraphs (a)(1) of this section.

(ii) *Clinical quality measures.* Recognized accrediting entities must include a clinical quality measure set in their accreditation standards for health plans that:

(A) Spans a breadth of conditions and domains, including, but not limited to, preventive care, mental health and substance abuse disorders, chronic care, and acute care.

(B) Includes measures that are applicable to adults and measures that are applicable to children.

(C) Aligns with the priorities of the National Strategy for Quality Improvement in Health Care issued by the Secretary of HHS and submitted to Congress on March 12, 2011;

(D) Only includes measures that are either developed or adopted by a voluntary consensus standards setting body (such as those described in the National Technology and Transfer Advancement of Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A–119 (1998)) or, where appropriate endorsed measures are unavailable, are in common use for health plan quality measurement and meet health plan industry standards; and

(E) Is evidence-based.

(iii) *Level of accreditation.* Recognized accrediting entities must provide accreditation at the Exchange product type level unless the product type level of accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception to authorize accreditation at an aggregated level.

(iv) *Network adequacy.* The network adequacy standards for accreditation used by the recognized accrediting entities must, at a minimum, be consistent with the general requirements

for network adequacy for QHP issuers codified in §156.230(a)(2) and (a)(3).

(3) *Methodological and scoring criteria for accreditation.* Recognized accrediting entities must use transparent and rigorous methodological and scoring criteria.

(4) *Documentation.* An accrediting entity applying to be recognized under the process described in (c)(1) of this section must provide the following documentation:

(i) To be recognized, an accrediting entity must provide current accreditation standards and requirements, processes and measure specifications for performance measures to demonstrate that it meets the conditions described in paragraphs (c)(2) and (3) of this section to HHS.

(ii) Recognized accrediting entities must provide to HHS any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days notice prior to public notification.

(5) *Data sharing requirements between the recognized accrediting entities and Exchanges.* When authorized by an accredited QHP issuer pursuant to paragraph (a)(2) of this section, recognized accrediting entities must provide the following QHP issuer's accreditation survey data elements to the Exchange, other than personally identifiable information (as described in OMB Memorandum M–07–16), in which the issuer plans to operate one or more QHPs during the annual certification period or as changes occur to these data throughout the coverage year—the name, address, Health Insurance Oversight System (HIOS) issuer identifier, and unique accreditation identifier(s) of the QHP issuer and its accredited product line(s) and type(s) which have been released; and for each accredited product type:

(i) HIOS product identifier (if applicable);

(ii) Accreditation status, survey type, or level (if applicable);

(iii) Accreditation score;

(iv) Expiration date of accreditation; and

(v) Clinical quality measure results and adult and child CAHPS measure survey results (and corresponding expiration dates of these data) at the level specified by the Exchange.

[77 FR 18469, Mar. 27, 2012, as amended at 77 FR 42671, July 20, 2012; 78 FR 12869, Feb. 25, 2013]

§ 156.280 Segregation of funds for abortion services.

(a) *State opt-out of abortion coverage.* A QHP issuer must comply with a State law that prohibits abortion coverage in QHPs.

(b) *Termination of opt out.* A QHP issuer may provide coverage of abortion services through the Exchange in a State described in paragraph (a) of this section if the State repeals such law.

(c) *Voluntary choice of coverage of abortion services.* Notwithstanding any other provision of title I of the Affordable Care Act (or any other amendment made under that title):

(1) Nothing in title I of the Affordable Care Act (or any amendments by that title) shall be construed to require a QHP issuer to provide coverage of services described in paragraph (d) of this section as part of its essential health benefits, as described in section 1302(b) of the Affordable Care Act, for any plan year.

(2) Subject to paragraphs (a) and (b) of this section, the QHP issuer must determine whether or not the QHP provides coverage of services described in paragraph (d) of this section as part of such benefits for the plan year.

(d) *Abortion services*—(1) *Abortions for which public funding is prohibited.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is not permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(2) *Abortions for which public funding is allowed.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(e) *Prohibition on the use of Federal funds.* (1) If a QHP provides coverage of services described in paragraph (d)(1) of this section, the QHP issuer must not use any amount attributable to any of

the following for the purposes of paying for such services:

(i) The credit under section 36B of the Code and the amount (if any) of the advance payment of the credit under section 1412 of the Affordable Care Act;

(ii) Any cost-sharing reduction under section 1402 of the Affordable Care Act and the amount (if any) of the advance payments of the reduction under section 1412 of the Affordable Care Act.

(2) *Establishment of allocation accounts.* In the case of a QHP to which paragraph (e)(1) of this section applies, the QHP issuer must:

(i) Collect from each enrollee in the QHP (without regard to the enrollee's age, sex, or family status) a separate payment for each of the following:

(A) An amount equal to the portion of the premium to be paid directly by the enrollee for coverage under the QHP of services other than services described in (d)(1) of this section (after reductions for credits and cost-sharing reductions described in paragraph (e)(1) of this section); and

(B) An amount equal to the actuarial value of the coverage of services described in paragraph (d)(1) of this section.

(ii) An issuer will be considered to satisfy the obligation in paragraph (e)(2)(i) of this section if it sends the policy holder a single monthly invoice or bill that separately itemizes the premium amount for coverage of abortion services described in paragraph (d)(1) of this section; sends the policy holder a separate monthly bill for these services; or sends the policy holder a notice at or soon after the time of enrollment that the monthly invoice or bill will include a separate charge for such services, and specifies the charge.

(iii) Deposit all such separate payments into separate allocation accounts as provided in paragraph (e)(3) of this section. In the case of an enrollee whose premium for coverage under the QHP is paid through employee payroll deposit, the separate payments required under paragraph (e)(2)(i) of this section shall each be paid by a separate deposit.

(3) *Segregation of funds.* (i) The QHP issuer to which paragraph (e)(1) of this section applies must establish allocation accounts described in paragraph (e)(3)(ii) of this section for enrollees receiving the amounts described in paragraph (e)(1) of this section.

(ii) *Allocation accounts.* The QHP issuer to which paragraph (e)(1) of this section applies must deposit:

(A) All payments described in paragraph (e)(2)(i)(A) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services other than the services described in paragraph (d)(1) of this section;

(B) All payments described in paragraph (e)(2)(i)(B) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services described in paragraph (d)(1) of this section.

(4) *Actuarial value.* The QHP issuer must estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under the QHP of services described in paragraph (d)(1) of this section. In making such an estimate, the QHP issuer:

(i) May take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care;

(ii) Must estimate such costs as if such coverage were included for the entire population covered; and

(iii) May not estimate such a cost at less than one dollar per enrollee, per month.

(5) *Ensuring compliance with segregation requirements.* (i) Subject to paragraph (e)(5)(iv) of this section, the QHP issuer must comply with the efforts or direction of the State health insurance commissioner to ensure compliance with this section through the segregation of QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget and guidance on accounting of the Government Accountability Office.

(ii) Each QHP issuer that participates in an Exchange and offers coverage for services described in paragraph (d)(1) of this section should, as a

condition of participating in an Exchange, submit a plan that details its process and methodology for meeting the requirements of section 1303(b)(2)(C), (D), and (E) (hereinafter, ''segregation plan'') to the State health insurance commissioner. The segregation plan should describe the QHP issuer's financial accounting systems, including appropriate accounting documentation and internal controls, that would ensure the segregation of funds required by section 1303(b)(2)(C), (D), and (E), and should include:

(A) The financial accounting systems, including accounting documentation and internal controls, that would ensure the appropriate segregation of payments received for coverage of services described in paragraph (d)(1) of this section from those received for coverage of all other services;

(B) The financial accounting systems, including accounting documentation and internal controls, that would ensure that all expenditures for services described in paragraph (d)(1) of this section are reimbursed from the appropriate account; and

(C) An explanation of how the QHP issuer's systems, accounting documentation, and controls meet the requirements for segregation accounts under the law.

(iii) Each QHP issuer participating in the Exchange must provide to the State insurance commissioner an annual assurance statement attesting that the plan has complied with section 1303 of the Affordable Care Act and applicable regulations.

(iv) Nothing in this clause shall prohibit the right of an individual or QHP issuer to appeal such action in courts of competent jurisdiction.

(f) *Rules relating to notice*—(1) *Notice.* A QHP that provides for coverage of services in paragraph (d)(1) of this section, must provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage.

(2) *Rules relating to payments.* The notice described in paragraph (f)(1) of this section, any advertising used by the QHP issuer with respect to the QHP, any information provided by the Exchange, and any other information specified by HHS must provide information only with respect to the total amount of the combined payments for services described in paragraph (d)(1) of this section and other services covered by the QHP.

(g) *No discrimination on basis of provision of abortion.* No QHP offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(h) *Application of State and Federal laws regarding abortions*—(1) *No preemption of State laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.

(2) *No effect on Federal laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to have any effect on Federal laws regarding:

(i) Conscience protection;

(ii) Willingness or refusal to provide abortion; and

(iii) Discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(3) *No effect on Federal civil rights law.* Nothing in section 1303(c) of the Affordable Care Act shall alter the rights and obligations of employees and employers under Title VII of the Civil Rights Act of 1964.

(i) *Application of emergency services laws.* Nothing in the Affordable Care Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Act (popularly known as ''EMTALA'').

[77 FR 18469, Mar. 27, 2012, as amended at 84 FR 71710, Dec. 27, 2019; 85 FR 2888, Jan. 17, 2020; 85 FR 27629, May 8, 2020; 86 FR 53506, Sept. 27, 2021]

§ 156.285 Additional standards specific to SHOP for plan years beginning prior to January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from the SHOP on behalf of a qualified employer or an enrollee in accordance with § 155.705(b)(4) of this subchapter;

(2) Adhere to the SHOP timeline for rate setting as established in § 155.705(b)(6) of this subchapter; and

(3) Charge the same contract rate for a plan year.

(4)(i) Adhere to the premium rating standards described in § 147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market; and

(ii) Effective in plan years beginning on or after January 1, 2015, a QHP issuer in a Federally-facilitated SHOP may not offer to an employer premiums that are based on average enrollee premium amounts under § 147.102(c)(3) of this subchapter, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(iv)(A) of this subchapter. This paragraph (a)(4)(ii) also applies to stand-alone dental plans in a Federally-facilitated SHOP, if the employer elects to offer coverage to its employees under § 155.705(b)(3)(v)(B) of this subchapter.

(b) *Enrollment periods for the SHOP.* QHP issuers offering a QHP through the SHOP must:

(1) Enroll a qualified employee in accordance with the qualified employer's initial and annual employee open enrollment periods described in § 155.725 of this subchapter;

(2) Provide special enrollment periods as described in § 155.725(j);

(3) Provide an enrollment period for an employee who becomes a qualified employee outside of the initial or annual open enrollment period as described in § 155.725(g) of this subchapter; and

(4) Adhere to effective dates of coverage established in accordance with § 155.725 of this subchapter.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Adhere to the enrollment timeline and process for the SHOP as described in § 155.720(b) of this subchapter;

(2) Receive enrollment information in an electronic format, in accordance with the requirements in §§ 155.260 and 155.270 of this subchapter, from the SHOP as described in § 155.720(c);

(3) Notify new enrollees of their effective date of coverage consistent with § 155.720(e) of this subchapter.

(4) Provide new enrollees with the enrollment information package as described in § 156.265(e);

(5) Send enrollment reconciliation files on at least a monthly basis, and, in a Federally-facilitated SHOP, according to a process, timeline, and file format established by the Federally-facilitated SHOP;

(6) Acknowledge receipt of enrollment information in accordance with SHOP standards; and

(7) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(8) A QHP issuer must enroll a qualified employee only if the SHOP—

(i) Notifies the QHP issuer that the employee is a qualified employee;

(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter; and

(iii) Effective for QHPs offered through a Federally-facilitated SHOP in plan years beginning on or after January 1, 2015, does not send a cancellation notice to the QHP issuer prior to the effective date of coverage.

(d) *Termination of coverage or enrollment in the SHOP.* QHP issuers offering a QHP through the SHOP must:

(1) Comply with the following requirements with respect to termination of enrollees in the SHOP:

(i)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage or enrollment established in § 155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) General requirements regarding termination of coverage or enrollment established in § 156.270(a).

(ii) If a QHP issuer terminates an enrollee's coverage or enrollment through the SHOP in accordance with

§155.735(d)(1)(iii) or (v) of this subchapter, the QHP issuer must notify the qualified employer and the enrollee of the termination. Such notice must include the termination effective date and reason for termination, and must be sent within 3 business days if an electronic notice is sent, and within 5 business days if a mailed hard copy notice is sent. When a primary subscriber and his or her dependents live at the same address, a separate termination notice need not be sent to each dependent at that address, provided that the notice sent to each primary subscriber at that address contains all required information about the termination for the primary subscriber and his or her dependents at that address.

(iii)(A) Effective in plan years beginning on or after January 1, 2015, requirements regarding termination of coverage or enrollment effective dates as set forth in §155.735 of this subchapter, if applicable to the coverage or enrollment being terminated; otherwise

(B) Requirements regarding termination of coverage or enrollment effective dates as set forth in §156.270(i).

(2) [Reserved]

(e) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with §155.705 of this subchapter.

(f) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Additional standards specific to SHOP for plan years beginning on or after January 1, 2018 are in §156.286.

[77 FR 18469, Mar. 27, 2012, as amended at 78 FR 15535, Mar. 11, 2013; 78 FR 33240, June 4, 2013; 78 FR 54143, Aug. 30, 2013; 79 FR 13840, Mar. 11, 2014; 80 FR 10874, Feb. 27, 2015; 80 FR 10875, Feb. 27, 2015; 81 FR 12350, Mar. 8, 2016; 83 FR 17069, Apr. 17, 2018]

§156.286 Additional standards specific to SHOP for plan years beginning on or after January 1, 2018.

(a) *SHOP rating and premium payment requirements.* QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from a qualified employer or an enrollee, or a SHOP on behalf of a qualified employer or enrollee, in accordance with applicable SHOP requirements.

(2) Adhere to the SHOP timeline for rate setting as established in §155.706(b)(6) of this subchapter;

(3) Charge the same contract rate for a plan year; and

(4) Adhere to the premium rating standards described in §147.102 of this subchapter regardless of whether the QHP being sold through the SHOP is sold in the small group market or the large group market.

(b) *Enrollment periods and processes for the SHOP.* QHP issuers offering a QHP through the SHOP must adhere to enrollment periods and processes established by the SHOP, consistent with §155.726 of this subchapter, and establish a uniform enrollment timeline and process for enrolling qualified employers and employer group members.

(c) *Enrollment process for the SHOP.* A QHP issuer offering a QHP through the SHOP must:

(1) Provide new enrollees with the enrollment information package as described in §156.265(e); and

(2) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Participation rules.* QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with §155.706 of this subchapter.

(e) *Employer choice.* QHP issuers offering a QHP through the SHOP must accept enrollments from groups in accordance with the employer choice policies applicable to the SHOP under §155.706(b)(3) of this subchapter.

(f) *Identification of SHOP enrollments.* QHP issuers offering a QHP through the SHOP must use a uniform enrollment form, maintain processes sufficient to identify whether a group market enrollment is an enrollment through the SHOP, and maintain records of SHOP enrollments for a period of 10 years following the enrollment.

(g) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17069, Apr. 17, 2018]

§ 156.290 Non-certification and decertification of QHPs.

(a) *Non-certification for a subsequent, consecutive certification cycle.* If a QHP issuer elects not to seek certification for a subsequent, consecutive certification cycle with the Exchange, the QHP issuer, at a minimum, must—

(1) Notify the Exchange of its decision prior to the beginning of the recertification process and adhere to the procedures adopted by the Exchange in accordance with §155.1075 of this subchapter;

(2) Fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year through the Exchange;

(3) Fulfill data reporting obligations from the last plan or benefit year of the certification;

(4) Provide notice to enrollees as described in paragraph (b) of this section; and

(5) Terminate the coverage or enrollment through the Exchange of enrollees in the QHP in accordance with §156.270, as applicable.

(b) *Notice of QHP non-availability.* When, for a subsequent, consecutive certification cycle, a QHP issuer elects not to seek certification with the Exchange, or the Exchange denies certification of a QHP, the QHP issuer must provide written notice to each enrollee in the form and manner specified by the Secretary under §147.106 of this subchapter.

(c) *Decertification.* If a QHP is decertified by the Exchange, the QHP issuer must terminate the enrollment of enrollees through the Exchange only after:

(1) The Exchange has made notification as described in §155.1080 of this subchapter; and

(2) Enrollees have an opportunity to enroll in other coverage.

[77 FR 18469, Mar. 27, 2012, as amended at 80 FR 10875, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016]

§ 156.295 Prescription drug distribution and cost reporting by QHP issuers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer that administers a prescription drug benefit without the use of a pharmacy benefit manager must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(b) *Limitation on disclosure.* Information disclosed by a QHP issuer under this section shall not be disclosed by HHS, except that HHS may disclose the information in a form which does not disclose the identity of a specific QHP or prices charged for specific drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A QHP issuer that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of subsection (b)(3)(C) of section 1927 of the Act.

[77 FR 18469, Mar. 27, 2012, as amended at 86 FR 24292, May 5, 2021]

Subpart D—Standards for Qualified Health Plan Issuers for Specific Types of Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.330 Changes of ownership of issuers of Qualified Health Plans in Federally-facilitated Exchanges.

When a QHP issuer that offers one or more QHPs in a Federally-facilitated Exchange undergoes a change of ownership as recognized by the State in which the issuer offers the QHP, the QHP issuer must notify HHS of the change in a manner to be specified by HHS, and provide the legal name and Taxpayer Identification Number (TIN) of the new owner and the effective date of the change at least 30 days prior to the effective date of the change of ownership. The new owner must agree to adhere to all applicable statutes and regulations.

[78 FR 65096, Oct. 30, 2013]

§ 156.340 Standards for downstream and delegated entities.

(a) *General requirement.* Effective October 1, 2013, notwithstanding any relationship(s) that a QHP issuer may have with delegated and downstream entities, a QHP issuer maintains responsibility for its compliance and the compliance of any of its delegated or downstream entities with all applicable Federal standards related to Exchanges. The applicable standards depend on the Exchange model type in which the QHP is offered, as described in paragraphs (a)(1) and (2) of this section.

(1) QHP issuers participating in Exchange models that do not use the Federal platform, including State Exchanges and State Exchange SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with the Federal standards related to Exchanges, including the standards in subpart C of this part with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §§ 155.705 and 155.706 of this subchapter, unless the standard is specifically applicable to a Federally-facilitated Exchange or FF–SHOP;

(2) QHP issuers participating in Exchanges that use the Federal platform, including Federally-facilitated Exchanges, FF–SHOPs, SBE–FPs, and SBE–FP–SHOPs. QHP issuers maintain responsibility for ensuring their downstream and delegated entities comply with Federal standards related to Exchanges, including the standards in subpart C of part 156 with respect to each of its QHPs on an ongoing basis, as well as the Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 of this subchapter and, in the small group market, §§ 155.705 and 155.706 of this subchapter if applicable to the Exchange type in which the QHP issuer is operating. QHP issuers are also responsible for their downstream and delegated entities' compliance with the standards of § 155.220 of this subchapter with respect to assisting with enrollment in QHPs, and the standards of §§ 156.705 and 156.715 of this subchapter for maintenance of records and compliance reviews if applicable to the Exchange type in which the QHP issuer is operating.

(b) *Delegation agreement specifications.* If any of the QHP issuer's activities or obligations, in accordance with paragraph (a) of this section, are delegated to other parties, the QHP issuer's agreement with any delegated or downstream entity must—

(1) Specify the delegated activities and reporting responsibilities;

(2) Provide for revocation of the delegated activities and reporting standards or specify other remedies in instances where HHS or the QHP issuer determines that such parties have not performed satisfactorily;

(3) Specify that the delegated or downstream entity must comply with all applicable laws and regulations relating to the standards specified under paragraph (a) of this section;

(4) Specify that the delegated or downstream entity must permit access by the Secretary and the OIG or their designees in connection with their right to evaluate through an audit, inspection, or other means, to the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period;

(5) All agreements between issuers offering QHPs through an Exchange and delegated or downstream entities the issuers engage to support the issuer's activities on an Exchange must include language stating that the relevant Exchange authority may demand and receive the delegated or downstream entity's books, contracts, computers, or other electronic systems, including medical records and documentation, relating to the QHP issuer's obligations in accordance with Federal standards under paragraph (a) of this section until 10 years from the final date of the agreement period.

[78 FR 54143, Aug. 30, 2013, as amended at 87 FR 27392, May 6, 2022]

§ 156.350 Eligibility and enrollment standards for Qualified Health Plan issuers on State-based Exchanges on the Federal platform.

(a) In order to participate in a State-based Exchange on the Federal platform, a QHP issuer must comply with HHS regulations, and guidance pertaining to issuer eligibility and enrollment functions as if the issuer were an issuer of a QHP on a Federally-facilitated Exchange. These requirements include—

(1) Section 156.285(a)(4)(ii) regarding the premiums for plans offered on the SHOP, for plan years beginning prior to January 1, 2018;

(2) Section 156.285(c)(5) and (c)(8)(iii) regarding the enrollment process for SHOP, for plan years beginning prior to January 1, 2018; and

(3) Section 156.715 regarding compliance reviews of QHP issuers, to the extent relating directly to applicable eligibility and enrollment functions.

(4) Section 156.265(d) of this subchapter regarding binder payments and premium payment deadlines.

(b) HHS will permit issuers of QHPs in each State-based Exchange on the Federal platform to directly enroll applicants in a manner that is considered to be through the Exchange, as if the issuers were issuers of QHPs on Federally-facilitated Exchanges under § 156.1230(a), to the extent permitted by applicable State law.

(c) If the State-based Exchange on the Federal platform does not substantially enforce a requirement in paragraph (a) of this section against the issuer or plan, then HHS may do so, in accordance with the enforcement remedies in subpart I of this part, subject to the administrative review process in subpart J of this part.

[81 FR 12351, Mar. 8, 2016, as amended at 81 FR 94181, Dec. 22, 2016; 83 FR 17069, Apr. 17, 2018]

Subpart E—Health Insurance Issuer Responsibilities With Respect to Advance Payments of the Premium Tax Credit and Cost-Sharing Reductions

SOURCE: 78 FR 15535, Mar. 11, 2013, unless otherwise noted.

§ 156.400 Definitions.

The following definitions apply to this subpart:

Advance payments of the premium tax credit has the meaning given to the term in § 155.20 of this subchapter.

Affordable Care Act has the meaning given to the term in § 155.20 of this subchapter.

Annual limitation on cost sharing means the annual dollar limit on cost sharing required to be paid by an enrollee that is established by a particular qualified health plan.

De minimis variation means the allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of

the health plan as established in §156.140(c).

De minimis variation for a silver plan variation means a −0 percentage point and +1 percentage point allowable AV variation.

Federal poverty level or *FPL* has the meaning given to the term in §155.300(a) of this subchapter.

Indian has the meaning given to the term in §155.300(a) of this subchapter.

Limited cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in §156.420(b)(2).

Maximum annual limitation on cost sharing means the highest annual dollar amount that qualified health plans (other than QHPs with cost-sharing reductions) may require in cost sharing for a particular year, as established for that year under §156.130.

Most generous or *more generous* means, as between a QHP (including a standard silver plan) or plan variation and one or more other plan variations of the same QHP, the standard plan or plan variation designed for the category of individuals last listed in §155.305(g)(3) of this subchapter. *Least generous* or *less generous* has the opposite meaning.

Plan variation means a zero cost sharing plan variation, a limited cost sharing plan variation, or a silver plan variation.

Reduced maximum annual limitation on cost sharing means the dollar value of the maximum annual limitation on cost sharing for a silver plan variation that remains after applying the reduction, if any, in the maximum annual limitation on cost sharing required by section 1402 of the Affordable Care Act as announced in the annual HHS notice of benefit and payment parameters.

Silver plan variation means, with respect to a standard silver plan, any of the variations of that standard silver plan described in §156.420(a).

Stand-alone dental plan means a plan offered through an Exchange under §155.1065 of this subchapter.

Standard plan means a QHP offered at one of the four levels of coverage, defined at §156.140, with an annual limitation on cost sharing that conforms to the requirements of §156.130(a). A standard plan at the bronze, silver, gold, or platinum level of coverage is referred to as a standard bronze plan, a standard silver plan, a standard gold plan, and a standard platinum plan, respectively.

Zero cost sharing plan variation means, with respect to a QHP at any level of coverage, the variation of such QHP described in §156.420(b)(1).

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 87 FR 27392, May 6, 2022]

§156.410 Cost-sharing reductions for enrollees.

(a) *General requirement.* A QHP issuer must ensure that an individual eligible for cost-sharing reductions, as demonstrated by assignment to a particular plan variation, pays only the cost sharing required of an eligible individual for the applicable covered service under the plan variation. The cost-sharing reduction for which an individual is eligible must be applied when the cost sharing is collected.

(b) *Assignment to applicable plan variation.* If an individual is determined to be eligible to enroll in a QHP in the individual market offered through an Exchange and elects to do so, the QHP issuer must assign the individual under enrollment and eligibility information submitted by the Exchange as follows—

(1) If the individual is determined eligible by the Exchange for cost-sharing reductions under §155.305(g)(2)(i), (ii), or (iii) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter) and chooses to enroll in a silver health plan, the QHP issuer must assign the individual to the silver plan variation of the selected silver health plan described in §156.420(a)(1), (2), or (3), respectively.

(2) If the individual is determined eligible by the Exchange for cost-sharing reductions for Indians with lower household income under §155.350(a) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the zero cost sharing plan variation of the selected QHP with all cost sharing eliminated described in §156.420(b)(1).

(3) If the individual is determined by the Exchange to be eligible for cost-sharing reductions for Indians regardless of household income under §155.350(b) of this subchapter (subject to the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the limited cost sharing plan variation of the selected QHP with the prohibition on cost sharing for benefits received from the Indian Health Service and certain other providers described in §156.420(b)(2).

(4) If the individual is determined by the Exchange not to be eligible for cost-sharing reductions (including eligibility under the special rule for family policies set forth in §155.305(g)(3) of this subchapter), and chooses to enroll in a QHP, the QHP issuer must assign the individual to the selected QHP with no cost-sharing reductions.

(c) *Improper cost-sharing reductions.* (1) If a QHP issuer fails to ensure that an individual assigned to a plan variation receives the cost-sharing reductions required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer must notify the enrollee of the improper application of any cost-sharing reduction within 45 calendar days of discovery of such improper application, and refund any resulting excess cost sharing paid by or for the enrollee as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper application.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund any remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(iii) If the excess cost sharing was not paid by the provider, and if a refund is requested by the enrollee, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

(2) If a QHP issuer provides an individual assigned to a plan variation greater cost-sharing reductions than required under the applicable plan variation, taking into account §156.425(b) concerning continuity of deductibles and out-of-pocket amounts (if applicable), then the QHP issuer will not be eligible for reimbursement of any excess cost-sharing reductions provided to the enrollee, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(d) *Improper assignment.* If a QHP issuer does not assign an individual to the applicable plan variation (or standard plan without cost-sharing reductions) in accordance with §§156.410(b) and 156.425(a) based on the eligibility and enrollment information or notification provided by the Exchange, then the QHP issuer must reassign the enrollee to the applicable plan variation (or standard plan without cost-sharing reductions) and notify the enrollee of the improper assignment such that:

(1) If the QHP issuer discovers the improper assignment between the first and fifteenth day of the month, the QHP issuer must reassign the enrollee to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the following month.

(2) If the QHP issuer discovers the improper assignment between the sixteen and the last day of the month, the QHP issuer must reassign the individual to the correct plan variation (or standard plan without cost-sharing reductions) by the first day of the second following month.

(3) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a more generous plan variation to a less generous plan variation of a QHP (or a standard plan without cost-sharing reductions), the QHP issuer will not be eligible for reimbursement for any of the excess cost-sharing reductions provided to the enrollee following the effective date of eligibility required by the Exchange, and may not seek reimbursement from the enrollee or the applicable provider for any of the excess cost-sharing reductions.

(4) If, pursuant to a reassignment under this paragraph (d), a QHP issuer reassigns an enrollee from a less generous plan variation (or a standard plan without cost-sharing reductions) to a more generous plan variation of a QHP, the QHP issuer must recalculate the enrollee's liability for cost sharing paid between the effective date of eligibility required by the Exchange and the date on which the issuer effectuated the change, and must refund any excess cost sharing paid by or for the enrollee during such period as follows:

(i) If the excess cost sharing was paid by the provider, the QHP issuer must refund the excess cost sharing to the provider within 45 calendar days of discovery of the improper assignment.

(ii) If the excess cost sharing was not paid by the provider and is not requested by the enrollee as a refund, the QHP issuer must, within 45 calendar days of discovery of the improper assignment, apply the excess cost sharing paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund the enrollee any remaining excess cost sharing paid by or for the enrollee within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(iii) If the excess cost sharing was not paid by the provider, then, if the enrollee requests a refund, the refund must be provided to the enrollee within 45 calendar days of the date of the request.

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 80 FR 10875, Feb. 27, 2015]

§ 156.420 Plan variations.

(a) *Submission of silver plan variations.* For each of its silver health plans that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit annually to the Exchange for certification prior to each benefit year the standard silver plan and three variations of the standard silver plan, as follows—

(1) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(i) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 94 percent plus or minus the de minimis variation for a silver plan variation;

(2) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(ii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 87 percent plus or minus the de minimis variation for a silver plan variation; and

(3) For individuals eligible for cost-sharing reductions under §155.305(g)(2)(iii) of this subchapter, a variation of the standard silver plan with:

(i) An annual limitation on cost sharing no greater than the reduced maximum annual limitation on cost sharing specified in the annual HHS guidance or notice of benefit and payment parameters for such individuals, and

(ii) Other cost-sharing reductions such that the AV of the silver plan variation is 73 percent plus or minus the de minimis variation for a silver plan variation (subject to §156.420(h)).

(b) *Submission of zero and limited cost sharing plan variations.* For each of its health plans at any level of coverage that an issuer offers, or intends to offer in the individual market on an Exchange, the issuer must submit to the Exchange for certification the health plan and two variations of the health plan, as follows—

(1) For individuals eligible for cost-sharing reductions under §155.350(a) of this subchapter, a variation of the health plan with all cost sharing eliminated; and

(2) For individuals eligible for cost-sharing reductions under §155.350(b) of this subchapter, a variation of the health plan with no cost sharing on any item or service that is an EHB furnished directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization (each as defined in 25 U.S.C. 1603), or through referral under contract health services.

(c) *Benefit and network equivalence in silver plan variations.* A standard silver plan and each silver plan variation thereof must cover the same benefits and providers. Each silver plan variation is subject to all requirements applicable to the standard silver plan (except for the requirement that the plan have an AV as set forth in §156.140(b)(2)).

(d) *Benefit and network equivalence in zero and limited cost sharing plan variations.* A QHP and each zero cost sharing plan variation or limited cost sharing plan variation thereof must cover the same benefits and providers. The out-of-pocket spending required of enrollees in the zero cost sharing plan variation of a QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the limited cost sharing plan variation of the QHP and the corresponding out-of-pocket spending required in the silver plan variation of the QHP for individuals eligible for cost-sharing reductions under §155.305(g)(2)(i) of this subchapter, in the case of a silver QHP. The out-of-pocket spending required of enrollees in the limited cost sharing plan variation of the QHP for a benefit that is not an essential health benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding out-of-pocket spending required in the QHP with no cost-sharing reductions. A limited cost sharing plan variation must have the same cost sharing for essential health benefits not described in paragraph (b)(2) of this section as the QHP with no cost-sharing reductions. Each zero cost sharing plan variation or limited cost sharing plan variation is subject to all requirements applicable to the QHP (except for the requirement that the plan have an AV as set forth in §156.140(b)).

(e) *Decreasing cost sharing and out-of-pocket spending in higher AV silver plan variations.* The cost sharing or out-of-pocket spending required of enrollees under any silver plan variation of a standard silver plan for a benefit from a provider (including a provider outside the plan's network) may not exceed the corresponding cost sharing or out-of-pocket spending required in the standard silver plan or any other silver plan variation thereof with a lower AV.

(f) *Minimum AV differential between 70 percent and 73 percent silver plan variations.* Notwithstanding any permitted de minimis variation in AV for a health plan or permitted de minimis variation for a silver plan variation, the AVs of a standard silver plan and the silver plan variation thereof described in paragraph (a)(3) of this section must differ by at least 2 percentage points.

(g) *Multi-state plans.* The U.S. Office of Personnel Management will determine the time and manner for multi-State plans, as defined in §155.1000(a) of this subchapter, to submit silver plan variations, zero cost sharing plan variations, and limited cost sharing plan variations.

(h) *Notice.* No later than November 1, 2015, for each plan variation that an issuer offers in accordance with the rules of this section, an issuer must provide a summary of benefits and coverage that accurately represents each plan variation consistent with the requirements set forth in §147.200 of this subchapter.

[78 FR 15535, Mar. 11, 2013, as amended at 79 FR 13840, Mar. 11, 2014; 80 FR 10875, Feb. 27, 2015; 86 FR 24292, May 5, 2021]

§156.425 Changes in eligibility for cost-sharing reductions.

(a) *Effective date of change in assignment.* If the Exchange notifies a QHP issuer of a change in an enrollee's eligibility for cost-sharing reductions (including a change in the individual's eligibility under the special rule for family policies set forth in §155.305(g)(3) of this subchapter due to a change in eligibility of another individual on the same policy), then the QHP issuer must change the individual's assignment such that the individual is assigned to the applicable standard plan or plan variation of the QHP as required under §156.410(b) as of the effective date of eligibility required by the Exchange.

(b) *Continuity of deductible and out-of-pocket amounts.* In the case of a change in assignment to a different plan variation (or standard plan without cost-sharing reductions) of the same QHP in the course of a benefit year under this section, the QHP issuer must ensure that any cost sharing paid by the applicable individual under previous plan variations (or standard plan without cost-sharing reductions) for that benefit year is taken into account in the new plan variation (or standard plan without cost-sharing reductions) for purposes of calculating cost sharing based on aggregate spending by the individual, such as for deductibles or for the annual limitations on cost sharing.

(c) *Notice upon assignment.* Beginning on January 1, 2016, if an individual's assignment to a standard plan or plan variation of the QHP changes in accordance with paragraph (a) of this section, the issuer must provide to that individual a summary of benefits and coverage that accurately reflects the new plan variation (or standard plan variation without cost-sharing reductions) in a manner consistent with §147.200 of this subchapter as soon as practicable following receipt of notice from the Exchange, but not later than 7 business days following receipt of notice.

[78 FR 15535, Mar. 11, 2013, as amended at 80 FR 10875, Feb. 27, 2015]

§156.430 Payment for cost-sharing reductions.

(a) [Reserved]

(b) *Advance payments for cost-sharing reductions.* (1) When there is an appropriation to make cost-sharing reduction payments to QHP issuers, a QHP issuer will receive periodic advance payments from HHS to the extent permitted by the appropriation and calculated in accordance with §155.1030(b)(3) of this subchapter.

(2) HHS may adjust the advance payment amount for a particular QHP during the benefit year if the QHP issuer provides evidence, certified by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies, that the advance payments for a particular QHP are likely to be substantially different than the cost-sharing reduction amounts that the QHP provides that will be reimbursed by HHS.

(c) *Submission of actual amounts*—(1) *General.* For each plan variation that a QHP issuer offers on the Exchange, it must submit to HHS, in the manner and timeframe established by HHS, for each policy, the total allowed costs for essential health benefits charged for the policy for the benefit year, broken down by all of the following:

(i) The amount the issuer paid.

(ii) The amount the enrollee(s) paid.

(iii) The amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions.

(2) *Standard methodology.* A QHP issuer must calculate the value of the amount the enrollee(s) would have paid under the standard plan without cost-sharing reductions by applying the actual cost-sharing requirements for the standard plan to the allowed costs for essential health benefits under the enrollee's policy for the benefit year.

(i) For reconciliation of cost-sharing reduction amounts advanced for the

2014 and 2015 benefit years, an issuer of a QHP using the standard or simplified methodology may calculate claims amounts attributable to EHB, including cost sharing amounts attributable to EHB, by reducing total claims amounts by the plan-specific percentage estimate of non-essential health benefit claims submitted on the Uniform Rate Review Template for the corresponding benefit year, if the following conditions are met:

(A) The non-essential health benefits percentage estimate is less than 2 percent; and

(B) Out-of-pocket expenses for non-EHB benefits are included in the calculation of amounts subject to a deductible or annual limitation on cost sharing, but copayments and coinsurance rates on non-EHB benefits are not reduced under the plan variation.

(ii) [Reserved]

(3) *Selection of methodology.* For benefit years 2014 through 2016, notwithstanding paragraph (c)(2) of this section, a QHP issuer may choose to calculate the amounts that would have been paid under the standard plan without cost-sharing reductions using the simplified methodology described in paragraph (c)(4) of this section.

(i) The QHP issuer must notify HHS prior to the start of each benefit year, in the manner and timeframe established by HHS, whether or not it selects the simplified methodology for the benefit year.

(ii) If the QHP issuer selects the simplified methodology, it must apply the simplified methodology to all plan variations it offers on the Exchange for a benefit year.

(iii) The QHP issuer may not select the simplified methodology for a benefit year if the QHP issuer did not select the simplified methodology for the prior benefit year.

(iv) Notwithstanding paragraphs (c)(3)(ii) and (iii) of this section, if a QHP issuer merges with or acquires another issuer of a QHP on the Exchange, or acquires a QHP offered on the Exchange from another QHP issuer, and if one, but not all, of the merging, acquiring, or acquired parties had selected the simplified methodology for the benefit year, then for the benefit year in which the merger or acquisition took place, the QHP issuer must calculate the amounts that would have been paid using the methodology (whether the standard methodology described in paragraph (c)(2) of this section or the simplified methodology described in paragraph (c)(4) of this section) selected with respect to the plan variation prior to the start of the benefit year (even if the selection was not made by that QHP issuer). For the next benefit year (if such benefit year is 2015 or 2016), the QHP issuer may select the simplified methodology (subject to paragraph (c)(3)(ii) of this section but, for that benefit year, not paragraph (c)(3)(iii) of this section) or the standard methodology.

(4) *Simplified methodology.* Subject to paragraph (c)(4)(v) of this section, a QHP issuer that selects the simplified methodology described in this paragraph (c)(4) must calculate the amount that the enrollees would have paid under the standard plan without cost-sharing reductions for each policy that was assigned to a plan variation for any portion of the benefit year by applying each set of the standard plan's effective cost-sharing parameters (as calculated under paragraphs (c)(3)(ii) and (iii) of this section) to the corresponding subgroup of total allowed costs for EHB for the policy (as described in paragraph (c)(4)(i) of this section).

(i) For plan variation policies with total allowed costs for EHB for the benefit year that are:

(A) Less than or equal to the effective deductible, the amount that the enrollees would have paid under the standard plan is equal to the total allowed costs for EHB under the policy for the benefit year multiplied by the effective pre-deductible coinsurance rate.

(B) Greater than the effective deductible but less than the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the sum of (x) the average deductible, plus (y) the effective non-deductible cost sharing, plus (z) the difference, if positive, between the total allowed costs under the policy for

the benefit year for EHB that are subject to a deductible and the average deductible, multiplied by the effective post-deductible coinsurance rate.

(C) Greater than or equal to the effective claims ceiling, the amount that the enrollees would have paid under the standard plan is equal to the annual limitation on cost sharing for the standard plan (as defined at 45 CFR 156.400), or, at the QHP issuer's election on a policy-by-policy basis, the amount calculated pursuant to the standard methodology described in paragraph (c)(2) of this section,

(ii) The QHP issuer must calculate one or more sets of effective cost-sharing parameters, as described in paragraph (c)(4)(iii) of this section, based on policies assigned to the standard plan without cost-sharing reductions for the entire benefit year and must separately apply each set of effective cost-sharing parameters to the corresponding subgroup of total allowed costs for EHB for each plan variation policy, as described in paragraph (c)(4)(i) of this section, as follows:

(A) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, but does not have separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the costs of enrollees in the standard plan with self-only coverage, and based on the costs of enrollees in the standard plan with other than self-only coverage.

(B) If the standard plan has separate cost-sharing parameters for pharmaceutical and medical services, but does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of the enrollees in the standard plan, and based on the pharmaceutical costs of the enrollees in the standard plan.

(C) If the standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, and also has separate cost-sharing parameters for pharmaceutical and medical services, the QHP issuer must calculate and apply separate sets of effective cost-sharing parameters based on the medical costs of enrollees in the standard plan with self-only coverage, based on the pharmaceutical costs of enrollees in the standard plan with self-only coverage, based on the medical costs of enrollees in the standard plan with other than self-only coverage, and based on the pharmaceutical costs of enrollees in the standard plan with other than self-only coverage.

(iii) The effective cost-sharing parameters for the standard plan without cost-sharing reductions must be calculated based on policies assigned to the standard plan for the entire benefit year for each of the required subgroups under paragraph (c)(4)(ii) of this section as follows:

(A) If the standard plan has only one deductible (for the applicable subgroup), the average deductible of the standard plan is that deductible amount. If the standard plan has more than one deductible (for the applicable subgroup), the average deductible is the weighted average of the deductibles, weighted by allowed costs for EHB under the standard plan for the benefit year that are subject to each separate deductible. Services that are not subject to any deductible (including services subject to copayments or coinsurance but not any deductible) are not to be incorporated into the calculation of the average deductible.

(B) The effective non-deductible cost sharing for the applicable subgroup is the average portion of total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year incurred for standard plan enrollees and payable by the enrollees as cost sharing. The effective non-deductible cost sharing must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(C) The effective deductible for the applicable subgroup is equal to the sum of the average deductible and the average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year.

The average total allowed costs for EHB that are not subject to any deductible for the standard plan for the benefit year must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the average deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(D) The effective pre-deductible coinsurance rate for the applicable subgroup is the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing. The effective pre-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are less than or equal to the effective deductible.

(E) The effective post-deductible coinsurance rate for the applicable subgroup is the quotient of (x) the portion of average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and payable by the enrollees as cost sharing other than through a deductible, over the difference of (y) the average allowed costs for EHB subject to a deductible incurred for enrollees for the benefit year, and (z) the average deductible. The effective post-deductible coinsurance rate must be calculated based only on standard plan policies with total allowed costs for EHB for the benefit year that are above the effective deductible but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(F) The effective claims ceiling for the applicable subgroup is calculated as the effective deductible plus the quotient of (x) the difference between the annual limitation on cost sharing and the sum of the average deductible and the effective non-deductible cost sharing, divided by (y) the effective post-deductible coinsurance rate.

(iv) If a QHP issuer uses the simplified methodology described in this paragraph (c)(4), and the QHP issuer's standard plan does not meet any of the criteria in paragraphs (c)(4)(v)(A) through (D) of this section, the QHP issuer must also submit to HHS, in the manner and timeframe established by HHS, the following information for each standard plan offered by the QHP issuer in the individual market through the Exchange for each of the required subgroups described in paragraph (c)(4)(ii) of this section:

(A) The average deductible for each applicable subgroup;

(B) The effective deductible for each applicable subgroup;

(C) The effective non-deductible cost sharing amount for each applicable subgroup;

(D) The effective pre-deductible coinsurance rate for each applicable subgroup;

(E) The effective post-deductible coinsurance rate for each applicable subgroup;

(F) The effective claims ceiling for each applicable subgroup; and

(G) A memorandum developed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies that describes how the QHP issuer calculated the effective cost-sharing parameters for each applicable subgroup for the standard plan.

(v) Notwithstanding paragraphs (c)(4)(i) through (iii) of this section, if a QHP issuer's standard plan meets the criteria in any of the following subparagraphs, and the QHP issuer has selected the simplified methodology described in this paragraph (c)(4), then the QHP issuer must calculate the amount that the enrollees in the plan variation would have paid under the standard plan without cost-sharing reductions as the lesser of the annual limitation on cost sharing for the standard plan or the amount equal to the product of, (x) one minus the standard plan's actuarial value, as calculated under 45 CFR 156.135, and (y) the total allowed costs for EHB for the benefit year under each policy that was assigned to a plan variation for any portion of the benefit year.

(A) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage, does not have separate cost-sharing parameters for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for

coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories –

(1) Self-only coverage; or

(2) Other than self-only coverage.

(B) The standard plan has separate cost-sharing parameters for pharmaceutical and medical services, does not have separate cost-sharing parameters for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in either of the following categories:

(1) Coverage of medical services; or

(2) Coverage of pharmaceutical services.

(C) The standard plan has separate cost-sharing parameters for self-only coverage and other than self-only coverage and for pharmaceutical and medical services, and has an enrollment during the benefit year of fewer than 12,000 member months for coverage with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing, in any of the following categories:

(1) Self-only coverage of medical services;

(2) Self-only coverage of pharmaceutical services;

(3) Other than self-only coverage of medical services; or

(4) Other than self-only coverage of pharmaceutical services.

(D) The standard plan does not have separate cost-sharing parameters for pharmaceutical and medical services, or for self-only coverage and other than self-only coverage, and has an enrollment during the benefit year of fewer than 12,000 member months with total allowed costs for EHB for the benefit year that are greater than the effective deductible, but for which associated cost sharing for EHB is less than the annual limitation on cost sharing.

(vi) Notwithstanding paragraphs (c)(4)(i)(A) and (B) of this section, and paragraphs (c)(4)(iii)(A) through (E) of this section, if more than eighty percent of the total allowed costs for EHB for the benefit year under a standard plan for a subgroup that requires a separate set of effective cost-sharing parameters pursuant to paragraph (c)(4)(ii) are not subject to a deductible, then:

(A) The average deductible, the effective non-deductible cost sharing, and the effective deductible for the subgroup equal zero;

(B) The effective pre-deductible coinsurance rate for the subgroup is equal to the effective post-deductible coinsurance rate for the subgroup, which is determined based on all standard plan policies for the applicable subgroup for which associated cost sharing for EHB is less than the annual limitation on cost sharing, and calculated for the applicable subgroup as the proportion of the total allowed costs for EHB under the standard plan for the benefit year incurred for standard plan enrollees and payable as cost sharing (including cost sharing payable through a deductible); and

(C) The amount that enrollees in the applicable subgroup in plan variation policies with total allowed costs for EHB for the benefit year that are less than the effective claims ceiling would have paid under the standard plan must be calculated using the formula in paragraph (c)(4)(i)(A).

(5) *Reimbursement of providers.* In the case of a benefit for which the QHP issuer compensates an applicable provider in whole or in part on a fee-for-service basis, allowed costs associated with the benefit may be included in the calculation of the amount that an enrollee(s) would have paid under the standard plan without cost-sharing reductions only to the extent the amount was either payable by the enrollee(s) as cost sharing under the plan variation or was reimbursed to the provider by the QHP issuer.

(d) *Cost-sharing reductions data submissions.* HHS will periodically provide

a submission window for issuers to submit cost-sharing reduction data documenting cost-sharing reduction amounts issuers paid, as specified in paragraphs (d)(1) and (2) of this section, in a form and manner specified by HHS in guidance, calculated in accordance with paragraph (c) of this section. When HHS makes cost-sharing reduction payments to QHP issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is mandatory for those issuers having received cost-sharing reduction payments for any part of the benefit year and voluntary for other issuers, and HHS will use the data to reconcile advance cost-sharing reduction payments to issuers against the actual amounts of cost-sharing reductions QHP issuers provided, as determined by HHS based on amounts specified in paragraphs (d)(1) and (2) of this section, as calculated in accordance with paragraph (c) of this section. In the absence of an appropriation to make cost-sharing reduction payments to issuers, HHS will notify QHP issuers that the submission of the cost-sharing data is voluntary. The cost-sharing data that must be submitted in either a voluntary or mandatory submission includes:

(1) The actual amount of cost-sharing reductions provided to enrollees and reimbursed to providers by the QHP issuer for benefits for which the QHP issuer compensates the applicable providers in whole or in part on a fee-for-service basis; and

(2) The actual amount of cost-sharing reductions provided to enrollees for benefits for which the QHP issuer compensates the applicable providers in any other manner.

(e) *Cost-sharing reductions payments and charges.* If the actual amounts of cost-sharing reductions determined by HHS based on amounts described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments HHS provided, and the QHP issuer has timely provided the data of actual amounts of cost-sharing reductions as required under paragraph (c) of this section, if an appropriation is available to make cost-sharing payments to QHP issuers, HHS will make a payment to the QHP issuer for the difference; or

(2) Less than the amount of advance payments provided, the QHP issuer must repay the difference to HHS in the manner and timeframe specified by HHS.

(f) *Cost-sharing reductions during special periods.* (1) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will not be eligible for reimbursement of any cost-sharing reductions provided following a termination of coverage effective date with respect to a grace period as described in §155.430(b)(2)(ii)(A) or (B) of this subchapter. However, the QHP issuer will be eligible for reimbursement of cost-sharing reductions provided prior to the termination of coverage effective date. Advance payments of cost-sharing reductions will be paid to a QHP issuer prior to a determination of termination (including during any grace period, but the QHP issuer will be required to repay any advance payments made with respect to any month after any termination of coverage effective date during a grace period).

(2) Notwithstanding the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the termination (or the late determination thereof) is the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will not be eligible for advance payments and reimbursement for cost-sharing reductions provided during the period following the termination of coverage effective date and prior to the determination of the termination.

(3) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, if the termination of coverage effective date is prior to the determination of termination other than in the circumstances described in paragraph (f)(1) of this section, and if the reason for the termination (or late determination thereof)

is not the fault of the QHP issuer, as reasonably determined by the Exchange, the QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during such period.

(4) Subject to the requirements of the cost-sharing reduction reconciliation process described in paragraphs (c) through (e) of this section, a QHP issuer will be eligible for advance payments and reimbursement for cost-sharing reductions provided during any period of coverage pending resolution of inconsistencies in information required to determine eligibility for enrollment under §155.315(f) of this subchapter.

(g) *Prohibition on reduction in payments to Indian health providers.* If an Indian is enrolled in a QHP in the individual market through an Exchange and is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or through referral under contract health services, the QHP issuer may not reduce the payment to any such entity for such item or service by the amount of any cost sharing that would be due from the Indian but for the prohibitions on cost sharing set forth in §156.410(b)(2) and (3).

(h) *Reconciliation of the cost-sharing reduction portion of advance payments discrepancies and appeals.* (1) If an issuer reports a discrepancy and seeks to dispute the notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments, it must report the discrepancy to HHS within 30 calendar days of notification of the amount of reconciliation of the cost-sharing reduction portion of advance payments as described in paragraph (e) of this section, in the manner set forth by HHS.

(2) An issuer may appeal the amount of reconciliation of the cost-sharing reduction portion of advance payments, under the process set forth in §156.1220.

[78 FR 15535, 15555, Mar. 11, 2013, as amended at 78 FR 65097, Oct. 30, 2013; 79 FR 13840, Mar. 11, 2014; 80 FR 10875, Feb. 27, 2015; 81 FR 94181, Dec. 22, 2016; 87 FR 27392, May 6, 2022]

§156.440 Plans eligible for advance payments of the premium tax credit and cost-sharing reductions.

Except as noted in paragraph (a) through (c) of this section, the provisions of this subpart apply to qualified health plans offered in the individual market on the Exchange.

(a) *Catastrophic plans.* The provisions of this subpart do not apply to catastrophic plans described in §156.155.

(b) *Stand-alone dental plans.* The provisions of this subpart, to the extent relating to cost-sharing reductions, do not apply to stand-alone dental plans. The provisions of this subpart, to the extent relating to advance payments of the premium tax credit, apply to stand-alone dental plans.

(c) *Child-only plans.* The provisions of this subpart apply to child-only QHPs, described in §156.200(c)(2).

§156.460 Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.

(a) *Reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* A QHP issuer that receives notice from the Exchange that an individual enrolled in the issuer's QHP is eligible for an advance payment of the premium tax credit must—

(1) Reduce the portion of the premium charged to or for the individual for the applicable month(s) by the amount of the advance payment of the premium tax credit;

(2) Notify the Exchange of the reduction in the portion of the premium charged to the individual in accordance with §156.265(g); and

(3) Include with each billing statement, as applicable, to or for the individual the amount of the advance payment of the premium tax credit for the applicable month(s), and the remaining premium owed.

(b) *Delays in payment.* A QHP issuer may not refuse to commence coverage under a policy or terminate coverage on account of any delay in payment of an advance payment of the premium tax credit on behalf of an enrollee if the QHP issuer has been notified by the

Exchange under § 155.340(a) of this subchapter that the QHP issuer will receive such advance payment.

(c) *Refunds to enrollees for improper reduction of enrollee's share of premium to account for advance payments of the premium tax credit.* If a QHP issuer discovers that it did not reduce the portion of the premium charged to or for an enrollee for the applicable month(s) by the amount of the advance payment of the premium tax credit in accordance with paragraph (a)(1) of this section, the QHP issuer must notify the enrollee of the improper reduction within 45 calendar days of the QHP issuer's discovery of the improper reduction and refund any excess premium paid by or for the enrollee, as follows:

(1) Unless a refund is requested by or for the enrollee, the QHP issuer must, within 45 calendar days of discovery of the error, apply the excess premium paid by or for the enrollee to the enrollee's portion of the premium (or refund the amount directly). If any excess premium remains, the QHP issuer must apply the excess premium to the enrollee's portion of the premium for each subsequent month for the remainder of the period of enrollment or benefit year until the excess is fully applied (or refund the remaining amount directly). If any excess premium remains at the end of the period of enrollment or benefit year, the QHP issuer must refund any excess premium within 45 calendar days of the end of the period of enrollment or benefit year, whichever comes first.

(2) If a refund is requested by or for the enrollee, the refund must be provided within 45 calendar days of the date of the request.

[78 FR 15535, Mar. 11, 2013, as amended at 78 FR 65100, Oct. 30, 2013]

§ 156.470 Allocation of rates for advance payments of the premium tax credit.

(a) *Allocation to additional health benefits for QHPs.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each health plan at any level of coverage offered, or intended to be offered, in the individual market on an Exchange, an allocation of the rate for the plan to:

(1) EHB, other than services described in § 156.280(d)(1); and

(2) Any other services or benefits offered by the health plan not described in paragraph (a)(1) of this section.

(b) *Allocation to additional health benefits for stand-alone dental plans.* An issuer must provide to the Exchange annually for approval, in the manner and timeframe established by HHS, for each stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange, a dollar allocation of the expected premium for the plan, to:

(1) The pediatric dental essential health benefit, and

(2) Any benefits offered by the stand-alone dental plan that are not the pediatric dental essential health benefit.

(c) *Allocation standards for QHPs.* The issuer must ensure that the allocation described in paragraph (a) of this section—

(1) Is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies;

(2) Reasonably reflects the allocation of the expected allowed claims costs attributable to EHB (excluding those services described in § 156.280(d)(1));

(3) Is consistent with the allocation applicable to State-required benefits to be submitted by the issuer under § 155.170(c) of this subchapter, and the allocation requirements described in § 156.280(e)(4) for certain services; and

(4) Is calculated under the fair health insurance premium standards described at 45 CFR 147.102, the single risk pool standards described at 45 CFR 156.80, and the same premium rate standards described at 45 CFR 156.255.

(d) *Allocation standards for stand-alone dental plans.* The issuer must ensure that the dollar allocation described in paragraph (b) of this section is performed by a member of the American Academy of Actuaries in accordance with generally accepted actuarial principles and methodologies.

(e) *Disclosure of attribution and allocation methods.* An issuer of a health plan at any level of coverage or a stand-alone dental plan offered, or intended to be offered, in the individual market on the Exchange must submit to the

Exchange annually for approval, an actuarial memorandum, in the manner and timeframe specified by HHS, with a detailed description of the methods and specific bases used to perform the allocations set forth in paragraphs (a) and (b), and demonstrating that the allocations meet the standards set forth in paragraphs (c) and (d) of this section, respectively.

(f) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must submit the allocations and actuarial memorandum described in this section to the U.S. Office of Personnel Management, in the time and manner established by the U.S. Office of Personnel Management.

[78 FR 15535, Mar. 11, 2013, as amended at 79 FR 13840, Mar. 11, 2014]

§156.480 Oversight of the administration of the advance payments of the premium tax credit, cost-sharing reductions, and user fee programs.

(a) *Maintenance of records.* An issuer that offers a QHP in the individual market through a State Exchange must adhere to, and ensure that any relevant delegated entities and downstream entities adhere to, the standards set forth in §156.705 concerning maintenance of documents and records, whether paper, electronic, or in other media, by issuers offering QHPs in a Federally-facilitated Exchange, in connection with cost-sharing reductions and advance payments of the premium tax credit.

(b) *Annual reporting requirements.* For each benefit year, an issuer that offers a QHP in the individual market through an Exchange must report to HHS, in the manner and timeframe required by HHS, summary statistics specified by HHS with respect to administration of cost-sharing reduction and advance payments of the premium tax credit programs, including any failure to adhere to the standards set forth under §§156.410(a) through (d), 156.425(a) through (b), and 156.460(a) through (c) of this part.

(c) *Audits and compliance reviews.* HHS or its designee may audit or conduct a compliance review of an issuer offering a QHP through an Exchange to assess its compliance with the applicable requirements of this subpart and 45 CFR 156.50. Compliance reviews conducted under this section will follow the standards set forth in §156.715.

(1) *Notice of audit.* HHS will provide at least 30 calendar days advance notice of its intent to conduct an audit of an issuer under this section.

(i) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(ii) [Reserved]

(2) *Compliance with audit activities.* To comply with an audit under this section, the issuer must:

(i) Ensure that its relevant employees, agents, contractors, subcontractors, downstream entities, and delegated entities cooperate with any audit or compliance review under this section;

(ii) Submit complete and accurate data to HHS or its designees that is necessary to complete the audit, in the format and manner specified by HHS, no later than 30 calendar days after the initial audit response deadline established by HHS at the entrance conference described under paragraph (c)(1)(i) of this section for the applicable benefit year;

(iii) Respond to all audit notices, letters, and inquiries, including requests for supplemental or supporting information, as requested by HHS, no later than 15 calendar days after the date of the notice, letter, request, or inquiry; and

(iv) In circumstances in which an issuer cannot provide the requested data or response to HHS within the timeframes under paragraph (c)(2)(ii) or (iii) of this section, as applicable, the issuer may make a written request for an extension to HHS. The extension request must be submitted within the timeframe established under paragraph (c)(2)(ii) or (iii), as applicable, and must detail the reason for the extension request and the good cause in support of the request. If the extension is granted, the issuer must respond within the timeframe specified in HHS's notice granting the extension of time.

(3) *Preliminary audit findings.* HHS will share its preliminary audit findings with the issuer, who will then have 30 calendar days to respond to

such findings in the format and manner specified by HHS.

(i) If the issuer does not dispute or otherwise respond to the preliminary findings, the audit findings will become final.

(ii) If the issuer responds and disputes the preliminary findings, HHS will review and consider such response and finalize the audit findings after such review.

(4) *Final audit findings.* If an audit results in the inclusion of a finding in the final audit report, the issuer must comply with the actions set forth in the final audit report in the manner and timeframe established by HHS, and the issuer must complete all of the following:

(i) Within 45 calendar days of the issuance of the final audit or compliance review report, provide a written corrective action plan to HHS for approval.

(ii) Implement that plan.

(iii) Provide to HHS written documentation of the corrective actions once taken.

(5) *Failure to comply with audit activities.* If an issuer fails to comply with the audit activities set forth in this section in the manner and timeframes specified by HHS:

(i) HHS will notify the issuer of payments received under this subpart that the issuer has not adequately substantiated; and

(ii) HHS will notify the issuer that HHS may recoup any payments identified in paragraph (c)(5)(i) of this section.

(6) *Circumstances requiring HHS enforcement.* If HHS determines that the State Exchange or State-based Exchange on the Federal platform is not enforcing or fails to substantially enforce the requirements of this subpart or § 156.50, then HHS may do so and may pursue the imposition of civil money penalties as specified in § 156.805 for non-compliance by QHP issuers participating in the State Exchange or State Exchange on the Federal platform.

[78 FR 65100, Oct. 30, 2013, as amended at 86 FR 24292, May 5, 2021]

Subpart F—Consumer Operated and Oriented Plan Program

§ 156.500 Basis and scope.

This subpart implements section 1322 of the Affordable Care Act by establishing the Consumer Operated and Oriented Plan (CO–OP) program to foster the creation of new consumer-governed, private, nonprofit health insurance issuers, known as ''CO–OPs.'' Under this program, loans are awarded to encourage the development of CO–OPs. Applicants that meet the eligibility standards of the CO–OP program may apply to receive loans to help fund start-up costs and meet the solvency requirements of States in which the applicant seeks to be licensed to issue CO–OP qualified health plans. This subpart sets forth the eligibility and governance requirements for the CO–OP program, CO–OP standards, and the terms for loans awarded under the CO–OP program.

§ 156.505 Definitions.

The following definitions apply to this subpart:

Applicant means an entity eligible to apply for a loan described in § 156.520 of this subpart.

Consumer operated and oriented plan (CO–OP) means a loan recipient that satisfies the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the timeframes specified in this subpart.

CO–OP qualified health plan means a health plan that has in effect a certification that it meets the standards described in subpart C of this part, except that the plan can be deemed certified by CMS or an entity designated by CMS as described in § 156.520(e).

Exchange has the meaning given to the term in § 155.20 of this subchapter.

Formation board means the initial board of directors of the applicant or loan recipient before it has begun accepting enrollment and had an election by the members of the organization to the board of directors.

Individual market has the meaning given to the term in § 155.20 of this subchapter.

Issuer has the meaning given to the term in § 155.20 of this subchapter.

Member means an individual covered under health insurance policies issued by a loan recipient.

Nonprofit member organization or *nonprofit member corporation* means a nonprofit, not-for-profit, public benefit, or similar membership entity organized as appropriate under State law.

Operational board means the board of directors elected by the members of the loan recipient after it has begun accepting enrollment.

Predecessor, with respect to a new entity, means any entity that participates in a merger, consolidation, purchase or acquisition of property or stock, corporate separation, or other similar business transaction that results in the formation of the new entity.

Pre-existing issuer means a health insurance issuer licensed by a State regulator that marketed individual or group health insurance benefit plans (other than Medicare or Medicaid Managed Care plans) on July 16, 2009.

Qualified nonprofit health insurance issuer means an entity that satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and §156.515 of this subpart within the time frames specified in this subpart, until such time as CMS determines the entity does not satisfy or cannot reasonably be expected to satisfy these standards.

Related entity means an entity that shares common ownership, control, or governance structure (including management team or Board members) with a pre-existing issuer, and satisfies at least one of the following conditions:

(1) Retains responsibilities for the services to be provided by the issuer.

(2) Furnishes services to the issuer's enrollees under an oral or written agreement.

(3) Performs some of the issuer's management functions under contract or delegation.

Representative means an officer, director, or trustee of an organization, or group of organizations; or a senior executive or high-level representative of the Federal government, or a State or local government or a sub-unit thereof.

SHOP has the meaning given to the term in §155.20 of this subchapter.

Small group market has the meaning given to the term in §155.20 of this subchapter.

Solvency Loan means a loan provided by CMS to a loan recipient in order to meet State solvency and reserve requirements.

Sponsor means an organization or individual that is involved in the development, creation, or organization of the CO–OP or provides 40 percent or more in total funding to a CO–OP (excluding any loans received from the CO–OP Program).

Start-up Loan means a loan provided by CMS to a loan recipient for costs associated with establishing a CO–OP.

State has the meaning given to the term in §155.20 of this subchapter.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012; 81 FR 29155, May 11, 2016; 81 FR 94181, Dec. 22, 2016]

§ 156.510 Eligibility.

(a) *General.* In addition to the eligibility standards set forth in the CO–OP program Funding Opportunity Announcement (FOA), to be eligible to apply for and receive a loan under the CO–OP program, an organization must intend to become a CO–OP and be a nonprofit member organization.

(b) *Exclusions from eligibility.* (1) Subject to paragraph (b)(2) of this section, an organization is not eligible to apply for a loan if:

(i) The organization or a sponsor of the organization is a pre-existing issuer, a holding company (an organization that exists primarily to hold stock in other companies) that controls a pre-existing issuer, a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, a foundation established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity;

(ii) The organization receives 25 percent or more of its total funding (excluding any loans received from the CO–OP Program) from pre-existing issuers, holding companies (organizations that exists primarily to hold stock in other companies) that control pre-existing issuers, trade associations comprised of pre-existing issuers and

whose purpose is to represent the interests of the health insurance industry, foundations established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity; or

(iii) A State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision is a sponsor of the organization. The organization receives 40 percent or more of its total funding (excluding any loans received from the CO–OP Program) from a State or local government, any political subdivision thereof, or any instrumentality of such a government or political subdivision.

(2) The exclusions in paragraphs (b)(1)(i) and (b)(1)(ii) of this section do not exclude from eligibility an applicant that:

(i) Has as a sponsor a nonprofit, not-for-profit, public benefit, or similarly organized entity that is also a sponsor for a pre-existing issuer but is not an issuer, a foundation established by a pre-existing issuer, a holding company that controls a pre-existing issuer, or a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, provided that the pre-existing issuer sponsored by the nonprofit organization does not share any of its board or the same chief executive with the applicant; or

(ii) Has purchased assets from a pre-existing issuer provided that it is an arm's-length transaction where each party acts independently and has no other relationship with the other party.

(3) The exclusion of any instrumentality of a State or local government in paragraph (b)(1)(iii) of this section does not exclude from eligibility or sponsorship an organization that:

(i) Is not a government organization under State law;

(ii) Has no employee of a State or local government serving in his or her official capacity as a senior executive (for example, President, Chief Executive Officer, or Chief Financial Officer) for the organization; and

(iii) Has a board of directors on which fewer than half of its directors are employees of a State or local government serving in their official capacities.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

§ 156.515 CO–OP standards.

(a) *General.* A CO–OP must satisfy the standards in this section in addition to all other statutory, regulatory, or other requirements.

(b) *Governance requirements.* A CO–OP must meet the following governance requirements:

(1) *Member control.* A CO–OP must implement policies and procedures to foster and ensure member control of the organization. Accordingly, a CO–OP must meet the following requirements:

(i) The CO–OP must be governed by an operational board with a majority of directors elected by a majority vote of a quorum of the CO–OP's members that are age 18 or older;

(ii) All members age 18 or older must be eligible to vote for each of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section;

(iii) Each member age 18 or older must have one vote in each election for each director subject to a vote of the members under paragraph (b)(1)(i) of this section in that election;

(iv) The first elected directors of the organization's operational board must be elected no later than one year after the effective date on which the organization provides coverage to its first member; the entire operational board must be elected or in place, and in full compliance with paragraph (b)(1)(i) of this section, no later than two years after the same date;

(v) Elections of the directors on the organization's operational board subject to a vote of the members under paragraph (b)(1)(i) of this section must be contested so that the total number of candidates for contested seats on the operational board exceeds the number of contested seats for such directors, except in cases where a seat is vacated mid- term due to death, resignation, or removal.

(2) *Standards for board of directors.* The operational board for a CO–OP must meet the following standards:

(i) Each director must meet ethical, conflict-of-interest, and disclosure standards;

(ii) Each director has one vote;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions); and

(iv) [Reserved]

(v) *Limitation on government and issuer participation.* No representative of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of any organization described in §156.510(b)(1)(i) (in the case of a representative of a State or local government or organization described in §156.510(b)(1)(i), with respect to a State in which the CO–OP issues policies), may serve on the CO–OP's formation board or as a director on the organization's operational board.

(3) *Ethics and conflict of interest protections.* The CO–OP must have governing documents that incorporate ethics, conflict of interest, and disclosure standards. The standards must protect against insurance industry involvement and interference. In addition, the standards must ensure that each director acts in the sole interest of the CO–OP, its members, and its local geographic community as appropriate, avoids self dealing, and acts prudently and consistently with the terms of the CO–OP's governance documents and applicable State and Federal law. At a minimum, these standards must include:

(i) A mechanism to identify potential ethical or other conflicts of interest;

(ii) A duty on the CO–OP's executive officers and directors to disclose all potential conflicts of interest;

(iii) A process to determine the extent to which a conflict exists;

(iv) A process to address any conflict of interest; and

(v) A process to be followed in the event a director or executive officer of the CO–OP violates these standards.

(4) *Consumer focus.* The CO–OP must operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

(c) *Standards for health plan issuance.* A CO–OP must meet several standards for the issuance of health plans in the individual and small group market.

(1) At least two-thirds of the policies or contracts for health insurance coverage issued by a CO–OP in each State in which it is licensed must be CO–OP qualified health plans offered in the individual and small group markets.

(2) Loan recipients must offer a CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in every individual market Exchange that serves the geographic regions in which the organization is licensed and intends to provide health care coverage. If offering at least one plan in the small group market, loan recipients must offer a CO–OP qualified health plan at both the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in each SHOP that serves the geographic regions in which the organization offers coverage in the small group market.

(3) Within the earlier of thirty-six months following the initial drawdown of the Start-up Loan or one year following the initial drawdown of the Solvency Loan, loan recipients must be licensed in a State and offer at least one CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the individual market Exchanges and if the loan recipient offers coverage in the small group market, at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the SHOPs. Loan recipients may only begin offering plans and accepting enrollment in the Exchanges for new CO–OP qualified health plans during the open enrollment period for each applicable Exchange.

(d) *Requirement to become a CO–OP.* Loan recipients must meet the standards of §156.515 no later than five years following initial drawdown of the Start-up Loan or three years following the initial drawdown of a Solvency Loan.

[76 FR 77411, Dec. 13, 2011, as amended at 81 FR 29155, May 11, 2016; 81 FR 94182, Dec. 22, 2016]

§ 156.520 Loan terms.

(a) *Overview of Loans.* Applicants may apply for the following loans under this section: Start-up Loans and Solvency Loans.

(1) *Use of loans.* All loans awarded under this subpart must be used in a manner that is consistent with the FOA, the loan agreement, and all other statutory, regulatory, or other requirements.

(2) *Solvency loans.* Solvency Loans awarded under this section will be structured in a manner that ensures that the loan amount is recognized by State insurance regulators as contributing to the State-determined reserve requirements or other solvency requirements (rather than debt) consistent with the insurance regulations for the States in which the loan recipient will offer a CO–OP qualified health plan.

(b) *Repayment period.* The loan recipient must make loan payments consistent with the approved repayment schedule in the loan agreement until the loan is paid in full consistent with State reserve requirements, solvency regulations, and requisite surplus note arrangements. Subject to their ability to meet State reserve requirements, solvency regulations, or requisite surplus note arrangements, the loan recipient must repay its loans and, if applicable, penalties within the repayment periods in paragraphs (b)(1), (b)(2), or (b)(3) of this section.

(1) The contractual repayment period for Start-up Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 5 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(2) The contractual repayment period for Solvency Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 15 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(3) Changes to the loan terms, including the repayment periods, may be executed if CMS determines that the loan recipient is unable to repay the loans as a result of State reserve requirements, solvency regulations, or requisite surplus note arrangements or without compromising coverage stability, member control, quality of care, or market stability. In the case of a loan modification or workout, the repayment period for loans awarded under this subpart is the repayment period established in the loan modification or workout. The revised terms must meet all other regulatory, statutory, and other requirements.

(c) *Interest rates.* Loan recipients will be charged interest for the loans awarded under this subpart. Interest will be accrued starting from the date of drawdown on the loan amounts that have been drawn down and not yet repaid by the loan recipient. The interest rate will be determined based on the date of award.

(1) *Start-up Loans.* Consistent with the terms of the loan agreement, the interest rate for Start-up Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus one percentage point or zero percent. If the loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(2) *Solvency Loans.* Consistent with the terms of the loan agreement, the interest rate for Solvency Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus two percentage points or zero percent. If a loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(3) *Penalty payment.* If CMS terminates a loan recipient's loan agreement because the loan recipient is not in compliance with program rules or the terms of its loan agreement, or CMS has reason to believe that the organization engages in, or has engaged in, criminal or fraudulent activities or activities that cause material harm to the organization's members or the government, the loan recipient must repay 110 percent of the aggregate amount of loans received under this subpart. In addition, the loan recipient must pay interest on the aggregate amount of loans received for the period the loans were outstanding equal to the average

interest rate on marketable Treasury securities of similar maturity.

(d) *Failure to pay.* Loan recipients that fail to make loan payments consistent with the repayment schedule or loan modification or workout approved by CMS will be subject to any and all remedies available to CMS under law to collect the debt.

(e) *Deeming of CO–OP qualified health plans.* Health plans offered by a loan recipient may be deemed certified as a CO–OP qualified health plan to participate in the Exchanges for two years and may be recertified every two years for up to ten years following the life of any loan awarded to the loan recipient under this subpart, consistent with section 1301(a)(2) of the Affordable Care Act.

(1) To be deemed as certified to participate in the Exchanges, the plan must comply with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(2) A loan recipient seeking to have a plan deemed as certified to participate in the Exchanges must provide evidence to CMS or an entity designated by CMS that the plan complies with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(3) If a plan offered by a loan recipient is deemed to be certified to participate in the Exchanges or loses its deemed status and is no longer certified to participate in the Exchanges, CMS or an entity designated by CMS will provide notice to the Exchanges in which the loan recipient offers CO–OP qualified health plans.

(f) *Conversions and voluntary terminations.* (1) The loan recipient shall not convert or sell to a for-profit or nonconsumer operated entity at any time after receiving a loan under this subpart. The loan recipient shall not undertake any transaction that would result in the CO–OP implementing a governance structure that does not meet the standards in this subpart.

(2) CMS may, in its sole discretion, approve a request by a loan recipient to voluntarily terminate its loan agreement with CMS, and cease to constitute a QNHII, for the purpose of permitting a loan recipient to pursue innovative business plans that are not otherwise consistent with the requirements of this subpart, provided that all outstanding CO–OP loans issued to the loan recipient are repaid in full prior to termination of the loan agreement, and CMS believes granting the request would meaningfully enhance consumer access to quality, affordable, member-focused, non-profit health care options in affected markets.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012; 89 FR 26426, Apr. 15, 2024]

Subpart G—Minimum Essential Coverage

SOURCE: 78 FR 39529, July 1, 2013, unless otherwise noted.

§ 156.600 The definition of minimum essential coverage.

The term *minimum essential coverage* has the same meaning as provided in section 5000A(f) of the Code and its implementing regulations for purposes of this subpart.

§ 156.602 Other coverage that qualifies as minimum essential coverage.

The following types of coverage are designated by the Secretary as minimum essential coverage for purposes of section 5000A(f)(1)(E) of the Code:

(a) *Self-funded student health coverage.* Coverage offered to students by an institution of higher education (as defined in the Higher Education Act of

1965), where the institution assumes the risk for payment of claims, are designated as minimum essential coverage for plan or policy years beginning on or before December 31, 2014. For coverage beginning after December 31, 2014, sponsors of self-funded student health coverage may apply to be recognized as minimum essential coverage pursuant to the process provided under 45 CFR 156.604.

(b) *Refugee Medical Assistance supported by the Administration for Children and Families.* Coverage under Refugee Medical Assistance, authorized under section 412(e)(7)(A) of The Immigration and Nationality Act, provides up to eight months of coverage to certain noncitizens who are considered Refugees, as defined in section 101(a)(42) of the Act.

(c) *Medicare advantage plans.* Coverage under the Medicare program pursuant to Part C of title XVIII of the Social Security Act, which provides Medicare Parts A and B benefits through a private insurer.

(d) *State high risk pool coverage.* A qualified high risk pool as defined by section 2744(c)(2) of the Public Health Service Act established on or before November 26, 2014 in any State.

(e) *Other coverage.* Other coverage that qualifies pursuant to §156.604.

[78 FR 39529, July 1, 2013, as amended at 80 FR 10875, Feb. 27, 2015]

§ 156.604 Requirements for recognition as minimum essential coverage for types of coverage not otherwise designated minimum essential coverage in the statute or this subpart.

(a) The Secretary may recognize ''other coverage'' as minimum essential coverage provided HHS determines that the coverage meets the following substantive and procedural requirements:

(1) *Coverage requirements.* A plan must meet substantially all the requirements of title I of the Affordable Care Act pertaining to non-grandfathered, individual health insurance coverage.

(2) *Procedural requirements for recognition as minimum essential coverage.* To be considered for recognition as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must submit the following information to HHS:

(i) Identity of the plan sponsor and appropriate contact persons;

(ii) Basic information about the plan, including:

(A) Name of the organization sponsoring the plan;

(B) Name and title of the individual who is authorized to make, and makes, this certification on behalf of the organization;

(C) Address of the individual named above;

(D) Phone number of the individual named above;

(E) Number of enrollees;

(F) Eligibility criteria;

(G) Cost sharing requirements, including deductible and out-of-pocket maximum limit;

(H) Essential health benefits covered; and

(I) A certification by the appropriate individual, named pursuant to paragraph (a)(3)(ii)(b), that the organization substantially complies with the requirements of title I of the Affordable Care Act that apply to non-grandfathered plans in the individual market and any plan documentation or other information that demonstrate that the coverage substantially comply with these requirements.

(b) CMS will publish a list of types of coverage that the Secretary has recognized as minimum essential coverage pursuant to this provision.

(c) If at any time the Secretary determines that a type of coverage previously recognized as minimum essential coverage no longer meets the coverage requirements of paragraph (a)(1) of this section, the Secretary may revoke the recognition of such coverage.

(d) *Notice.* Once recognized as minimum essential coverage, the sponsor of the coverage, government agency, health insurance issuer, or plan administrator must provide notice to all enrollees of its minimum essential coverage status and must comply with the information reporting requirements of section 6055 of the Internal Revenue Code and implementing regulations.

[78 FR 39529, July 1, 2013, as amended at 79 FR 30351, May 27, 2014]

§ 156.606 HHS audit authority.

The Secretary may audit a plan or program recognized as minimum essential coverage under § 156.604 at any time to ensure compliance with the requirements of § 156.604(a).

Subpart H—Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

SOURCE: 78 FR 65100, Oct. 30, 2013, unless otherwise noted.

§ 156.705 Maintenance of records for Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all documents and records (whether paper, electronic, or other media) and other evidence of accounting procedures and practices, necessary for HHS to do the following:

(1) Periodically audit financial records related to QHP issuers' participation in a Federally-facilitated Exchange, and evaluate the ability of QHP issuers to bear the risk of potential financial losses; and

(2) Conduct compliance reviews or otherwise monitor QHP issuers' compliance with all Exchange standards applicable to issuers offering QHPs in a federally-facilitated Exchange as listed in this part.

(b) *Records.* The records described in paragraph (a) of this section include the sources listed in § 155.1210(b)(2), (3), and (5) of this subchapter.

(c) *Record retention timeframe.* Issuers offering QHPs in a Federally-facilitated Exchange must maintain all records referenced in paragraph (a) of this section for 10 years.

(d) *Record availability.* Issuers offering QHPs in a Federally-facilitated Exchange must make all records in paragraph (a) of this section available to HHS, the OIG, the Comptroller General, or their designees, upon request.

§ 156.715 Compliance reviews of QHP issuers in Federally-facilitated Exchanges.

(a) *General standard.* Issuers offering QHPs in a Federally-facilitated Exchange may be subject to compliance reviews to ensure ongoing compliance with Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange.

(b) *Records.* In preparation for or in the course of the compliance review, a QHP issuer must make available for HHS to review the records of the QHP issuer that pertain to its activities within a Federally-facilitated Exchange. Such records may include, but are not limited to the following:

(1) The QHP issuer's books and contracts, including the QHP issuer's policy manuals and other QHP plan benefit information provided to the QHP issuer's enrollees;

(2) The QHP issuer's policies and procedures, protocols, standard operating procedures, or other similar manuals related to the QHP issuer's activities in a Federally-facilitated Exchange;

(3) Any other information reasonably necessary for HHS to—

(i) Evaluate the QHP issuer's compliance with QHP certification standards and other Exchange standards applicable to issuers offering QHPs in a Federally-facilitated Exchange;

(ii) Evaluate the QHP's performance, including its adherence to an effective compliance plan, within a Federally-facilitated Exchange;

(iii) Verify that the QHP issuer has performed the duties attested to as part of the QHP certification process; and

(iv) Assess the likelihood of fraud or abuse.

(c) *Interest of Qualified Individuals and Qualified Employers.* HHS's findings from the compliance reviews under this section may be in conjunction with other findings related to the QHP issuers' compliance with certification standards, used to confirm that permitting the issuer's QHPs to be available through a Federally-facilitated Exchange is in the interest of the qualified individuals and qualified employers as provided under § 155.1000(c)(2) of this subchapter.

(d) *Onsite and desk reviews.* The QHP issuer will make available, for the purposes listed in paragraph (c) of this section, its premises, physical facilities and equipment (including computer and other electronic systems), for HHS

to conduct a compliance review as provided under this section.

(1) A compliance review under this section will be carried out as an onsite or desk review based on the specific circumstances.

(2) Unless otherwise specified, nothing in this section is intended to preempt Federal laws and regulations related to information privacy and security.

(e) *Compliance review timeframe.* A QHP issuer may be subject to a compliance review up to 10 years from the last day of that plan benefit year, or 10 years from the last day that the QHP certification is effective if the QHP is no longer available through a Federally-facilitated Exchange; provided, however, that if the 10 year review period falls during an ongoing compliance review, the review period would be extended until the compliance review is completed.

(f) *Failure to comply.* A QHP issuer that fails to comply with a compliance review under this section may be subject to enforcement remedies under subpart I of this part.

[78 FR 65100, Oct. 30, 2013, as amended at 81 FR 94182, Dec. 22, 2016]

Subpart I—Enforcement Remedies in the Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.800 Available remedies; Scope.

(a) *Kinds of sanctions.* HHS may impose the following types of sanctions on QHP issuers in an Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in an Exchange:

(1) Civil money penalties as specified in § 156.805; and

(2) Decertification of a QHP offered by the non-compliant QHP issuer in a Federally-facilitated Exchange as described in § 156.810.

(b) *Scope.* Sanctions under subpart I are applicable for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange. Sanctions under paragraph (a)(1) of this section are also applicable for non-compliance by QHP issuers participating in State Exchanges and State-based Exchanges on the Federal platform when HHS is responsible for enforcement of the requirements in subpart E of this part and 45 CFR 156.50.

(c) *Compliance standard.* For calendar years 2014 and 2015, sanctions under this subpart will not be imposed if the QHP issuer has made good faith efforts to comply with applicable requirements.

(d) *Information sharing.* HHS may consult and share information about QHP issuers with other Federal and State regulatory and enforcement entities to the extent that the consultation and information is necessary for purposes of State or Federal oversight and enforcement activities.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014; 80 FR 10875, Feb. 27, 2015; 86 FR 24293, May 5, 2021]

§ 156.805 Bases and process for imposing civil money penalties in Federally-facilitated Exchanges.

(a) *Grounds for imposing civil money penalties.* Civil money penalties may be imposed on an issuer in an Exchange if, based on credible evidence, HHS has reasonably determined that the issuer has engaged in one or more of the following actions:

(1) Misconduct in the Federally-facilitated Exchange or substantial noncompliance with the Exchange standards and requirements applicable to issuers offering QHPs in the Federally-facilitated Exchange, including but not limited to issuer standards and requirements under parts 153 and 156 of this subchapter;

(2) Limiting the QHP's enrollees' access to medically necessary items and services that are required to be covered as a condition of the QHP issuer's ongoing participation in the Federally-facilitated Exchange, if the limitation has adversely affected or has a substantial likelihood of adversely affecting one or more enrollees in the QHP offered by the QHP issuer;

(3) Imposing on enrollees premiums in excess of the monthly beneficiary

premiums permitted by Federal standards applicable to QHP issuers participating in the Federally-facilitated Exchange;

(4) Engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment into a QHP offered by the issuer (except as permitted by this part) by qualified individuals whose medical condition or history indicates the potential for a future need for significant medical services or items;

(5) Intentionally or recklessly misrepresenting or falsifying information that it furnishes—

(i) To HHS or an Exchange; or

(ii) To an individual or entity upon which HHS relies to make its certifications or evaluations of the QHP issuer's ongoing compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated Exchange;

(6) Failure to remit user fees assessed under §156.50(c); or

(7) Failure to comply with the cost-sharing reductions and advance payments of the premium tax credit standards of subpart E of this part.

(b) *Factors in determining the amount of civil money penalties assessed.* In determining the amount of civil money penalties, HHS may take into account the following:

(1) The QHP issuer's previous or ongoing record of compliance;

(2) The level of the violation, as determined in part by—

(i) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread; and

(ii) The magnitude of financial and other impacts on enrollees and qualified individuals; and

(3) Aggravating or mitigating circumstances, or other such factors as justice may require, including complaints about the issuer with regard to the issuer's compliance with the medical loss ratio standards required by the Affordable Care Act and as codified by applicable regulations.

(c) *Maximum penalty.* The maximum amount of penalty imposed for each violation is $100 as adjusted annually under 45 CFR part 102 for each day for each QHP issuer for each individual adversely affected by the QHP issuer's non-compliance; and where the number of individuals cannot be determined, HHS may estimate the number of individuals adversely affected by the violation.

(d) *Request for hearing.* (1) An issuer may appeal the assessment of a civil money penalty under this section by filing a request for hearing under an applicable administrative hearing process.

(2) If an issuer files a request for hearing under this paragraph (d), the assessment of a civil money penalty will not occur prior to the issuance of the final administrative decision in the appeal.

(e) *Failure to request a hearing.* (1) If the QHP issuer does not request a hearing within 30 days of the issuance of the notice described in paragraph (d)(1) of this section, HHS may assess the proposed civil money penalty.

(2) HHS will notify the issuer in writing of any penalty that has been assessed under this subpart and of the means by which the QHP issuer or another responsible entity may satisfy the CMP assessment.

(3) The QHP issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with the requirements of the applicable administrative hearing process unless the QHP issuer can show good cause, as determined under §156.905(b), for failing to timely exercise its right to a hearing.

(f) *Circumstances requiring HHS enforcement in State Exchanges and State-based Exchanges on the Federal platform.* (1) HHS will enforce the requirements of subpart E of this part and 45 CFR 156.50 if a State Exchange or State-based Exchange on the Federal platform notifies HHS that it is not enforcing these requirements or if HHS makes a determination using the process set forth at 45 CFR 150.201, *et seq.* that a State Exchange or State-based Exchange on the Federal platform is failing to substantially enforce these requirements.

(2) If HHS is responsible under paragraph (f)(1) of this section for enforcement of the requirements set forth in subpart E of this part or 45 CFR 156.50,

HHS may impose civil money penalties on an issuer in a State Exchange or State-based Exchange on the Federal platform, in accordance with the bases and process for imposing civil money penalties set forth in this section.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 15245, Mar. 19, 2014; 79 FR 30351, May 27, 2014; 81 FR 12351, Mar. 8, 2016; 81 FR 61581, Sept. 6, 2016; 86 FR 24293, May 5, 2021]

§ 156.806 Notice of non-compliance.

If HHS learns of a potential violation described in § 156.805 or if a State informs HHS of a potential violation, prior to imposing any CMPs, HHS must provide a written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the QHP issuer to respond and to provide additional information to refute an alleged violation.

(c) State that a civil money penalty may be assessed if the allegations are not, as determined by HHS, refuted.

[79 FR 30351, May 27, 2014]

§ 156.810 Bases and process for decertification of a QHP offered by an issuer through a Federally-facilitated Exchange.

(a) *Bases for decertification.* A QHP may be decertified on one or more of the following grounds:

(1) The QHP issuer substantially fails to comply with the Federal laws and regulations applicable to QHP issuers participating in the Federally-facilitated Exchange;

(2) The QHP issuer substantially fails to comply with the standards related to the risk adjustment, reinsurance, or risk corridors programs under 45 CFR part 153, including providing HHS with valid risk adjustment, reinsurance or risk corridors data;

(3) The QHP issuer substantially fails to comply with the transparency and marketing standards in §§ 156.220 and 156.225;

(4) The QHP issuer substantially fails to comply with the standards regarding advance payments of the premium tax credit and cost-sharing in subpart E of this part;

(5) The QHP issuer is operating in the Federally-facilitated Exchange in a manner that hinders the efficient and effective administration of the Exchange;

(6) The QHP no longer meets the applicable standards set forth under subpart C of this part.

(7) Based on credible evidence, the QHP issuer has committed or participated in fraudulent or abusive activities, including submission of false or fraudulent data;

(8) The QHP issuer substantially fails to meet the requirements under § 156.230 related to network adequacy standards or, § 156.235 related to inclusion of essential community providers;

(9) The QHP issuer substantially fails to comply with the law and regulations related to internal claims and appeals and external review processes;

(10) The State recommends to HHS that the QHP should no longer be available in a Federally-facilitated Exchange;

(11) The QHP issuer substantially fails to comply with the privacy or security standards set forth in § 156.260;

(12) The QHP issuer substantially fails to meet the requirements related to the cases forwarded to QHP issuers under subpart K of this part;

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part;

(14) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(15) HHS reasonably believes that the QHP issuer lacks the financial viability to provide coverage under its QHPs until the end of the plan year.

(b) *State sanctions and determinations*—(1) *State sanctions.* HHS may consider regulatory or enforcement actions taken by a State against a QHP issuer as a factor in determining whether to decertify a QHP offered by that issuer.

(2) *State determinations.* HHS may decertify a QHP offered by an issuer in a Federally-facilitated Exchange based on a determination or action by a State as it relates to the issuer offering QHPs in a Federally-facilitated Exchange, including when a State places an issuer or its parent organization

into receivership or when the State recommends to HHS that the QHP no longer be available in a Federally-facilitated Exchange.

(c) *Standard decertification process.* For decertification actions on grounds other than those described in paragraphs (a)(7), (8), or (9) of this section, HHS will provide written notices to the QHP issuer, enrollees in that QHP, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

(1) The effective date of the decertification, which will be a date specified by HHS that is no earlier than 30 days after the date of issuance of the notice;

(2) The reason for the decertification, including the regulation or regulations that are the basis for the decertification;

(3) For the written notice to the QHP issuer, information about the effect of the decertification on the ability of the issuer to offer the QHP in the Federally-facilitated Exchange and must include information about the procedure for appealing the decertification by making a hearing request; and

(4) The written notice to the QHP enrollees must include information about the effect of the decertification on enrollment in the QHP and about the availability of a special enrollment period, as described in §155.420 of this subchapter.

(d) *Expedited decertification process.* For decertification actions on grounds described in paragraphs (a)(6), (7), (8), or (9) of this section, HHS will provide written notice to the QHP issuer, enrollees, and the State department of insurance in the State in which the QHP is being decertified. The written notice must include the following:

(1) The effective date of the decertification, which will be a date specified by HHS; and

(2) The information required by paragraphs (c)(2) through (4) of this section.

(e) *Request for hearing.* An issuer may appeal the decertification of a QHP offered by that issuer under paragraph (c) or (d) of this section by filing a request for hearing under an applicable administrative hearing process.

(1) If an issuer files a request for hearing under this paragraph (e):

(i) If the decertification is under paragraph (b)(1) of this section, the decertification will not take effect prior to the issuance of the final administrative decision in the appeal, notwithstanding the effective date specified in paragraph (b)(1) of this section.

(ii) If the decertification is under paragraph (b)(2) of this section, the decertification will be effective on the date specified in the notice of decertification, but the certification of the QHP may be reinstated immediately upon issuance of a final administrative decision that the QHP should not be decertified.

(2) [Reserved]

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014; 81 FR 12351, Mar. 8, 2016]

§156.815 Plan suppression.

(a) *Suppression* means temporarily making a QHP certified to be offered through the Federally-facilitated Exchange unavailable for enrollment through the Federally-facilitated Exchange.

(b) *Grounds for suppression.* A QHP may be suppressed as described in paragraph (a) of this section on one or more of the following grounds:

(1) The QHP issuer notifies HHS of its intent to withdraw the QHP from a Federally-facilitated Exchange when one of the exceptions to guaranteed renewability of coverage related to discontinuing a particular product or discontinuing all coverage under §147.106(c) or (d) of this subchapter applies;

(2) Data submitted for the QHP is incomplete or inaccurate;

(3) The QHP is in the process of being decertified as described in §156.810(c) or (d), or the QHP issuer is appealing a completed decertification as described in subpart J of this part;

(4) The QHP issuer offering the QHP is the subject of a pending, ongoing, or final State regulatory or enforcement action or determination that could affect the issuer's ability to enroll consumers or otherwise relates to the issuer offering QHPs in the Federally-facilitated Exchanges; or

(5) One of the exceptions to guaranteed availability of coverage related to

special rules for network plans or financial capacity limits under §147.104(c) or (d) of this subchapter applies.

(c) A multi-State plan as defined in §155.1000(a) of this subchapter may be suppressed as described in paragraph (a) of this section if OPM notifies the Exchange that:

(1) OPM has found a compliance violation within the multi-State plan, or

(2) One of the grounds for suppression in paragraph (b) of this section exists for the multi-State plan.

[80 FR 10875, Feb. 27, 2015]

Subpart J—Administrative Review of QHP Issuer Sanctions

SOURCE: 78 FR 65101, Oct. 30, 2013, unless otherwise noted.

§ 156.901 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of HHS.

Filing date means the date filed electronically.

Hearing includes a hearing on a written record as well as an in-person, telephone, or video teleconference hearing.

Party means HHS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to §156.805 or a notice of decertification pursuant to §156.810(c) or (d).

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.903 Scope of Administrative Law Judge's (ALJ) authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act (5 U.S.C. 554a), to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty of a QHP offered in a Federally-facilitated Exchange, State Exchange, and State-based Exchange on the Federal platform, or the decertification of a QHP offered in a Federally-facilitated Exchange.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedures Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.905 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with §156.907(a), within 30 days after the date of issuance of either HHS' notice of proposed assessment under §156.805, notice of decertification of a QHP under §156.810(c) or §156.810(d). The request for hearing should be addressed as instructed in the notice of proposed determination. ''date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 156.907 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment or decertifications with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) Identify the relevant notice of assessment or decertification by date and attach a copy of the notice.

§ 156.909 Amendment of notice of assessment or decertification request for hearing.

The ALJ may permit CMS to amend its notice of assessment or decertification, or permit the respondent to amend a request for hearing that complies with §156.907(a), if the ALJ finds that no undue prejudice to either party will result.

§ 156.911 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by §156.905(a) or any extension of time granted by the ALJ pursuant to §156.905(b).

(b) The request for hearing fails to meet the requirements of §156.907.

(c) The entity that filed the request for hearing is not a respondent under §156.901.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 156.913 Settlement.

HHS has exclusive authority to settle any issue or any case, without the consent of the ALJ at any time before or after the ALJ's decision.

§ 156.915 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor (DOL) or the Internal Revenue Service (IRS) may intervene without regard to paragraphs (a)(1) through (3) of this section.

§ 156.917 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(3) Whether a basis exists to decertify a QHP offered by the respondent in a Federally-facilitated Exchange.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Will apply the factors that are identified in §156.805 for civil money penalties.

(2) May consider evidence of record relating to any factor that HHS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that HHS assessed.

§ 156.919 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, by telephone, or by video teleconference. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.921 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 156.923 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 156.925 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 156.927 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed electronically and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as ''Motion for Discovery'').

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. If a party is represented by an attorney, service must be made on the attorney. An electronically filed submission is considered served on all parties using the electronic filing system.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.929 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, the time begins with the day following the act, event, or default and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal government, in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in § 156.901) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in § 156.905(b)).

§ 156.931 Acknowledgement of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a written notice to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case,

and provides instructions for filing submissions and other general information concerning procedures. The ALJ will set out the next steps in the case either as part of the acknowledgement or on a later date.

[86 FR 24293, May 5, 2021]

§ 156.935 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 156.937(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 156.937 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(5) The disclosure of information responsive to the discovery request is prohibited by law.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 156.937 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in § 156.931, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment or decertification (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment or decertification that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing

exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 156.939 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 156.937 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 156.941 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 156.937 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 156.941 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 156.937 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person, telephone, or video teleconference hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§ 156.943 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment or decertification; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 156.945 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent

provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §156.805 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether HHS' notice sent in accordance with §156.805 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after HHS' notice under §156.805(d) or §156.810(c) or §156.810(d).

§156.947 The record.

(a) Any testimony that is taken in-person, by telephone, or by video teleconference is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

[78 FR 65101, Oct. 30, 2013, as amended at 86 FR 24293, May 5, 2021]

§156.951 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§156.953 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under §156.957.

§156.955 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§156.957 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this section may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under §156.953.

(b) The Administrator may decide to review an initial agency decision if it

appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 156.959 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty or decertification of a QHP is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to HHS.

(b) *Certification of administrative record.* HHS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of HHS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 156.961 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 156.963 Final order not subject to review.

In an action brought under § 156.961, the validity and appropriateness of the final order imposing a civil money penalty is not subject to review.

Subpart K—Cases Forwarded to Qualified Health Plans and Qualified Health Plan Issuers in Federally-facilitated Exchanges

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§ 156.1010 Standards.

(a) A case is a communication brought by a complainant that expresses dissatisfaction with a specific person or entity subject to State or Federal laws regulating insurance, concerning the person or entity's activities related to the offering of insurance, other than a communication with respect to an adverse benefit determination as defined in §147.136(a)(2)(i) of this subchapter. Issues related to adverse benefit determinations are not addressed in this section and are subject to the provisions in §147.136 of this subchapter governing internal claims appeals and external review. Issues related to eligibility determination processes and appeals are not addressed in this section and are subject to the provisions in subpart F of part 155.

(b) QHP issuers operating in a Federally-facilitated Exchange must investigate and resolve, as appropriate, cases from the complainant forwarded to the issuer by HHS. Cases received by a QHP issuer operating in a Federally-facilitated Exchange directly from a complainant or the complainant's authorized representative will be handled by the issuer through its internal customer service process.

(c) Cases may be forwarded to a QHP issuer operating in a Federally-facilitated Exchange through a casework tracking system developed by HHS or other means as determined by HHS.

(d) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from HHS must be resolved within 15 calendar days of receipt of the case. Urgent cases as defined in paragraph (e) of this section that do not otherwise fall within the scope of §147.136 of this subchapter must be resolved no later than 72 hours after receipt of the case. Where applicable State laws and regulations establish timeframes for case resolution that are stricter than the standards contained in this paragraph, QHP issuers operating in a Federally-facilitated Exchange must comply with such stricter laws and regulations.

(e) For cases received from HHS by a QHP issuer operating in a Federally-facilitated Exchange, an urgent case is one in which there is an immediate need for health services because the non-urgent standard could seriously jeopardize the enrollee's or potential enrollee's life, or health or ability to attain, maintain, or regain maximum function; or one in which the process for non-urgent cases would jeopardize the enrollee's or potential enrollee's ability enroll in a QHP through the Federally-facilitated Exchange.

(f) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange are required to notify complainants regarding the disposition of the as soon as possible upon resolution of the case, but in no event later than three (3) business days after the case is resolved.

(1) For the purposes of meeting the requirement in this paragraph (f), notification may be by verbal or written means as determined most appropriate by the QHP issuer.

(2) In instances when the initial notification of a case's disposition is not written, written notification must be provided to the consumer in a timely manner.

(g) For cases received from HHS, QHP issuers operating in a Federally-facilitated Exchange must use the casework tracking system developed by HHS, or other means as determined by HHS, to document the following:

(1) The date of resolution of a case received from HHS;

(2) A resolution summary of the case no later than seven (7) business days after resolution of the case. The record must include a clear and concise narrative explaining how the case was resolved including information about how and when the complainant was notified of the resolution; and

(3) For a case in which a State agency, including but not limited to a State department of insurance, conducts an investigation related to that case, any compliance issues identified by the State agency implicating the QHP or QHP issuer.

(h) Cases received by a QHP issuer operating in a Federally-facilitated Exchange from a State in which the issuer offers QHPs must be investigated and resolved according to applicable State laws and regulations. With respect to cases directly handled by the State, HHS or any other appropriate regulatory authority, QHP

issuers operating in a Federally-facilitated Exchange must cooperate fully with the efforts of the State, HHS, or other regulatory authority to resolve the case.

Subpart L—Quality Standards

SOURCE: 78 FR 65105, Oct. 30, 2013, unless otherwise noted.

§ 156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.

(a) *Application for approval.* An enrollee satisfaction survey vendor must be approved by HHS, in a form and manner to be determined by HHS, to administer, on behalf of a QHP issuer, enrollee satisfaction surveys to QHP enrollees. HHS will approve enrollee satisfaction survey vendors on an annual basis, and each enrollee satisfaction survey vendor must submit an application for each year that approval is sought.

(b) *Standards.* To be approved by HHS, an enrollee satisfaction survey vendor must meet each of the following standards:

(1) Sign and submit an application form for approval in accordance with paragraph (a) of this section;

(2) Ensure, on an annual basis, that appropriate staff participate in enrollee satisfaction survey vendor training and successfully complete a post-training certification exercise as established by HHS;

(3) Ensure the accuracy of their data collection, calculation and submission processes and attest to HHS the veracity of the data and these processes;

(4) Sign and execute a standard HHS data use agreement, in a form and manner to be determined by HHS, that establishes protocols related to the disclosure, use, and reuse of HHS data;

(5) Adhere to the enrollee satisfaction survey protocols and technical specifications in a manner and form required by HHS;

(6) Develop and submit to HHS a quality assurance plan and any supporting documentation as determined to be relevant by HHS. The plan must describe in adequate detail the implementation of and compliance with all required protocols and technical specifications described in paragraph (b)(5) of this section;

(7) Adhere to privacy and security standards established and implemented under §155.260 of this subchapter by the Exchange with which they are associated;

(8) Comply with all applicable State and Federal laws;

(9) Become a registered user of the enrollee satisfaction survey data warehouse to submit files to HHS on behalf of its authorized QHP contracts;

(10) Participate in and cooperate with HHS oversight for quality-related activities, including, but not limited to: review of the enrollee satisfaction survey vendor's quality assurance plan and other supporting documentation; analysis of the vendor's submitted data and sampling procedures; and site visits and conference calls; and,

(11) Comply with minimum business criteria as established by HHS.

(c) *Approved list.* A list of approved enrollee satisfaction survey vendors will be published on an HHS Web site.

(d) *Monitoring.* HHS will periodically monitor HHS-approved enrollee satisfaction survey vendors to ensure ongoing compliance with the standards in paragraph (b) of this section. If HHS determines that an HHS-approved enrollee satisfaction survey vendor is non-compliant with the standards required in paragraph (b) of this section, the survey vendor may be removed from the approved list described in paragraph (c) of this section and/or the submitted survey results may be ineligible to be included for ESS results.

(e) *Appeals.* An enrollee satisfaction survey vendor that is not approved by HHS after submitting the application described in paragraph (a) of this section may appeal HHS's decision by notifying HHS in writing within 15 days from receipt of the notification of not being approved and submitting additional documentation demonstrating how the vendor meets the standards in paragraph (b) of this section. HHS will review the submitted documentation and make a final approval determination within 30 days from receipt of the additional documentation.

[78 FR 65105, Oct. 30, 2013, as amended at 79 FR 30351, May 27, 2014]

§ 156.1110 Establishment of patient safety standards for QHP issuers.

(a) *Patient safety standards.* A QHP issuer that contracts with a hospital with greater than 50 beds must verify that the hospital, as defined in section 1861(e) of the Act:

(1) For plan years beginning before January 1, 2017, is Medicare-certified or has been issued a Medicaid-only CMS Certification Number (CCN) and is subject to the Medicare Hospital Conditions of Participation requirements for—

(i) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(ii) Discharge planning as specified in 42 CFR 482.43.

(2) For plan years beginning on or after January 1, 2017—

(i)(A) Utilizes a patient safety evaluation system as defined in 42 CFR 3.20; and

(B) Implements a mechanism for comprehensive person-centered hospital discharge to improve care coordination and health care quality for each patient; or

(ii) Implements an evidence-based initiative, to improve health care quality through the collection, management and analysis of patient safety events that reduces all cause preventable harm, prevents hospital readmission, or improves care coordination.

(3) A QHP issuer must ensure that each of its QHPs meets the patient safety standards in accordance with this section.

(b) *Documentation.* A QHP issuer must collect:

(1) For plan years beginning before January 1, 2017, the CCN from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(1) of this section; and

(2) For plan years beginning on or after January 1, 2017, information, from each of its contracted hospitals with greater than 50 beds, to demonstrate that those hospitals meet patient safety standards required in paragraph (a)(2) of this section.

(c) *Reporting.* (1) A QHP issuer must make available to the Exchange the documentation referenced in paragraph (b) of this section, upon request by the Exchange, in a time and manner specified by the Exchange.

(2) Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the documentation described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 13841, Mar. 11, 2014, as amended at 81 FR 12351, Mar. 8, 2016]

§ 156.1120 Quality rating system.

(a) *Data submission requirement.* (1) A QHP issuer must submit data to HHS and Exchanges to support the calculation of quality ratings for each QHP that has been offered in an Exchange for at least one year.

(2) In order to ensure the integrity of the data required to calculate the QRS, a QHP issuer must submit data that has been validated in a form and manner specified by HHS.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(b) *Timeline.* A QHP issuer must annually submit data necessary to calculate the QHP's quality ratings to HHS and Exchanges, on a timeline and in a standardized form and manner specified by HHS.

(c) *Marketing requirement.* A QHP issuer may reference the quality ratings for its QHPs in its marketing materials, in a manner specified by HHS.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (a) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 30352, May 27, 2014]

§ 156.1125 Enrollee satisfaction survey system.

(a) *General requirement.* A QHP issuer must contract with an HHS-approved enrollee satisfaction survey (ESS) vendor, as identified by §156.1105, in order to administer the Enrollee Satisfaction Survey of the QHP's enrollees. A QHP

issuer must authorize its contracted ESS vendor to report survey results to HHS and the Exchange on the issuer's behalf.

(b) *Data requirement.* (1) A QHP issuer must collect data for each QHP, with more than 500 enrollees in the previous year that has been offered in an Exchange for at least one year and following a survey sampling methodology provided by HHS.

(2) In order to ensure the integrity of the data required to conduct the survey, a QHP issuer must submit data that has been validated in a form and manner specified by HHS, and submit this data to its contracted ESS vendor.

(3) A QHP issuer must include in its data submission information only for those QHP enrollees at the level specified by HHS.

(c) *Marketing requirement.* A QHP issuer may reference the survey results for its QHPs in its marketing materials, in a manner specified by HHS.

(d) *Timeline.* A QHP issuer must annually submit data necessary to conduct the survey to its contracted ESS vendor on a timeline and in a standardized form and manner specified by HHS.

(e) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the time and manner specified by the U.S. Office of Personnel Management.

[79 FR 30352, May 27, 2014]

§156.1130 Quality improvement strategy.

(a) *General requirement.* A QHP issuer participating in an Exchange for 2 or more consecutive years must implement and report on a quality improvement strategy including a payment structure that provides increased reimbursement or other market-based incentives in accordance with the health care topic areas in section 1311(g)(1) of the Affordable Care Act, for each QHP offered in an Exchange, consistent with the guidelines developed by HHS under section 1311(g) of the Affordable Care Act.

(b) *Data requirement.* A QHP issuer must submit data that has been validated in a manner and timeframe specified by the Exchange to support the evaluation of quality improvement strategies in accordance with §155.200(d) of this subchapter.

(c) *Timeline.* A QHP issuer must submit data annually to evaluate compliance with the standards for a quality improvement strategy in accordance with paragraph (a) of this section, in a manner and timeframe specified by the Exchange.

(d) *Multi-State plans.* Issuers of multi-State plans, as defined in §155.1000(a) of this subchapter, must provide the data described in paragraph (b) of this section to the U.S. Office of Personnel Management, in the manner and timeframe specified by the U.S. Office of Personnel Management.

[80 FR 10876, Feb. 27, 2015]

Subpart M—Qualified Health Plan Issuer Responsibilities

SOURCE: 78 FR 54143, Aug. 30, 2013, unless otherwise noted.

§156.1210 Dispute submission.

(a) *Responses to reports.* Within 90 calendar days of the date of a payment and collections report from HHS, the issuer must, in a form and manner specified by HHS or the State Exchange describe to HHS or the State Exchange (as applicable) any inaccuracies it identifies in the report.

(b) *Inaccuracies identified after 90-day period.* With respect to an inaccuracy described under paragraph (a) of this section that is identified and submitted to HHS or the State Exchange (as applicable) by the issuer after the end of the 90-day period described in such paragraph, HHS will consider and work with the issuer or the State Exchange (as applicable) to resolve the inaccuracy so long as—

(1) The issuer promptly notifies HHS or the State Exchange (as applicable) upon identifying the inaccuracy, but in no case later than 15 calendar days after identifying the inaccuracy; and

(2) The failure to identify the inaccuracy and submit it to HHS or the State Exchange (as applicable) in a timely manner was not unreasonable or due to the issuer's misconduct or negligence.

(c) *Deadline for describing inaccuracies.* To be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before the end of the 3-year period beginning at the end of the plan year to which the inaccuracy relates. For plan years 2015 through 2019, to be eligible for resolution under paragraph (b) of this section, an issuer must describe all inaccuracies identified in a payment and collections report before January 1, 2024. If a payment error is discovered after the timeframe set forth in this paragraph (c), the issuer must notify HHS, the State Exchange, or State-based Exchanges on the Federal platform (SBE–FP) (as applicable) and repay any overpayments to HHS.

(d) *Confirmation of HHS payment and collections reports.* At the end of each payment year, the issuer must, in a form and manner specified by HHS, confirm to HHS that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the Federal Government and the payments owed to the issuer by the Federal Government, or that the issuer has disputed any identified inaccuracies.

[85 FR 29262, May 14, 2020, as amended at 86 FR 24294, May 5, 2021; 88 FR 25923, Apr. 27, 2023]

§ 156.1215 Payment and collections processes.

(a) *Netting of payments and charges for 2014.* In 2014, as part of its monthly payment and collections process, HHS will net payments owed to QHP issuers and their affiliates under the same taxpayer identification number against amounts due to the Federal government from the QHP issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of cost-sharing reductions, and payment of Federally-facilitated Exchange user fees.

(b) *Netting of payments and charges for later years.* As part of its payment and collections process, HHS may net payments owed to issuers and their affiliates operating under the same tax identification number against amounts due to the Federal Government from the issuers and their affiliates under the same taxpayer identification number for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, payment of federally facilitated Exchange user fees, payment of State Exchanges utilizing the Federal platform user fees, HHS risk adjustment, reinsurance, and risk corridors payments and charges, and administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with §149.510(d)(2) of this subchapter.

(c) *Determination of debt.* Any amount owed to the Federal Government by an issuer and its affiliates for advance payments of the premium tax credit, advance payments of and reconciliation of cost-sharing reductions, Federally-facilitated Exchange user fees, including any fees for State-based Exchanges utilizing the Federal platform, HHS risk adjustment, reinsurance, risk corridors, and unpaid administrative fees for utilizing the Federal Independent Dispute Resolution process in accordance with §149.510(d)(2), after HHS nets amounts owed by the Federal Government under these programs, is a determination of a debt.

[79 FR 13841, Mar. 11, 2014, as amended at 81 FR 12351, Mar. 8, 2016; 86 FR 24294, May 5, 2021; 89 FR 26426, Apr. 15, 2024]

§ 156.1220 Administrative appeals.

(a) *Requests for reconsideration*—(1) *Matters for reconsideration.* An issuer may file a request for reconsideration under this section to contest a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error only with respect to the following:

(i) The amount of advance payment of the premium tax credit, advance payment of cost-sharing reductions or Federally-facilitated Exchange user fees charge for a benefit year;

(ii) The amount of a risk adjustment payment or charge for a benefit year, including an assessment of risk adjustment user fees;

(iii) The amount of a reinsurance payment for a benefit year;

(iv) The amount of a risk adjustment default charge for a benefit year;

(v) The amount of a reconciliation payment or charge for cost-sharing reductions for a benefit year;

(vi) The amount of a risk corridors payment or charge for a benefit year;

(vii) The findings of a second validation audit as a result of risk adjustment data validation (if applicable) with respect to risk adjustment data for the 2016 benefit year and beyond; or

(viii) The calculation of a risk score error rate as a result of risk adjustment data validation with respect to risk adjustment data for the 2016 benefit year and beyond.

(2) *Materiality threshold.* Notwithstanding paragraph (a)(1) of this section, an issuer may file a request for reconsideration under this section only if the amount in dispute under paragraph (a)(1)(i) through (viii) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in such paragraphs (a)(1)(i) through (viii) of this section payable to or due from the issuer for the benefit year, or $10,000, whichever is less.

(3) *Time for filing a request for reconsideration.* The request for reconsideration must be filed in accordance with the following timeframes:

(i) For advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fee charges, or State-based Exchanges utilizing the Federal platform fees, within 60 calendar days after the date of the final reconsideration notification specifying the aggregate amount of advance payments of the premium tax credit, advance payments of cost-sharing reductions, Federally-facilitated Exchange user fees, and State-based Exchanges utilizing the Federal platform fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 30 calendar days of the date of the notification under §153.310(e) of this subchapter;

(iii) For the findings of a second validation audit (if applicable), or the calculation of a risk score error rate as a result of risk adjustment data validation, within 30 calendar days of publication of the applicable benefit year's Summary Report of Benefit Year Risk Adjustment Data Validation Adjustments to Risk Adjustment Transfers;

(iv) For a reinsurance payment, within 30 calendar days of the date of the notification under §153.240(b)(1)(ii) of this subchapter;

(v) For a default risk adjustment charge, within 30 calendar days of the date of the notification of the default risk adjustment charge;

(vi) For reconciliation of the cost-sharing reduction portion of advance payments, within 60 calendar days of the date of the cost-sharing reduction reconciliation discrepancy resolution decision; and

(vii) For a risk corridors payment or charge, within 30 calendar days of the date of the notification under §153.510(d) of this subchapter.

(4) *Content of request.* (i) The request for reconsideration must specify the findings or issues specified in paragraph (a)(1) of this section that the issuer challenges, and the reasons for the challenge.

(ii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to a processing error by HHS, HHS's incorrect application of the relevant methodology, or HHS's mathematical error may be requested only if, to the extent the issue could have been previously identified, the issuer notified HHS of the dispute through the applicable process for reporting a discrepancy set forth in §§153.630(d)(2) and (3) and 153.710(d)(2) of this subchapter and §156.430(h)(1), it was so identified and remains unresolved.

(iii) Notwithstanding paragraph (a)(1) of this section, a reconsideration with respect to advance payments of the premium tax credit, advance payments of cost-sharing reductions, and Federally-facilitated Exchange user fees may be requested only if, to extent the issue could have been previously identified by the issuer to HHS under §156.1210, it was so identified and remains unresolved. An issuer may request reconsideration if it previously identified an issue under §156.1210 after the 15-calendar-day deadline, but late discovery of the issue was not due to misconduct on the part of the issuer.

(iv) The issuer may include in the request for reconsideration additional

documentary evidence that HHS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(5) *Scope of review for reconsideration.* In conducting the reconsideration, HHS will review the appropriate payment and charge determinations, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the issuer. HHS may also review any other evidence it believes to be relevant in deciding the reconsideration, which will be provided to the issuer with a reasonable opportunity to review and rebut the evidence. The issuer must prove its case by a preponderance of the evidence with respect to issues of fact.

(6) *Reconsideration decision.* HHS will inform the issuer of the reconsideration decision in writing. A reconsideration decision is final and binding for decisions regarding the advance payments of the premium tax credit, advance payment of cost-sharing reductions, or Federally-facilitated Exchange user fees. A reconsideration decision with respect to other matters is subject to the outcome of a request for informal hearing filed in accordance with paragraph (b) of this section.

(b) *Informal hearing.* An issuer may request an informal hearing before a CMS hearing officer to appeal HHS's reconsideration decision.

(1) *Manner and timing for request.* A request for an informal hearing must be made in writing and filed with HHS within 30 calendar days of the date of the reconsideration decision under paragraph (a)(5) of this section. If the last day of this period is not a business day, the request for an informal hearing must be made in writing and filed by the next applicable business day.

(2) *Content of request.* The request for informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision that the issuer challenges, and its reasons for the challenge. HHS may submit for review by the CMS hearing officer a statement of its reasons for the reconsideration decision.

(3) *Informal hearing procedures.* (i) The issuer will receive a written notice of the time and place of the informal hearing at least 15 calendar days before the scheduled date.

(ii) The CMS hearing officer will neither receive testimony nor accept any new evidence that was not presented with the reconsideration request and HHS statement under paragraph (b) of this section. The CMS hearing officer will review only the documentary evidence provided by the issuer and HHS, and the record that was before HHS when HHS made its reconsideration determination. The issuer may be represented by counsel in the informal hearing, and must prove its case by clear and convincing evidence with respect to issues of fact.

(4) *Decision of the CMS hearing officer.* The CMS hearing officer will send the informal hearing decision and the reasons for the decision to the issuer. The decision of the CMS hearing officer is final and binding, but is subject to the results of any Administrator's review initiated in accordance with paragraph (c) of this section.

(c) *Review by the Administrator of CMS.* (1) Either the issuer or CMS may request review by the Administrator of CMS of the CMS hearing officer's decision. A request for review of the CMS hearing officer's decision must be submitted to the Administrator of CMS within 15 calendar days of the date of the CMS hearing officer's decision, and must specify the findings or issues that the issuer or CMS challenges. The issuer or CMS may submit for review by the Administrator of CMS a statement supporting the decision of the CMS hearing officer.

(2) After receiving a request for review, the Administrator of CMS has the discretion to elect to review the CMS hearing officer's decision or to decline to review the CMS hearing officer's decision. If the Administrator of CMS elects to review the CMS hearing officer's decision, the Administrator of CMS will also review the statements of the issuer and CMS, and any other information included in the record of the CMS hearing officer's decision, and will determine whether to uphold, reverse, or modify the CMS hearing officer's decision. The issuer or CMS must prove

its case by clear and convincing evidence for issues of fact. The Administrator of CMS will send the decision and the reasons for the decision to the issuer.

(3) The Administrator of CMS's determination is final and binding.

[79 FR 13841, Mar. 11, 2014, as amended at 80 FR 10876, Feb. 27, 2015; 81 FR 12352, Mar. 8, 2016; 81 FR 94182, Dec. 22, 2016; 86 FR 24294, May 5, 2021; 88 FR 25923, Apr. 27, 2023]

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

(a) A QHP issuer that is directly contacted by a potential applicant may, at the Exchange's option, enroll such applicant in a QHP in a manner that is considered through the Exchange. In order for the enrollment to be made directly with the issuer in a manner that is considered to be through the Exchange, the QHP issuer needs to comply with at least the following requirements:

(1) *QHP issuer general requirements.* (i) The QHP issuer follows the enrollment process for qualified individuals consistent with § 156.265.

(ii) The QHP issuer's Web site provides applicants the ability to view QHPs offered by the issuer with the data elements listed in § 155.205(b)(1)(i) through (viii) of this subchapter.

(iii) The QHP issuer's Web site clearly distinguishes between QHPs for which the consumer is eligible and other non-QHPs that the issuer may offer, and indicate that advance payments of the premium tax credit and cost sharing reductions apply only to QHPs offered through the Exchange.

(iv) The QHP issuer informs all applicants of the availability of other QHP products offered through the Exchange through an HHS-approved universal disclaimer and displays the Web link to and describes how to access the Exchange Web site.

(v) The QHP issuer's Web site allows applicants to select and attest to an advance payment of the premium tax credit amount, if applicable, in accordance with § 155.310(d)(2) of this subchapter.

(2) [Reserved]

(b) *Direct enrollment in a Federally-facilitated Exchange.* The individual market Federally-facilitated Exchanges will permit issuers of QHPs in each Federally-facilitated Exchange to directly enroll applicants in a manner that is considered to be through the Exchange, pursuant to paragraph (a) of this section, to the extent permitted by applicable State law.

(1) The QHP issuer must comply with applicable requirements in § 155.221 of this subchapter.

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex (which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes).

[78 FR 54143, Aug. 30, 2013, as amended at 81 FR 94182, Dec. 22, 2016; 83 FR 17070, Apr. 17, 2018; 84 FR 17568, Apr. 25, 2019; 85 FR 37248, June 19, 2020; 89 FR 37703, May 6, 2024]

§ 156.1240 Enrollment process for qualified individuals.

(a) *Premium payment.* A QHP issuer must—

(1) Follow the premium payment process established by the Exchange in accordance with § 155.240.

(2) At a minimum, for all payments in the individual market, accept paper checks, cashier's checks, money orders, EFT, and all general-purpose pre-paid debit cards as methods of payment and present all payment method options equally for a consumer to select their preferred payment method.

(3) For payments in the individual market made using a payment method described in paragraph (a)(2) of this section, accept premium payments made by or on behalf of an enrollee in connection with an individual coverage HRA (as described in § 146.123(b) of this

subchapter) or qualified small employer health reimbursement arrangement (as described in section 9831(d)(2) of the Internal Revenue Code of 1986, as amended) in which the enrollee is enrolled.

(b) [Reserved]

[78 FR 54143, Aug. 30, 2013, as amended at 86 FR 6178, Jan. 19, 2021]

§ 156.1250 Acceptance of certain third party payments.

Issuers offering individual market QHPs, including stand-alone dental plans, and their downstream entities, must accept premium and cost-sharing payments for the QHPs from the following third-party entities from plan enrollees (in the case of a downstream entity, to the extent the entity routinely collects premiums or cost sharing):

(a) A Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;

(b) An Indian tribe, tribal organization, or urban Indian organization; and

(c) A local, State, or Federal government program, including a grantee directed by a government program to make payments on its behalf.

[81 FR 12352, Mar. 8, 2016]

§ 156.1255 Renewal and re-enrollment notices.

A health insurance issuer that is renewing an enrollment group's coverage in an individual market QHP offered through the Exchange (including a renewal with modifications) in accordance with §147.106 of this subchapter, or that is nonrenewing coverage offered through the Exchange and automatically enrolling an enrollee in a QHP under a different product offered by the same QHP issuer through the Exchange in accordance with §155.335 of this subchapter, must include the following information in the applicable notice described in §147.106(b)(5), (c)(1), or (f)(1) of this subchapter:

(a) Premium and advance payment of the premium tax credit information sufficient to notify the enrollment group of its expected monthly premium payment under the renewed coverage, in a form and manner specified by the Exchange, provided that if the Exchange does not provide this information to enrollees and does not require issuers to provide this information to enrollees, consistent with this section, such information must be provided in a form and manner specified by HHS;

(b) An explanation of the requirement to report changes to the Exchange, as specified in §155.335(e) of this subchapter, the timeframe and channels through which changes can be reported, and the implications of not reporting changes;

(c) For an enrollment group that includes an enrollee on whose behalf advance payments of the premium tax credit are being provided, an explanation of the reconciliation process for advance payments of the premium tax credit established in accordance with 26 CFR 1.36B–4; and

(d) For an enrollment group that includes an enrollee being provided cost-sharing reductions, but for whom no QHP under the product remains available for renewal at the silver level, an explanation that in accordance with §155.305(g)(1)(ii) of this subchapter, cost-sharing reductions are only available to an individual who is not an Indian if he or she is enrolled in a silver-level QHP.

[79 FR 53006, Sept. 5, 2014]

§ 156.1256 Other notices.

As directed by a Federally-facilitated Exchange, a health insurance issuer that is offering QHP coverage through a Federally-facilitated Exchange or a State-based Exchange on the Federal platform must notify its enrollees of material plan or benefit display errors and the enrollees' eligibility for a special enrollment period, included in §155.420(d)(12) of this subchapter, within 30 calendar days after being notified by a Federally-facilitated Exchange that the error has been fixed, if directed to do so by a Federally-facilitated Exchange.

[81 FR 94183, Dec. 22, 2016]

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

Subpart A—General Provisions

Sec.
157.10 Basis and scope.
157.20 Definitions.

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

157.200 Eligibility of qualified employers to participate in a SHOP.
157.205 Qualified employer participation process in a SHOP for plan years beginning prior to January 1, 2018.
157.206 Qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018.

AUTHORITY: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

SOURCE: 77 FR 18474, Mar. 27, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 157.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care:

(1) 1311. Affordable choices of health benefits plans.

(2) 1312. Consumer Choice.

(3) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(4) 1411. Procedures for determining eligibility for Exchange participation, advance payments of the premium tax credit and cost-sharing reductions, and individual responsibility exemptions.

(5) 1412. Advance determination and payment of the premium tax credit and cost-sharing reductions.

(b) *Scope.* This part establishes the requirements for employers in connection with the operation of Exchanges.

§ 157.20 Definitions.

The following definitions apply to this part, unless otherwise indicated:

Federally-facilitated SHOP has the meaning given to the term in § 155.20 of this subchapter.

Full-time employee has the meaning given to the term in § 155.20 of this subchapter.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified employee has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Small employer has the meaning given to the term in § 155.20 of this subchapter.

[77 FR 18474, Mar. 27, 2012, as amended at 78 FR 15539, Mar. 11, 2013]

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

§ 157.200 Eligibility of qualified employers to participate in a SHOP.

(a) *General requirement.* Only a qualified employer may participate in the SHOP in accordance with § 155.710 of this subchapter.

(b) *Continuing participation for growing small employers.* A qualified employer may continue to participate in the SHOP if it ceases to be a small employer in accordance with § 155.710 of this subchapter.

(c) *Participation in multiple SHOPs.* A qualified employer may participate in multiple SHOPs in accordance with § 155.710 of this subchapter.

§ 157.205 Qualified employer participation process in a SHOP for plan years beginning prior to January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with § 155.705 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Payment.* A qualified employer must submit any contribution towards the premiums of any qualified employee according to the standards and processes described in §155.705 of this subchapter.

(e) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with:

(1) An enrollment period to seek coverage in a QHP in accordance with §155.725(g) of this subchapter; and

(2) Information about the enrollment process in accordance with §155.725 of this subchapter.

(f) *New employees and changes in employee eligibility.* Qualified employers participating in the SHOP must provide the SHOP with information about dependents or employees whose eligibility status for coverage purchased through the employer in the SHOP has changed, including:

(1) Newly eligible dependents and newly qualified employees. In a Federally-facilitated SHOP or in a State Exchange that uses the Federal platform for SHOP functions, a qualified employer must provide information about a newly qualified employee on or before the thirtieth day after the day that the employee becomes a newly qualified employee; and

(2) Loss of qualified employee status.

(g) *Annual employer election period.* Qualified employers must adhere to the annual employer election period to change their program participation for the next plan year described in §155.725(c) of this subchapter.

(h) *Applicability date.* The provisions of this section apply for plan years beginning prior to January 1, 2018. Section 157.206 is applicable for plan years beginning on or after January 1, 2018.

[77 FR 18474, Mar. 27, 2012, as amended at 81 FR 94183, Dec. 22, 2016; 83 FR 17070, Apr. 17, 2018]

§ 157.206 Qualified employer participation process in a SHOP for plan years beginning on or after January 1, 2018.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with §155.706 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with information about the enrollment process.

(e) *Participation in the SHOP and termination of coverage or enrollment through the SHOP.* (1) Changes affecting participation. Employers must submit a new single employer application to the SHOP or withdraw from participating in the SHOP if the employer makes a change that could end its eligibility under §155.710 of this subchapter.

(2) If an employer receives a determination of ineligibility to participate in the SHOP or the SHOP terminates its eligibility to participate in the SHOP, unless the SHOP notifies the issuer or issuers of the determination of ineligibility or termination of eligibility, the employer must notify the issuer or issuers of QHPs in which their group members are enrolled in coverage of its ineligibility or termination of eligibility within 5 business days of the end of any applicable appeal process under §155.741 of this subchapter, which could include when the time to file an appeal lapses without an appeal being filed, when the appeal is rejected

or dismissed, or when the appeal process concludes with an adjudication by the appeals entity, as applicable.

(3) Employers must promptly notify the issuer or issuers of QHPs in which their group members are enrolled in coverage if it wishes to terminate coverage or enrollment through the SHOP, unless the SHOP notifies the issuer or issuers.

(f) *Applicability date.* The provisions of this section apply for plan years beginning on or after January 1, 2018.

[83 FR 17070, Apr. 17, 2018]

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

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AUTHORITY: 42 U.S.C. 300gg–18.

SOURCE: 75 FR 74921, Dec. 1, 2010, unless otherwise noted.

§ 158.101 Basis and scope.

(a) *Basis.* This part implements section 2718 of the Public Health Service Act (PHS Act).

(b) *Scope.* Subpart A of this part establishes the requirements for health insurance issuers (''issuers'') offering group or individual health insurance coverage to report information concerning premium revenues and the use of such premium revenues for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. Subpart B describes how this information will be used to determine, with respect to each medical loss ratio (MLR) reporting year, whether the ratio of the amount of adjusted premium revenue expended by the issuer on permitted costs to the total amount of adjusted premium revenue (MLR) meets or exceeds the percentages established by section 2718(b)(1) of the PHS Act. Subpart B also addresses requirements for calculating any rebate amounts that may be due in the event an issuer does not meet the applicable MLR standard. Subpart C implements the provision of section 2718(b)(1)(A)(ii) of the PHS Act allowing the Secretary to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market. Subparts D through F provide for enforcement of this part, including requirements for issuers to maintain records and civil monetary penalties that may be assessed against issuers who violate the requirements of this part.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010]

§ 158.102 Applicability.

General requirements. The requirements of this part apply to issuers offering group or individual health insurance coverage, including a grandfathered health plan as defined in §147.140 of this subpart.

§ 158.103 Definitions.

For the purposes of this part, the following definitions apply unless specified otherwise.

Blended rate means a single rate charged for health insurance coverage provided to a single employer through two or more of an issuer's affiliated companies for employees in one or more States.

Contract reserves means reserves that are established by an issuer which, due to the gross premium pricing structure at issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

Direct paid claims means claim payments before ceded reinsurance and excluding assumed reinsurance except as otherwise provided in this part.

Enrollee means an individual who is enrolled, within the meaning of §144.103 of this title, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year.

Experience rating refund means the return of a portion of premiums pursuant to a retrospectively rated funding arrangement when the sum of incurred losses, retention and margin are less than earned premium.

Group conversion charges means the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability.

Health Plan means health insurance coverage offered through either individual coverage or a group health plan.

Individual market has the meaning given the term in section 2791(e)(1) of the PHS Act and section 1304(a)(2) of the Affordable Care Act.

Large Employer has the meaning given the term in §144.103 of this subchapter.

Large group market has the meaning given the term in section 2791(e)(3) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer.

Policyholder means any entity that has entered into a contract with an issuer to receive health insurance coverage as defined in section 2791(b) of the PHS Act.

Prescription drug rebates and other price concessions means all remuneration received by or on behalf of an issuer, including remuneration received by and on behalf of entities providing pharmacy benefit management services to the issuer, that decrease the costs of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, or vendor). Prescription drug rebates and other price concessions include discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits to the extent the value of these items reduce costs for the issuer, and excluding bona fide service fees. Prescription drug rebates and other price concessions exclude any remuneration, coupons, or price concessions for which the full value is passed on to the enrollee. Bona fide service fees mean fees paid by a drug manufacturer to an entity providing pharmacy benefit management services to the issuer that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Situs of the contract means the jurisdiction in which the contract is issued or delivered as stated in the contract.

Small Employer has the meaning given the term in §144.103 of this subchapter.

Small group market has the meaning in section 2791(e)(5) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

Student administrative health fee has the meaning given the term in §147.145 of this subchapter.

Student health insurance coverage has the meaning given the term in §147.145 of this subchapter.

Student market means the market for student health insurance coverage.

Subscriber refers to both the group market and the individual market. In the group market, subscriber means the individual, generally the employee, whose eligibility is the basis for the enrollment in the group health plan and who is responsible for the payment of premiums. In the individual market, subscriber means the individual who purchases an individual policy and who is responsible for the payment of premiums.

Unearned premium means that portion of the premium paid in the MLR reporting year that is intended to provide coverage during a period which extends beyond the MLR reporting year.

Unpaid Claim Reserves means reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 81 FR 12352, Mar. 8, 2016; 86 FR 24294, May 5, 2021]

Subpart A—Disclosure and Reporting

§158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued. Reporting requirements of this part that apply to expenses incurred directly by the issuer also apply to expenses for functions outsourced to

or services provided by other entities retained by the issuer.

(b) *Timing and form of report.* The report for each of the 2011, 2012, and 2013 MLR reporting years must be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary. Beginning with the 2014 MLR reporting year, the report for each MLR reporting year must be submitted to the Secretary by July 31 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

(c) *Transfer of business.* Issuers that purchase a line or block of business from another issuer during an MLR reporting year are responsible for submitting the information and reports required by this part for the assumed business, including for that part of the MLR reporting year that was prior to the purchase.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011; 78 FR 15539, Mar. 11, 2013; 85 FR 29262, May 14, 2020]

§ 158.120 Aggregate reporting.

(a) *General requirements.* For purposes of submitting the report required in § 158.110 of this subpart, the issuer must submit a report for each State in which it is licensed to issue health insurance coverage that includes the experience of all policies issued in the State during the MLR reporting year covered by the report. The report must aggregate data for each entity licensed within a State, aggregated separately for the large group market, the small group market and the individual market. Experience with respect to each policy must be included on the report submitted with respect to the State where the contract was issued, except as specified in § 158.120(d) of this subpart.

(b) *Group Health Insurance Coverage in Multiple States.* Group coverage issued by a single issuer that covers employees in multiple States must be attributed to the applicable State based on the situs of the contract. Group coverage issued by multiple affiliated issuers that covers employees in multiple States must be attributed by each issuer to each State based on the situs of the contract.

(c) *Group Health Insurance Coverage With Dual Contracts.* Where a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, solely for the purpose of providing a group health plan that offers both in-network and out-of-network benefits, experience may be treated as if it were all related to the contract provided by the in-network issuer. However, if the issuer chooses this method of aggregation, it must apply it for a minimum of 3 MLR reporting years.

(d) *Exceptions.* (1) For individual market business sold through an association or trust, the experience of the issuer must be included in the State report for the issue State of the certificate of coverage.

(2) For employer business issued through a group trust or multiple employer welfare association (MEWA), the experience of the issuer must be included in the State report for the State where the employer (if sold through a trust) or the MEWA (if the MEWA is the policyholder) has its principal place of business.

(3) An issuer with policies that have a total annual limit of $250,000 or less must report the experience from such policies separately from other policies.

(4) An issuer with group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country, must aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies.

(5) An issuer in the student market must aggregate and report the experience from these policies on a national basis, separately from other policies.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 76 FR 76592, Dec. 7, 2011; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

§ 158.121 Newer experience.

If, for any aggregation as defined in § 158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

[81 FR 94183, Dec. 22, 2016]

§ 158.130 Premium revenue.

(a) *General requirements.* An issuer must report to the Secretary earned premium for each MLR reporting year. Earned premium means all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, including any fees or other contributions associated with the health plan.

(1) Earned premium is to be reported on a direct basis except as provided in paragraph (b) of this section.

(2) All earned premium for policies issued by one issuer and later assumed by another issuer must be reported by the assuming issuer for the entire MLR reporting year during which the policies were assumed and no earned premium for that MLR reporting year must be reported by the ceding issuer.

(3) Reinsured earned premium for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(b) *Adjustments.* Earned premium must include adjustments to:

(1) Account for assessments paid to or subsidies received from Federal and State high risk pools.

(2) Account for portions of premiums associated with group conversion charges.

(3) Account for any experience rating refunds incurred, excluding any rebate paid based upon an issuer's MLR.

(4) Account for unearned premium.

(5) Account for the net payments or receipts related to the risk adjustment, risk corridors (using an adjustment percentage, as described in § 153.500 of this subchapter, equal to zero percent), and reinsurance programs under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 28790, May 16, 2012; 78 FR 15539, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014]

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the medical claim portion of lawsuits, and any incurred experience rating refunds. Reimbursement for clinical services, as defined in this section, is referred to as ''incurred claims.'' All components of and adjustments to incurred claims, with the exception of contract reserves, must be calculated based on claims incurred only during the MLR reporting year and paid through March 31st of the following year. Contract reserves must be calculated as of December 31st of the applicable year.

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. If an issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting,

these amounts must be added to or subtracted from incurred claims.

(2) Incurred claims must include the current year's unpaid claims reserves, including claims reported in the process of adjustment, percentage withholds from payments made to contracted providers, claims that are recoverable for anticipated coordination of benefits (COB), and claim recoveries received as a result of subrogation.

(3) Incurred claims must include claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(4) Incurred claims must include changes in other claims-related reserves.

(5) Incurred claims must include incurred experience rating refunds and exclude rebates paid as required by §158.240 based upon prior MLR reporting year experience.

(b) *Adjustments to incurred claims.* (1) Adjustments that must be deducted from incurred claims:

(i)(A) For MLR reporting years before 2022, prescription drug rebates received by the issuer;

(B) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions received and retained by the issuer, and prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

(ii) Overpayment recoveries received from providers.

(iii) Cost-sharing reduction payments received by the issuer to the extent not reimbursed to the provider furnishing the item or service.

(2) Adjustments that must be included in incurred claims:

(i) Market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments.

(ii) State subsidies based on a stop-loss payment methodology.

(iii) The amount of incentive and bonus payments made to providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

(iv) The amount of claims payments recovered through fraud reduction efforts not to exceed the amount of fraud reduction expenses.

(3) Adjustments that must not be included in incurred claims:

(i) Amounts paid to third party vendors for secondary network savings.

(ii) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management. For example, if an issuer contracts with a behavioral health, chiropractic network, or high technology radiology vendor, or a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the issuer a higher amount to cover its network development, utilization management costs, and profits, then the amount that exceeds the reimbursement to the provider must not be included in incurred claims.

(iii) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee. For example, medical record copying costs, attorneys' fees, subrogation vendor fees, compensation to paraprofessionals, janitors, quality assurance analysts, administrative supervisors, secretaries to medical personnel and medical record clerks must not be included in incurred claims.

(iv) Amounts paid to a provider for services that do not represent reimbursement for covered services provided to an enrollee and are directly covered by a student administrative health fee.

(4) Adjustments that must be either included in or deducted from incurred claims:

(i) Payment to and from unsubsidized State programs designed to address distribution of health risks across issuers via charges to low risk issuers that are distributed to high risk issuers must be included in or deducted from incurred claims, as applicable.

(ii) Receipts related to the transitional reinsurance program and net

payments or receipts related to the risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in §153.500 of this subchapter, equal to zero percent) under sections 1341, 1342, and 1343 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, 18062, 18063.

(5) Other adjustments to incurred claims:

(i) Affiliated issuers that offer group coverage at a blended rate may choose whether to make an adjustment to each affiliate's incurred claims and activities to improve health care quality, to reflect the experience of the issuer with respect to the employer as a whole, according to an objective formula that must be defined by the issuer prior to January 1 of the MLR reporting year, so as to result in each affiliate having the same ratio of incurred claims to earned premium for that employer group for the MLR reporting year as the ratio of incurred claims to earned premium calculated for the employer group in the aggregate.

(ii) [Reserved]

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 78 FR 15539, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014; 80 FR 10876, Feb. 27, 2015; 85 FR 29262, May 14, 2020; 87 FR 27393, May 6, 2022]

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in §158.110 must include expenditures directly related to activities that improve health care quality, as such activities are described in this section.

(b) *Activity requirements.* Activities conducted by an issuer to improve quality must meet the following requirements:

(1) The activity must be designed to:

(i) Improve health quality.

(ii) Increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) Be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(2) The activity must be primarily designed to:

(i) Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and reduce health disparities among specified populations.

(A) Examples include the direct interaction of the issuer (including those services delegated by contract for which the issuer retains ultimate responsibility under the insurance policy), providers and the enrollee or the enrollee's representative (for example, face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes, including activities such as:

(*1*) Effective case management, care coordination, chronic disease management, and medication and care compliance initiatives including through the use of the medical homes model as defined in section 3502 of the Affordable Care Act.

(*2*) Identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine.

(*3*) Quality reporting and documentation of care in non-electronic format.

(*4*) Health information technology to support these activities.

(*5*) Accreditation fees directly related to quality of care activities.

(*6*) Commencing with the 2012 reporting year and extending through the first reporting year in which the Secretary requires ICD–10 as the standard medical data code set, implementing ICD–10 code sets that are designed to improve quality and are adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, limited to 0.3 percent of an issuer's earned premium as defined in §158.130.

(B) [Reserved]

(ii) Prevent hospital readmissions through a comprehensive program for hospital discharge. Examples include:

(A) Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;

(B) Patient-centered education and counseling.

(C) Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

(D) Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and lower infection and mortality rates.

(A) Examples of activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates include:

(*1*) The appropriate identification and use of best clinical practices to avoid harm.

(*2*) Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

(*3*) Activities to lower the risk of facility-acquired infections.

(*4*) Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

(*5*) Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

(*6*) Health information technology to support these activities.

(B) [Reserved]

(iv) Implement, promote, and increase wellness and health activities:

(A) Examples of activities primarily designed to implement, promote, and increase wellness and health activities, include—

(*1*) Wellness assessments;

(*2*) Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;

(*3*) Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition;

(*4*) Public health education campaigns that are performed in conjunction with State or local health departments;

(*5*)(*i*) For MLR reporting years before 2021, actual rewards, incentives, bonuses, and reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(*ii*) Beginning with the 2021 MLR reporting year, actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims, to the extent permitted by section 2705 of the PHS Act;

(*6*) Any quality reporting and related documentation in non-electronic form for wellness and health promotion activities;

(*7*) Coaching or education programs and health promotion activities designed to change member behavior and conditions (for example, smoking or obesity); and

(*8*) Health information technology to support these activities.

(B) [Reserved]

(v) Enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology consistent with §158.151 of this subpart.

(c) *Exclusions.* Expenditures and activities that must not be included in quality improving activities are:

(1) Those that are designed primarily to control or contain costs;

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans;

(3) Those which otherwise meet the definitions for quality improvement activities but which were paid for with grant money or other funding separate from premium revenue;

(4) Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services;

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including maintenance of ICD–10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality;

(7) All retrospective and concurrent utilization review;

(8) Fraud prevention activities;

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason;

(10) Provider credentialing;

(11) Marketing expenses;

(12) Costs associated with calculating and administering individual enrollee or employee incentives;

(13) That portion of prospective utilization that does not meet the definition of activities that improve health quality; and

(14) Any function or activity not expressly included in paragraph (a) or (b) of this section, unless otherwise approved by and within the discretion of the Secretary, upon adequate showing by the issuer that the activity's costs support the definitions and purposes in this part or otherwise support monitoring, measuring or reporting health care quality improvement.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011; 77 FR 28790, May 16, 2012; 79 FR 30352, May 27, 2014; 85 FR 29262, May 14, 2020; 87 FR 27393, May 6, 2022]

§ 158.151 Expenditures related to Health Information Technology and meaningful use requirements.

(a) *General requirements.* An issuer may include as activities that improve health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in § 158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

(1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their ''meaningful use'' as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in § 158.140 of this subpart;

(2) Implementing systems to track and verify the adoption and meaningful use of certified electronic health records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;

(3) Providing technical assistance to support adoption and meaningful use of certified electronic health records technologies;

(4) Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.

(5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.

(6) Advancing the ability of enrollees, providers, issuers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care,

which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient's medical history and to support care management.

(7) Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.

(8) Provision of electronic health records, patient portals, and tools to facilitate patient self-management.

(b) [Reserved]

§ 158.160 Other non-claims costs.

(a) *General requirements.* The report required in §158.110 of this subpart must include non-claims costs described in paragraph (b) of this section and must provide an explanation of how premium revenue is used, other than to provide reimbursement for clinical services covered by the benefit plan, expenditures for activities that improve health care quality, and Federal and State taxes and licensing or regulatory fees as specified in this part.

(b) *Non-claims costs other than taxes and regulatory fees.* (1) The report required in §158.110 of this subpart must include any expenses for administrative services that do not constitute adjustments to premium revenue as provided in §158.130 of this subpart, reimbursement for clinical services to enrollees as defined in §158.140 of this subpart, or expenditures on quality improvement activities as defined in §§158.150 and 158.151 of this subpart.

(2) Expenses for administrative services include the following:

(i) Cost-containment expenses not included as an expenditure related to an activity at §158.150 of this subpart.

(ii) Loss adjustment expenses not classified as a cost containment expense.

(iii) Direct sales salaries, workforce salaries and benefits.

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

(vii) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

[75 FR 74921, Dec. 1, 2010, as amended at 85 FR 29262, May 14, 2020]

§ 158.161 Reporting of Federal and State licensing and regulatory fees.

(a) *Licensing and regulatory fees included.* The report required in §158.110 must include statutory assessments to defray operating expenses of any State or Federal department, transitional reinsurance contributions assessed under section 1341 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18061, and examination fees in lieu of premium taxes as specified by State law.

(b) *Licensing and regulatory fees excluded.* The report required in §158.110 must include fines and penalties of regulatory authorities, and fees for examinations by any State or Federal departments other than as specified in §158.161(a) as other non-claims costs, but not as an adjustment to premium revenue.''

[75 FR 82279, Dec. 30, 2010, as amended at 78 FR 15539, Mar. 11, 2013]

§ 158.162 Reporting of Federal and State taxes.

(a) *Federal taxes.* The report required in §158.110 of this subpart must separately report:

(1) Federal taxes excluded from premium under subpart B which include all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act.

(2) Federal taxes not excluded from premium under subpart B of this part which include Federal income taxes on investment income and capital gains, as well as Federal employment taxes, as other non-claims costs.

(b) *State taxes and assessments.* The report required in §158.110 of this subpart must separately report:

(1) State taxes and assessments excluded from premium under subpart B which include:

(i) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of providing indigent care or other access to health care throughout the State.

(ii) Guaranty fund assessments.

(iii) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(iv) Advertising required by law, regulation or ruling, except advertising associated with investments.

(v) State income, excise, and business taxes other than premium taxes.

(vi) State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes.

(vii) Payments made by a Federal income tax exempt issuer for community benefit expenditures as defined in paragraph (c) of this section, limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the issuer's earned premium in the applicable State market.

(viii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer that is not exempt from Federal income tax may choose to report payment for community benefit expenditures as described in paragraph (c) of this section, limited to the highest premium tax rate in the State for which the report is being submitted multiplied by the issuer's earned premium in the applicable State market.

(2) State taxes and assessments not excluded from premium under subpart B which include:

(i) State sales taxes if the issuer does not exercise options of including such taxes with the cost of goods and services purchased.

(ii) Any portion of commissions or allowances on reinsurance assumed that represent specific reimbursement of premium taxes.

(iii) Any portion of commissions or allowances on reinsurance ceded that represents specific reimbursement of premium taxes.

(iv) State employment and similar taxes and assessments.

(c) *Community benefit expenditures.* Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:

(1) Are available broadly to the public and serve low-income consumers;

(2) Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);

(3) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;

(4) Leverage or enhance public health department activities such as childhood immunization efforts; and

(5) Otherwise would become the responsibility of government or another tax-exempt organization.

[75 FR 74921, Dec. 1, 2010. Redesignated and amended at 75 FR 82279, Dec. 30, 2010; 76 FR 76593, Dec. 7, 2011; 78 FR 15540, Mar. 11, 2013; 80 FR 10876, Feb. 27, 2015]

§ 158.170 Allocation of expenses.

(a) *General requirements.* Each expense must be reported under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses. Expenditures that benefit lines of business or products other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(b) *Description of the methods used to allocate expenses.* The report required in §158.110 must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing

or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

(1) Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.

(2) Many entities operate within a group where personnel and facilities are shared. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(3) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

(c) *Disclosure of allocation methods.* The issuer must identify in the report required in §158.110 of this subpart the specific basis used to allocate expenses reported under this part to States and, within States, to lines of business including the individual market, small group market, large group market, supplemental health insurance coverage, health insurance coverage offered to beneficiaries of public programs (such as Medicare and Medicaid), and group health plans as defined in §145.103 of this chapter and administered by the issuer.

(d) *Maintenance of records.* The issuer must maintain and make available to the Secretary upon request the data used to allocate expenses reported under this part together with all supporting information required to determine that the methods identified and reported as required under paragraph (b) of this section were accurately implemented in preparing the report required in §158.110 of this subpart.

[75 FR 74921, Dec. 1, 2010, as amended at 87 FR 27393, May 6, 2022]

Subpart B—Calculating and Providing the Rebate

§158.210 Minimum medical loss ratio.

Subject to the provisions of §158.211 of this subpart:

(a) *Large group market.* For all policies issued in the large group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85 percent, as determined in accordance with this part.

(b) *Small group market.* For all policies issued in the small group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this part.

(c) *Individual market.* For all policies issued in the individual market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this part.

(d) *Adjustment by the Secretary.* If the Secretary has adjusted the percentage that issuers in the individual market in a specific State must meet, then the adjusted percentage determined by the Secretary in accordance with §158.301 of this part *et seq.* must be substituted for 80 percent in paragraph (c) of this section.

§158.211 Requirement in States with a higher medical loss ratio.

(a) *State option to set higher minimum loss ratio.* For coverage offered in a State whose law provides that issuers

in the State must meet a higher MLR than that set forth in §158.210, the State's higher percentage must be substituted for the percentage stated in §158.210. If a State requires the small group market and individual market to be merged and also sets a higher MLR standard for the merged market, the State's higher percentage must be substituted for the percentage stated in §158.210 for both the small group and individual markets.

(b) *Considerations in setting a higher minimum loss ratio.* In adopting a higher minimum loss ratio than that set forth in §158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

[75 FR 74921, Dec. 1, 2010, as amended at 79 FR 30352, May 27, 2014]

§ 158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) *Aggregation by State and by market.* In general, an issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if a State requires the small group market and individual market to be merged, then the data reported separately under subpart A of this part for the small group and individual market in that State must be merged for purposes of calculating an issuer's MLR and any rebates owing.

(b) *Years of data to include in calculating MLR.* Subject to paragraphs (c) and (d) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in §158.221 of this subpart and aggregating the data reported under this part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) *Requirements for MLR reporting years 2011 and 2012.* (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year—

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year and the 2012 MLR reporting year.

(d) *Requirements for MLR reporting years 2013 and 2014 for the student market only.* (1) For the 2013 MLR reporting year, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year only.

(2) For the 2014 MLR reporting year—

(i) If an issuer's experience for the 2014 MLR reporting year is fully credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2014 MLR reporting year.

(ii) If an issuer's experience for the 2014 MLR reporting year is partially credible or non-credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year and the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012; 79 FR 30352, May 27, 2014]

§ 158.221 Formula for calculating an issuer's medical loss ratio.

(a) *Medical loss ratio.* (1) An issuer's MLR is the ratio of the numerator, as defined in paragraph (b) of this section, to the denominator, as defined in paragraph (c) of this section, subject to the applicable credibility adjustment, if any, as provided in §158.232 of this subpart.

(2) An issuer's MLR shall be rounded to three decimal places. For example, if an MLR is 0.7988, it shall be rounded to 0.799 or 79.9 percent. If an MLR is 0.8253 or 82.53 percent, it shall be rounded to 0.825 or 82.5 percent.

(b) *Numerator.* The numerator of an issuer's MLR for an MLR reporting year must be the issuer's incurred

claims, as defined in §158.140 of this part, plus the issuer's expenditures for activities that improve health care quality, as defined in §158.150 and §158.151 of this part, that are reported for the years specified in §158.220 of this subpart.

(1) The numerator of the MLR for the 2012 MLR reporting year may include any rebate paid under §158.240 of this subpart for the 2011 MLR reporting year if the 2012 MLR reporting year experience is not fully credible as defined in §158.230 of this subpart.

(2) The numerator of the MLR for the 2013 MLR reporting year may include any rebate paid under §158.240 for the 2011 MLR reporting year or the 2012 MLR reporting year.

(3) The numerator of the MLR for policies that are reported separately under §158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 2012 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.75, for the 2013 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.50, and for the 2014 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.25.

(4) The numerator of the MLR for policies that are reported separately under §158.120(d)(4) of this part must be the amount specified in paragraph (b) of this section, except that the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 2.00.

(5) The numerator of the MLR for policies that are reported separately under §158.120(d)(5) of this part must be the amount specified in paragraph (b) of this section, except that for the 2013 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality is then multiplied by a factor of 1.15.

(6) The numerator of the MLR in the individual and small group markets in States that adopted the transitional policy outlined in the CMS letter dated November 14, 2013 must be the amount specified in paragraph (b) of this section, except that issuers that provided transitional coverage may multiply the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market by a factor of 1.0001.

(7) The numerator of the MLR in the individual and small group markets for issuers participating in the State and Federal Exchanges (sometimes referred to as ''Marketplaces'') must be the amount specified in paragraph (b) of this section, except that the total incurred claims and expenditures for activities that improve health care quality incurred in 2014 in the respective State and market may be multiplied by a factor of 1.0004.

(8) Beginning with the 2020 MLR reporting year, an issuer may include in the numerator of the MLR any shared savings payments the issuer has made to an enrollee as a result of the enrollee choosing to obtain health care from a lower-cost, higher-value provider.

(c) *Denominator*. The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in §158.130, excluding the issuer's Federal and State taxes and licensing and regulatory fees, described in §§158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts related to risk adjustment, risk corridors, and reinsurance, described in §158.130(b)(5).

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011; 77 FR 16469, Mar. 21, 2012; 78 FR 15540, Mar. 11, 2013; 79 FR 30352, May 27, 2014; 83 FR 17070, Apr. 17, 2018; 85 FR 72310, Nov. 12, 2020; 86 FR 24294, May 5, 2021]

§158.230 Credibility adjustment.

(a) *General rule*. An issuer may add to the MLR calculated under §158.221(a) of this subpart the credibility adjustment specified by §158.232 of this section, if such MLR is based on partially credible experience as defined in paragraph (c)(2) of this section. An issuer may not apply the credibility adjustment if the issuer's experience is fully credible, as

defined in paragraph (c)(1) of this section, or non-credible, as defined in paragraph (c)(3) of this section.

(b) *Life-years.* The credibility of an issuer's experience is based upon the number of life-years covered by the issuer. Life-years means the total number of months of coverage for enrollees whose premiums and claims experience is included in the report to the Secretary required by § 158.110 of this part, divided by 12.

(c) *Credible experience.* (1) An MLR calculated under § 158.221(a) through (c) of this subpart is fully credible if it is based on the experience of 75,000 or more life-years.

(2) An MLR calculated under § 158.221(a) through (c) of this subpart is partially credible if it is based on the experience of at least 1,000 life-years and fewer than 75,000 life-years.

(3) An MLR calculated under § 158.221(a) through (c) of this subpart is non-credible if it is based on the experience of less than 1,000 life-years.

(d) If an issuer's MLR is non-credible, it is presumed to meet or exceed the minimum percentage required by § 158.210 or § 158.211 of this subpart.

§ 158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years. If a State requires the small group market and individual market to be merged, then life-years used to determine credibility must be the life-years from the small group market and the individual market for the MLR reporting year plus the life-years from the small group market and the individual market for the two prior MLR reporting years.

(b) For the 2011 MLR reporting year, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year only.

(c) For the 2012 MLR reporting year-

(1) If an issuer's experience for the 2012 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2012 MLR reporting year only;

(2) If an issuer's experience for the 2012 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year plus the life-years for the 2012 MLR reporting year.

(d) For the 2013 MLR reporting year for the student market only, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year only.

(e) For the 2014 MLR reporting year for the student market only—

(1) If an issuer's experience for the 2014 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2014 MLR reporting year only;

(2) If an issuer's experience for the 2014 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year plus the life-years for the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 79 FR 30353, May 27, 2014]

§ 158.232 Calculating the credibility adjustment.

(a) *Formula.* An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the deductible factor, as determined under paragraph (c) of this section.

(b) *Base credibility factor.* (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under § 158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

TABLE 1 TO § 158.232: BASE CREDIBILITY FACTORS

Life-years	Base credibility factor
<1,000	No Credibility.
1,000	8.3%.
2,500	5.2%.
5,000	3.7%.
10,000	2.6%.
25,000	1.6%.
50,000	1.2%.
≥75,000	0.0% (Full Credibility).

(c) *Deductible factor.* (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under § 158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be the lesser of: the deductible applicable to each of the individual family members; or the overall family deductible for the subscriber and subscriber's family divided by two (regardless of the total number of individuals covered through the subscriber).

(ii) The average deductible for an aggregation is calculated weighted by the life-years of experience for each deductible level of policies included in the aggregation.

(2) An issuer may choose to use a deductible factor of 1.0 in lieu of calculating a deductible factor based on the average of policies included in the aggregation.

TABLE 2 TO § 158.232: DEDUCTIBLE FACTOR

Health plan deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

(d) *No credibility adjustment.* Beginning with the 2013 MLR reporting year, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(e) *No credibility adjustment.* Beginning with the 2015 MLR reporting year for the student market only, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) Each year in the aggregation included experience of at least 1,000 life-years; and

(2) The issuer's preliminary MLR, as defined under paragraph (f) of this section, for each year in the aggregation was below the applicable MLR standard, as established under §§ 158.210 and 158.211.

(f) *Preliminary MLR.* Preliminary MLR means the ratio of the numerator, as defined in § 158.221(b) and calculated as of March 31st of the year following the year for which the MLR report required in § 158.110 is being submitted, to the denominator, as defined in § 158.221(c), calculated using only a single year of experience, and without applying any credibility adjustment.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012; 78 FR 15540, Mar. 11, 2013; 78 FR 66655, Nov. 6, 2013; 81 FR 94183, Dec. 22, 2016]

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

(a) *General requirement.* For each MLR reporting year, an issuer must provide a rebate to each enrollee if the issuer's MLR does not meet or exceed the minimum percentage required by §§ 158.210 and 158.211 of this subpart.

(b) *Definition of enrollee for purposes of rebate.* For the sole purpose of determining whom is entitled to receive a rebate pursuant to this part, the term ''enrollee'' means the subscriber, policyholder, and/or government entity that paid the premium for health care

coverage received by an individual during the respective MLR reporting year.

(c) *Amount of rebate to each enrollee.* (1) For each MLR reporting year, an issuer must rebate to the enrollee, subject to paragraph (d) of this section, the total amount of premium revenue, as defined in §158.130, received by the issuer from the enrollee, after subtracting Federal and State taxes and licensing and regulatory fees as provided in §§158.161(a) and 158.162(a)(1) and (b)(1), and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance as provided in §158.130(b)(5), multiplied by the difference between the MLR required by §158.210 or §158.211, and the issuer's MLR as calculated under §158.221.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the individual market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the individual market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting a pro rata portion of taxes and fees and accounting for payments or receipts related to the reinsurance, risk adjustment and risk corridors programs (calculated using an adjustment percentage, as described in §153.500 of this subchapter, equal to zero percent). If the issuer's total earned premium for the MLR reporting year in the individual market in the State is $200,000, the issuer received transitional reinsurance payments of $2,500, and made net payments related to risk adjustment and risk corridors of $20,000 (calculated using an adjustment percentage, as described in §153.500 of this subchapter, equal to zero percent), the issuer's gross earned premium in the individual market in the State would be $200,000 plus $2,500 minus $20,000, for a total of $182,500. If the issuer's Federal and State taxes and licensing and regulatory fees, including reinsurance contributions, that may be excluded from premium revenue as described in §§158.161(a), 158.162(a)(1) and 158.162(b)(1), allocated to the individual market in the State are $15,000, and the net payments related to risk adjustment and risk corridors, reduced by reinsurance receipts, that must be accounted for in premium revenue as described in §§158.130(b)(5), 158.221, and 158.240, are $17,500 ($20,000 reduced by $2,500), then the issuer would subtract $15,000 and add $17,500 to gross premium revenue of $182,500, for a base of $185,000 in premium. The issuer would owe rebates of 5 percent of $185,000, or $9,250 in the individual market in the State. In this example, if an enrollee of the issuer in the individual market in the State paid $2,000 in premiums for the MLR reporting year, or 1/100 of the issuer's total premium in that State market, then the enrollee would be entitled to 1/100 of the total rebates owed by the issuer, or $92.50.

(d) *Limitation on total rebate payable for each year in the aggregation.* For any State and market, an issuer may elect to limit the amount of rebate payable for the MLR reporting year to the issuer's total outstanding rebate liability with respect to all years included in the aggregation. If an issuer elects this option, the outstanding rebate liability with respect to a specific year in the aggregation must be calculated by multiplying the denominator with respect to that year, as defined in §158.221(c), by the difference between the MLR required by §158.210 or §158.211 for the MLR reporting year, and the sum of the issuer's preliminary MLR for that year, as defined under §158.232(f), and the credibility adjustment applicable to the current MLR reporting year. The outstanding rebate liability with respect to a specific year must be reduced by any rebate payments applied against it in prior MLR reporting years. A rebate paid for an MLR reporting year must be applied first to reduce the outstanding rebate liability with respect to the earliest year in the aggregation.

(e) *Timing of rebate.* For each of the 2011, 2012, and 2013 MLR reporting years, an issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year. Beginning with the 2014 MLR reporting year, an issuer must provide any rebate owing to an enrollee

no later than September 30 following the end of the MLR reporting year.

(f) *Late payment interest.* An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (e) of this section or to take other required action within the time periods set forth in this part must, in addition to providing the required rebate to the enrollee, pay the enrollee interest at the current Federal Reserve Board lending rate or ten percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under paragraph (e) of this section.

(g) *Rebate prepayment and safe harbor.* An issuer may choose to pay a portion or all of its estimated rebate amount for a given MLR reporting year to enrollees in any form specified in §158.241 prior to the rebate payment deadlines set forth in §§158.240(e) and 158.241(a)(2) and in advance of submitting the MLR report required in §158.110 to the Secretary. Issuers that choose to prepay a portion or all of their rebates must do so for all eligible enrollees in a given state and market in a non-discriminatory manner, and consistently with State law or other applicable state authority. If, after submitting the MLR report required in §158.110, an issuer determines that its rebate prepayment amount in a given state and market is at least 95 percent, but less than 100 percent, of the total rebate amount owed for the applicable MLR reporting year to enrollees in that state and market, the issuer may, without penalty or late payment interest under paragraph (f) of this section, provide the remaining rebate amount to those enrollees no later than the rebate deadlines in §§158.240(e) and 158.241(a)(2) applicable to the following MLR reporting year. If the total rebate owed to an enrollee for the MLR reporting year is above the *de minimis* threshold established in §158.243(a), the issuer cannot treat the remaining rebate owed to an enrollee after prepayment as *de minimis*, even if the remaining rebate is below the *de minimis* threshold.

[75 FR 74921, Dec. 1, 2010, as amended at 78 FR 15540, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014; 81 FR 94183, Dec. 22, 2016; 86 FR 24294, May 5, 2021]

§ 158.241 Form of rebate.

(a) *Current enrollees.* (1) An issuer may choose to provide any rebates owing to current enrollees in the form of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium.

(2) For each of the 2011, 2012, and 2013 MLR reporting years, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with the 2014 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after September 30 following the MLR reporting year. If the amount of the rebate exceeds the premium due for October, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited. Beginning with rebates due for the 2020 MLR reporting year, any rebate provided in the form of a premium credit must be provided by applying the full amount due to the monthly premium that is due no later than October 30 following the MLR reporting year. If the amount of the rebate exceeds the monthly premium, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

(b) *Former enrollees in the individual market.* Rebates owing to former enrollees in the individual market must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011; 78 FR 15540, Mar. 11, 2013; 86 FR 24295, May 5, 2021]

§ 158.242 Recipients of rebates.

(a) *Individual market.* An issuer must meet its obligation to provide any rebate due to an enrollee in the individual market by providing it to the enrollee. For individual policies that cover more than one person, one lump-sum rebate may be provided to the subscriber on behalf of all enrollees covered by the policy.

(b) *Large group and small group markets.* Except as provided in paragraphs (b)(3) and (4) of this section, an issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the policyholder.

(1) In the case of a policyholder that is a non-Federal governmental group health plan, the policyholder must use the amount of the rebate that is proportionate to the total amount of premium paid by all subscribers under the policy, for the benefit of subscribers in one of the following ways, at the option of the policyholder:

(i) For all subscribers covered under any option offered under the policyholder's group health plan at the time the rebate is received by the policyholder, to reduce the subscribers' portion of premium for the subsequent policy year;

(ii) For subscribers covered, at the time the rebate is received by the policyholder, under the group health plan option for which the issuer is providing a rebate, to reduce the subscribers' portion of premium for the subsequent policy year;

(iii) A cash refund to subscribers of the group health plan option for which the issuer is providing a rebate, who were enrolled in the group health plan option either during the MLR reporting year that resulted in the issuer providing the rebate or at the time the rebate is received by the policyholder;

(iv) The reduction in future premium or the cash refund provided under paragraphs (b)(1)(i), (ii), or (iii) of this section may, at the option of the policyholder, be: Divided evenly among such subscribers; divided based on each subscriber's actual contributions to premium; or apportioned in a manner that reasonably reflects each subscriber's contributions to premium; and

(v) All rebate distributions made under paragraphs (b)(1)(i), (ii), or (iii) of this section must be made within 3 months of the policyholder's receipt of the rebate. Rebate distributions made after 3 months must include late payment interest at the current Federal Reserve Board lending rate or 10 percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under this section.

(2) In the case of a policyholder that is a non-Federal governmental group health plan, the portion of a rebate based upon former subscribers' contributions to premium must be aggregated and used for the benefit of current subscribers in the group health plan in any manner permitted by paragraph (b)(1) of this section.

(3) If the policyholder is a group health plan that is not a governmental plan and not subject to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*) (ERISA), rebates may only be paid to the policyholder if the issuer receives a written assurance from the policyholder that the rebates will be used as provided in paragraphs (b)(1) and (2) of this section; otherwise, the issuer must distribute the rebate directly to the subscribers of the group health plan covered by the policy during the MLR reporting year on which the rebate is based by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

(4) If the group health plan has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder whose plan participants or employees were enrolled in the group health plan, the issuer must distribute the rebate directly to the subscribers of the terminated group health plan by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without

regard to how much each subscriber actually paid toward premiums.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, 76599, Dec. 7, 2011; 80 FR 10876, Feb. 27, 2015]

§ 158.243 *De minimis* rebates.

(a) *Minimum threshold.* An issuer is not required to provide a rebate to an enrollee based upon the premium that enrollee paid, under the following circumstances:

(1) For a group policy for which the issuer distributes the rebate to the policyholder, if the total rebate owed to the policyholder and the subscribers combined is less than $20 for a given MLR reporting year; or for a group policy for which the issuer distributes the rebate directly to the subscribers, as provided in §158.242(a)(3) and (4) of this subpart, if the total rebate owed to each subscriber is less than $5.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) *Distribution.* (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee's rebate by $0.20.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011]

§ 158.244 Unclaimed rebates.

An issuer must make a good faith effort to locate and deliver to an enrollee any rebate required under this part. If, after making a good faith effort, an issuer is unable to locate a former enrollee, the issuer must comply with any applicable State law.

§ 158.250 Notice of rebates.

(a) *Notice of rebates to policyholders and subscribers of group health plans.* For each MLR reporting year, at the time any rebate of premium is provided to a policyholder of a group health plan in accordance with this part, an issuer must provide each policyholder who receives a rebate and subscribers whose policyholder receives a rebate, or each subscriber who receives a rebate directly from an issuer, the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with §158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §158.162(a)(1) and (b)(1) of this part;

(6) The rebate percentage and the amount owed to enrollees, as defined in section 158.240(b), based upon the difference between the issuer's MLR and the applicable MLR standard; and

(7) The fact that, as provided by this subpart, the total aggregated rebate for the group health plan is being provided to the policyholder:

(i) If the policy provides benefits for a plan subject to ERISA, a statement that the policyholder may have additional obligations under ERISA's fiduciary responsibility provisions with respect to the handling of rebates and contact information for questions regarding the rebate;

(ii) If the policyholder is a non-Federal governmental plan, the proportion of the rebate attributable to subscribers' contribution to premium

must be used for the benefit of subscribers, using one of the methods set forth in §158.242(b)(1) of this subpart; and

(iii) If the policyholder is a group health plan that is not a governmental plan and is not subject to ERISA,

(A) The policyholder has provided written assurance that the proportion of the rebate attributable to subscribers' contribution to premium will be used for the benefit of current subscribers, using one of the methods set forth in §158.242(b)(1) of this subpart, or

(B) If the policyholder did not provide such written assurance, the issuer must distribute the rebate evenly among the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

(b) *Notice of rebates to subscribers in the individual market.* For each MLR reporting year, at the time any rebate of premium is provided to a subscriber in the individual market in accordance with this part, an issuer must provide each subscriber that is receiving the rebate the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with §158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §158.162(a)(1) and (b)(1) of this part; and

(6) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

[76 FR 76593, Dec. 7, 2011]

§ 158.251 Notice of MLR information.

(a) *Notice of MLR information when the MLR standard is met or exceeded*—(1) *General requirement.* Except as provided in paragraph (b) of this section, for the 2011 MLR reporting year, an issuer whose MLR meets or exceeds the applicable MLR standard required by §158.210 or §158.211 must provide each policyholder and subscriber of a group health plan, and each subscriber in the individual market, a notice in accordance with the requirements of this section.

(2) *Timing.* An issuer must provide the notice required in this paragraph (a) with the first plan document that the issuer provides to enrollees on or after July 1, 2012.

(3) *Form and appearance.* The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the plan document or as a separate notice. The notice may be provided electronically, if the requirements for electronic disclosure under section 2715 of the Public Health Service Act are met.

(4) *Language.* The following language must be used to satisfy the notice requirement of this paragraph (a):

Medical Loss Ratio Information—The Affordable Care Act requires health insurers in the individual and small group markets to spend at least 80 percent of the premiums they receive on health care services and activities to improve health care quality (in the large group market, this amount is 85 percent). This is referred to as the Medical Loss Ratio (MLR) rule or the 80/20 rule. If a health insurer does not spend at least 80 percent of the premiums it receives on health care services and activities to improve health care quality, the insurer must rebate the difference.

A health insurer's Medical Loss Ratio is determined separately for each State's individual, small group and large group markets in which the health insurer offers health insurance. In some States, health insurers must meet a higher or lower Medical Loss Ratio. No later than August 1, 2012, health insurers must send any rebates due for 2011 and information to employers and individuals regarding any rebates due for 2011.

You are receiving this notice because your health insurer had a Medical Loss Ratio for 2011 that met or exceeded the required Medical Loss Ratio. For more information on Medical Loss Ratio and your health insurer's Medical Loss Ratio, visit *www.HealthCare.gov*.''

(b) *Exceptions.* The requirements of paragraph (a) of this section do not apply to an issuer that reports its experience separately under §158.120(d)(3) or (d)(4), or to an issuer whose experience is non-credible as defined in

§ 158.230(c)(3) and determined in accordance with § 158.231.

[77 FR 28797, May 16, 2012]

§ 158.260 Reporting of rebates.

(a) *General requirement.* For each MLR reporting year, an issuer must submit to the Secretary a report concerning the rebates provided to and on behalf of enrollees pursuant to this subpart.

(b) *Aggregation of information in the report.* The information in the report must be aggregated in the same manner as required by § 158.120.

(c) *Information to report.* The report required by this section must include the total:

(1) Number of subscribers in the individual, small group and large group markets to whom the issuer paid a rebate directly, and number of small group and large group policyholders receiving a rebate on behalf of enrollees;

(2) Amount of rebates provided as premium credit;

(3) Amount of rebates provided as lump sum payment regardless of whether in cash, reimbursement to an enrollee's credit card, or direct payment to an enrollee's bank account;

(4) Amount of rebates that were de minimis as provided in § 158.243 of this subpart and the number of enrollees who did not receive a rebate because it was de minimis; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

(d) *Timing and form of report.* The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under § 158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under § 158.110 for the subsequent MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76594, Dec. 7, 2011]

§ 158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in the Secretary's discretion, the Secretary determines that there is a reasonable likelihood that an adjustment to the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act will help stabilize the individual market in that State.

[83 FR 17070, Apr. 17, 2018]

§ 158.310 Who may request adjustment to the medical loss ratio.

A request for an adjustment to the MLR standard for a State must be submitted by the State's insurance commissioner, superintendent, or comparable official of that State in order to be considered by the Secretary.

§ 158.311 Duration of adjustment to the medical loss ratio.

A State may request that an adjustment to the MLR standard be for up to three MLR reporting years.

§ 158.320 Information supporting a request for adjustment to the medical loss ratio.

A State must submit in electronic format the information required by §§ 158.321 through 158.323 of this subpart in order for the request for adjustment to the MLR standard for the State to be considered by the Secretary. A State may submit to the Secretary any additional information it determines would support its request. In the event that certain data are unavailable or that the collection of certain data is unduly burdensome, a State may provide written notice to the Secretary and the Secretary may, at her discretion, request alternative supporting data or move forward with her determination.

§ 158.321 Information regarding the State's individual health insurance market.

(a) Subject to § 158.320, the State must provide, for each issuer who actively offers coverage in the individual market in the State, the following information, in accordance with paragraph (b) of this section, for the preceding calendar year and, at the State's option, for the current year:

(1) Total earned premium and incurred claims;

(2) Total number of enrollees (life-years and covered lives);

(3) Total agents' and brokers' commission expenses;

(4) Net underwriting gain;

(5) Risk-based capital level; and

(6) Whether the issuer has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

(b) The information required in paragraphs (a)(1) through (4) and (6) of this section must be provided separately for the issuer's individual market plans grouped by the following categories, as applicable: On-Exchange, off-Exchange, grandfathered health plans as defined in § 147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage. The information required in paragraph (a)(5) of this section must be provided at the issuer level.

(c) The State must also provide information regarding whether any issuer other than those described in paragraph (a) of this section has provided notice to the State's insurance commissioner, superintendent, or comparable State authority that the issuer will cease or begin offering individual market coverage on the Exchange, certain geographic areas, or the entire individual market in the State.

[83 FR 17070, Apr. 17, 2018]

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to

the MLR standard. This proposal must include an explanation of how an adjustment to the MLR standard for the State's individual market will help stabilize the State's individual market.

[83 FR 17071, Apr. 17, 2018]

§ 158.323 State contact information.

A State must provide the name, telephone number, e-mail address, and mailing address of the person the Secretary may contact regarding the request for an adjustment to the MLR standard.

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether an adjustment to the 80 percent MLR standard, as calculated in accordance with this subpart, would be reasonably likely to help stabilize the individual market in a State that has requested such adjustment:

(a) The number and financial performance (based on data provided by a State under §158.321) of issuers actively offering individual health insurance coverage on- and off-Exchange, grandfathered health plans as defined in §147.140 of this subchapter, coverage that meets the criteria for transitional policies outlined in applicable guidance, and non-grandfathered single risk pool coverage; the number of issuers reasonably likely to cease or begin offering individual market coverage in the State; and the likelihood that an adjustment to the 80 percent MLR standard could help increase competition in the individual market in the State, including in underserved areas.

(b) Whether an adjustment to the 80 percent MLR standard for the individual market may improve consumers' access to agents and brokers.

(c) The capacity of any new issuers or issuers remaining in the individual market to write additional business in the event one or more issuers were to cease offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(d) The impact on premiums charged, and on benefits and cost sharing provided, to consumers by issuers remaining in or entering the individual market in the event one or more issuers were to cease or begin offering individual market coverage on the Exchange, in certain geographic areas, or in the entire individual market in the State.

(e) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

[83 FR 17071, Apr. 17, 2018]

§ 158.340 Process for submitting request for adjustment to the medical loss ratio.

(a) *Electronic submission.* A State must submit electronically, to an address and in a format prescribed by the Secretary, all of the information required by this subpart in order for its request for an adjustment to the MLR standard for its individual market to be considered by the Secretary.

(b) *Submission by mail.* A State may also submit by overnight delivery service or by U.S mail, return receipt requested, to an address and in a format prescribed by the Secretary, its request for an adjustment to the MLR standard for its individual market.

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document. Instructions for how to access documents related to a State's request for an adjustment to the MLR standard will be made available on the Secretary's website.

[83 FR 17071, Apr. 17, 2018]

§ 158.342 Invitation for public comments.

The Secretary will invite public comment regarding a State's request for an adjustment to the MLR standard. All public comments must be submitted in writing within 10 days of the posting of the request, and must be submitted in the manner prescribed by the Secretary. The Secretary will consider timely public comments in assessing a State's request for an adjustment to the MLR standard.

§ 158.343 Optional State hearing.

Any State that submits a request for adjustment to the MLR standard may, at its option, hold a public hearing and create an evidentiary record with respect to its application. If a State does so, the Secretary will take the evidentiary record of the hearing into consideration in making her determination.

§ 158.344 Secretary's discretion to hold a hearing.

The Secretary may, at her discretion, conduct a public hearing with respect to a State's request for an adjustment to the MLR standard. All testimony and materials received in connection with any public hearing will be made part of the public record, and shall be considered by the Secretary in assessing a State's request for an adjustment to the MLR standard.

§ 158.345 Determination on a State's request for adjustment to the medical loss ratio.

(a) *General time frame.* The Secretary will make a determination as to whether to grant a State's request for an adjustment to the MLR standard within 30 days after determining that the information required by this subpart has been received.

(b) *Extension at the discretion of the Secretary.* The Secretary may, in her discretion, extend the 30 day time period in paragraph (a) of this section for as long a time as necessary not to exceed 30 days.

§ 158.346 Request for reconsideration.

(a) *Requesting reconsideration.* A State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

(b) *Reconsideration determination.* The Secretary will issue her determination on a State's request for reconsideration within 20 days of receiving the reconsideration request.

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its prior requests, if any, to improve the stability of the State's individual market.

[83 FR 17071, Apr. 17, 2018]

Subpart D—HHS Enforcement

§ 158.401 HHS enforcement.

HHS enforces the reporting and rebate requirements described in subparts A and B, including but not limited to:

(a) The requirement that such reports be submitted timely.

(b) The requirement that the data reported complies with the definitions and criteria set forth in this part.

(c) The requirement that rebates be paid timely and accurately.

§ 158.402 Audits.

(a) *Notice of Audit.* HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an

issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with §158.240(d) of this part.

§ 158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E—Additional Requirements on Issuers

§ 158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§ 158.502 Maintenance of records.

(a) *Basic rule.* Each issuer subject to the requirements of this part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this part

comply with the definitions and criteria set forth in this part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under §158.501 of this subpart.

Subpart F—Federal Civil Penalties

§158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties, as described in this subpart, may be imposed.

§158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in §158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§158.603 Notice to responsible entities.

If HHS learns of a potential violation described in §158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in §158.602 of this subpart.

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§ 158.606 Amount of penalty—general.

A civil monetary penalty for each violation of §158.602 of this subpart may not exceed $100 as adjusted annually under 45 CFR part 102 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

[75 FR 74921, Dec. 1, 2010, as amended at 81 FR 61581, Sept. 6, 2016]

§ 158.607 Factors HHS uses to determine the amount of penalty.

In determining the amount of any penalty, HHS may take into account the following:

(a) *The entity's previous record of compliance.* This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation(s), HHS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of Affordable Care Act requirements regarding minimum loss ratios.

(2) Evidence that the responsible entity has never had a complaint for noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by §158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in §158.607 of this subpart, HHS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under §158.603 of this subpart, implemented and followed a compliance plan as described in §158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she, or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by §158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§158.611 Settlement authority.

Nothing in §158.606 through §158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with §158.603 of this subpart or to compromise on any penalty provided for in §§158.606 through 158.610 of this subpart.

§158.612 Limitations on penalties.

(a) *Circumstances under which a civil monetary penalty is not imposed.* HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in §158.607 through §158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with §158.615 of this subpart.

(b) *Delivery of notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§ 158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this part may appeal that penalty in accordance with §150.400 *et seq.*

§ 158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in §158.613 of this subpart, HHS may assess the proposed civil monetary penalty indicated in such notice and may impose additional penalties as described in §158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this subchapter, unless the responsible entity can show good cause, as determined at §150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

PART 159—HEALTH CARE REFORM INSURANCE WEB PORTAL

Sec.

159.100 Basis and Scope.
159.110 Definitions.
159.120 Data Submission for the individual and small group markets.

AUTHORITY: Section 1103 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24482, May 5, 2010, unless otherwise noted.

§ 159.100 Basis and scope.

This part establishes provisions governing a Web portal that will provide information on health insurance coverage options in each of the 50 States and the District of Columbia. It sets forth data submission requirements for health insurance issuers. It covers the individual market and the small group market.

§ 159.110 Definitions.

For purposes of part 159, the following definitions apply unless otherwise provided:

Health Insurance Coverage: We adopt the Public Health Service Act (PHSA) definition of ''health insurance coverage'' found at section 2791(b)(1) of the Public Health Service Act (PHSA).

Health Insurance Issuer: We adopt the PHSA definition of ''health insurance issuer'' found at section 2791(b)(2) of the PHSA.

Health Insurance Product: Means a package of benefits that an issuer offers that is reported to State regulators in an insurance filing.

Individual Health Insurance Coverage: We adopt the PHSA definition of ''individual health insurance coverage'' found at section 2791(b)(5) of the PHSA.

Individual Market: We adopt the Affordable Care Act definition of ''individual market'' found at section 1304(a)(2) of the Affordable Care Act and 2791(e)(1)(A) of the PHSA.

Portal Plan: Means the discrete pairing of a package of benefits and a particular cost sharing option (not including premium rates or premium quotes).

Section 1101 High Risk Pools: We define section 1101 high risk pools as any entity described in regulations implementing section 1101 of the Affordable Care Act.

Small Employer: We adopt the Affordable Care Act definition of ''small employer'' found at section 1304(b)(2) and (3).

Small Group Coverage: Means health insurance coverage offered to employees of small employers in the small group market.

Small Group Market: We adopt the Affordable Care Act definition of ''small group market'' found at section 1304(a)(3).

State Health Benefits High Risk Pools: Means nonprofit organizations created by State law to offer comprehensive health insurance to individuals who otherwise would be unable to secure such coverage because of their health status.

§ 159.120 Data submission for the individual and small group markets.

(a) Health insurance issuers (hereinafter referred to as issuers) must, in accordance with guidance issued by the Secretary, submit corporate and contact information; administrative information; enrollment data by health insurance product; product names and types; whether enrollment is currently open for each health insurance product; geographic availability information; customer service phone numbers; and Web site links to the issuer Web site, brochure documents, and provider networks; and financial ratings on or before May 21, 2010, and annually thereafter.

(b) Issuers must, as determined by the Secretary, submit pricing and benefit information for their portal plans on or before September 3, 2010, and annually thereafter.

(c) Issuers must submit updated pricing and benefit data for their portal plans whenever they change premiums, cost-sharing, types of services covered, coverage limitations, or exclusions for one or more of their individual or small group portal plans.

(d) Issuers must submit pricing and benefit data for portal plans associated with products that are newly open or newly reopened for enrollment within 30 days of opening for enrollment.

(e) Issuers must annually verify the data submitted under paragraphs (a) through (d) of this section, and make corrections to any errors that are found.

(f) Issuers must submit administrative data on products and portal plans, and these performance ratings, percent of individual market and small group market policies that are rescinded; the percent of individual market policies sold at the manual rate; the percent of claims that are denied under individual market and small group market policies; and the number and disposition of appeals on denials to insure, pay claims and provide required preauthorizations, for future releases of the Web portal in accordance with guidance issued by the Secretary.

(g) The issuer's CEO or CFO must electronically certify to the completeness and accuracy of all data submitted for the October 1, 2010, release of the Web portal and for any future updates to these requirements.

SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

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160.552 Harmless error.

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

SOURCE: 65 FR 82798, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171–1180 of the Social Security Act (the Act), sections 262 and 264 of Public Law 104–191, section 105 of Public Law 110–233, sections 13400–13424 of Public Law 111–5, and section 1104 of Public Law 111–148.

[78 FR 5687, Jan. 25, 2013]

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under

this subchapter apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.

(c) To the extent required under the Social Security Act, 42 U.S.C. 1320a–7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 78 FR 5687, Jan. 25, 2013]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d–1320d–4, 1320d–7, 1320d–8, and 1320d–9;

(2) Section 264 of Pub. L. 104–191;

(3) Sections 13400–13424 of Public Law 111–5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in §164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of §164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the

extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or *penalty* means the amount determined under §160.404 of this part and includes the plural of these terms.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Family member means, with respect to an individual:

(1) A dependent (as such term is defined in 45 CFR 144.103), of the individual; or

(2) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(i) First-degree relatives include parents, spouses, siblings, and children.

(ii) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(iii) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(iv) Fourth-degree relatives include great-great grandparents, great-great

grandchildren, and children of first cousins.

Genetic information means:

(1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(2) Any reference in this subchapter to genetic information concerning an individual or family member of an individual shall include the genetic information of:

(i) A fetus carried by the individual or family member who is a pregnant woman; and

(ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

(3) Genetic information excludes information about the sex or age of any individual.

Genetic services means:

(1) A genetic test;

(2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(3) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and ''value-added'' networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg–91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq*.

(vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, 42 U.S.C. 1395w–101 through 1395w–152.

(vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.

(ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(x) The health care program for uniformed services under title 10 of the United States Code.

(xi) The veterans health care program under 38 U.S.C. chapter 17.

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq*.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq*.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq*.

(xv) The Medicare Advantage program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg–91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Manifestation or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

Public health, as used in the terms ''public health surveillance,'' ''public health investigation,'' and ''public health intervention,'' means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.
(4) Health care claim status.
(5) Enrollment and disenrollment in a health plan.
(6) Eligibility for a health plan.
(7) Health plan premium payments.
(8) Referral certification and authorization.
(9) First report of injury.
(10) Health claims attachments.
(11) Health care electronic funds transfers (EFT) and remittance advice.
(12) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012; 78 FR 5687, Jan. 25, 2013; 89 FR 33062, Apr. 26, 2024]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

§ 160.105 Compliance dates for implementation of new or modified standards and implementation specifications.

Except as otherwise provided, with respect to rules that adopt new standards and implementation specifications or modifications to standards and implementation specifications in this subchapter in accordance with § 160.104 that become effective after January 25, 2013, covered entities and business associates must comply with the applicable new standards and implementation specifications, or modifications to standards and implementation specifications, no later than 180 days from the effective date of any such standards or implementation specifications.

[78 FR 5689, Jan. 25, 2013]

Subpart B—Preemption of State Law

§ 160.201 Statutory basis.

The provisions of this subpart implement section 1178 of the Act, section 262 of Public Law 104–191, section 264(c) of Public Law 104–191, and section 13421(a) of Public Law 111–5.

[78 FR 5689, Jan. 25, 2013]

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity or business associate would find it impossible to comply with both the State and Federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104–191, or sections 13400–13424 of Public Law 111–5, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity or business associate is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 74 FR 42767, Aug. 24, 2009; 78 FR 5689, Jan. 25, 2013]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or

that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Investigations

SOURCE: 71 FR 8424, Feb. 16, 2006, unless otherwise noted.

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, business associates, and others with respect to ascertaining the compliance by covered entities and business associates with, and the enforcement of, the applicable provisions of this part 160 and parts 162 and 164 of this subchapter.

[78 FR 5690, Jan. 25, 2013]

§ 160.302 [Reserved]

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable and consistent with the provisions of this subpart, seek the cooperation of covered entities and business associates in obtaining compliance with the applicable

administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities and business associates to help them comply voluntarily with the applicable administrative simplification provisions.

[78 FR 5690, Jan. 25, 2013]

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity or business associate is not complying with the administrative simplification provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* (1) The Secretary will investigate any complaint filed under this section when a preliminary review of the facts indicates a possible violation due to willful neglect.

(2) The Secretary may investigate any other complaint filed under this section.

(3) An investigation under this section may include a review of the pertinent policies, procedures, or practices of the covered entity or business associate and of the circumstances regarding any alleged violation.

(4) At the time of the initial written communication with the covered entity or business associate about the complaint, the Secretary will describe the acts and/or omissions that are the basis of the complaint.

[71 FR 8424, Feb. 16, 2006, as amended at 78 FR 5690, Jan. 25, 2013]

§ 160.308 Compliance reviews.

(a) The Secretary will conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions when a preliminary review of the facts indicates a possible violation due to willful neglect.

(b) The Secretary may conduct a compliance review to determine whether a covered entity or business associate is complying with the applicable administrative simplification provisions in any other circumstance.

[78 FR 5690, Jan. 25, 2013]

§ 160.310 Responsibilities of covered entities and business associates.

(a) *Provide records and compliance reports.* A covered entity or business associate must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity or business associate has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity or business associate must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity or business associate to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity or business associate must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable administrative

simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity or business associate must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity or business associate under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity or business associate must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, if otherwise required by law, or if permitted under 5 U.S.C. 552a(b)(7).

[78 FR 5690, Jan. 25, 2013]

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates noncompliance, the Secretary may attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity or business associate and provide the covered entity or business associate an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410 of this part. The covered entity or business associate must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity or business associate of such finding in a notice of proposed determination in accordance with § 160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity or business associate and, if the matter arose from a complaint, the complainant, in writing.

[78 FR 5690, Jan. 25, 2013]

§ 160.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), 1320a–7a(j), and 1320d–5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation or compliance review pursuant to this part. For purposes of this paragraph, a person other than a natural person is termed an ''entity.''

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person must

testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the district court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are nonpublic investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner as prescribed under §160.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

(c) Consistent with §160.310(c)(3), testimony and other evidence obtained in an investigational inquiry may be used

by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 160.316 Refraining from intimidation or retaliation.

A covered entity or business associate may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

(a) Filing of a complaint under § 160.306;

(b) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under this part; or

(c) Opposing any act or practice made unlawful by this subchapter, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of protected health information in violation of subpart E of part 164 of this subchapter.

[71 FR 8424, Feb. 16, 2006, as amended at 78 FR 5691, Jan. 25, 2013]

Subpart D—Imposition of Civil Money Penalties

SOURCE: 71 FR 8426, Feb. 16, 2006, unless otherwise noted.

§ 160.400 Applicability.

This subpart applies to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d–5.

§ 160.401 Definitions.

As used in this subpart, the following terms have the following meanings:

Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.

Reasonable diligence means the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.

Willful neglect means conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

[74 FR 56130, Oct. 30, 2009, as amended at 78 FR 5691, Jan. 25, 2013]

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity or business associate if the Secretary determines that the covered entity or business associate has violated an administrative simplification provision.

(b) *Violation by more than one covered entity or business associate.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity or business associate.* (1) A covered entity is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member or business associate, acting within the scope of the agency.

(2) A business associate is liable, in accordance with the Federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the business associate, including a workforce member or subcontractor, acting within the scope of the agency.

[78 FR 5691, Jan. 25, 2013]

§ 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section, and §§ 160.406, 160.408, and 160.412. These amounts were adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990, (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, (section 701 of Pub. L. 114–74), and appear at 45 CFR part 102. These amounts will be updated annually and published at 45 CFR part 102.

(b) The amount of a civil money penalty that may be imposed is subject to the following limitations:

(1) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty—

(i) In the amount of more than $100 for each violation; or

(ii) In excess of $25,000 for identical violations during a calendar year (January 1 through the following December 31);

(2) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty—

(i) For a violation in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such provision,

(A) In the amount of less than $100 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(ii) For a violation in which it is established that the violation was due to reasonable cause and not to willful neglect,

(A) In the amount of less than $1,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iii) For a violation in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $10,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iv) For a violation in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31).

(3) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56130, Oct. 30, 2009; 78 FR 5691, Jan. 25, 2013; 81 FR 61581, Sept. 6, 2016]

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's or business associate's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity or business associate is in violation of the provision.

[78 FR 5691, Jan. 25, 2013]

§ 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary will consider the following factors, which may be mitigating or aggravating as appropriate:

(a) The nature and extent of the violation, consideration of which may include but is not limited to:

(1) The number of individuals affected; and

(2) The time period during which the violation occurred;

(b) The nature and extent of the harm resulting from the violation, consideration of which may include but is not limited to:

(1) Whether the violation caused physical harm;

(2) Whether the violation resulted in financial harm;

(3) Whether the violation resulted in harm to an individual's reputation; and

(4) Whether the violation hindered an individual's ability to obtain health care;

(c) The history of prior compliance with the administrative simplification provisions, including violations, by the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the current violation is the same or similar to previous indications of noncompliance;

(2) Whether and to what extent the covered entity or business associate has attempted to correct previous indications of noncompliance;

(3) How the covered entity or business associate has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity or business associate has responded to prior complaints;

(d) The financial condition of the covered entity or business associate, consideration of which may include but is not limited to:

(1) Whether the covered entity or business associate had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity or business associate to continue to provide, or to pay for, health care; and

(3) The size of the covered entity or business associate; and

(e) Such other matters as justice may require.

[78 FR 5691, Jan. 25, 2013]

§ 160.410 Affirmative defenses.

(a) The Secretary may not:

(1) Prior to February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that the violation is punishable under 42 U.S.C. 1320d–6.

(2) On or after February 18, 2011, impose a civil money penalty on a covered entity or business associate for an act that violates an administrative simplification provision if the covered entity or business associate establishes that a penalty has been imposed under 42 U.S.C. 1320d–6 with respect to such act.

(b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violation, including the following:

(1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or

(2) The violation is—

(i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate

based on the nature and extent of the failure to comply.

(c) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity or business associate for a violation if the covered entity or business associate establishes to the satisfaction of the Secretary that the violation is—

(1) Not due to willful neglect; and

(2) Corrected during either:

(i) The 30-day period beginning on the first date the covered entity or business associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(ii) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[78 FR 5692, Jan. 25, 2013]

§ 160.412 Waiver.

For violations described in §160.410(b)(2) or (c) that are not corrected within the period specified under such paragraphs, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

[8 FR 5692, Jan. 25, 2013]

§ 160.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with §160.420, within 6 years from the date of the occurrence of the violation.

§ 160.416 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d–5(b)(1) and 42 U.S.C. 299b–22(f)(3), a penalty imposed under this part is in addition to any other penalty prescribed by law.

[78 FR 5692, Jan. 25, 2013]

§ 160.420 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed (except that, in any case where the Secretary is relying upon a statistical sampling study in accordance with §160.536 of this part, the notice must provide a copy of the study relied upon by the Secretary);

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty and a reference to the subparagraph of §160.404 upon which it is based.

(5) Any circumstances described in §160.408 that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 90 days permits the imposition of the proposed penalty without the right to a hearing under §160.504 or a right of appeal under §160.548 of this part, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with §160.504 of this part.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56131, Oct. 30, 2009]

§ 160.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §160.504 of this part and the matter is not settled pursuant to §160.416, the Secretary will impose the proposed penalty or any lesser penalty permitted by 42 U.S.C. 1320d–5. The Secretary will notify the respondent by certified mail, return receipt requested, of any penalty that has been

imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under §160.548 of this part with respect to which the respondent has not timely requested a hearing.

§ 160.424 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary, subject to the first sentence of 42 U.S.C. 1320a–7a(f).

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, 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 42 U.S.C. 1320a–7a(e), may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 160.426 Notification of the public and other agencies.

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1320a–7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).

Subpart E—Procedures for Hearings

SOURCE: 71 FR 8428, Feb. 16, 2006, unless otherwise noted.

§ 160.500 Applicability.

This subpart applies to hearings conducted relating to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d–5.

§ 160.502 Definitions.

As used in this subpart, the following term has the following meaning:

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, who issue decisions in panels of three.

§ 160.504 Hearing before an ALJ.

(a) A respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

(1) The respondent; and

(2) The officer(s) or employee(s) of HHS to whom the enforcement authority involved has been delegated.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 90 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual

and legal basis for opposing the penalty, except that a respondent may raise an affirmative defense under §160.410(b)(1) at any time.

(d) The ALJ must dismiss a hearing request where—

(1) On motion of the Secretary, the ALJ determines that the respondent's hearing request is not timely filed as required by paragraphs (b) or does not meet the requirements of paragraph (c) of this section;

(2) The respondent withdraws the request for a hearing;

(3) The respondent abandons the request for a hearing; or

(4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§160.506 Rights of the parties.

(a) Except as otherwise limited by this subpart, each party may—

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this subpart;

(4) Agree to stipulations of fact or law that will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

(c) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of 42 U.S.C. 406, which authorizes the Secretary to specify or limit their fees.

§160.508 Authority of the ALJ.

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this subpart;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and

(13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.

(c) The ALJ—

(1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must give deference to published guidance to the extent not inconsistent with statute or regulation;

(2) May not enter an order in the nature of a directed verdict;

(3) May not compel settlement negotiations;

(4) May not enjoin any act of the Secretary; or

(5) May not review the exercise of discretion by the Secretary with respect to whether to grant an extension under §160.410(b)(2)(ii)(B) or (c)(2)(ii) of

this part or to provide technical assistance under 42 U.S.C. 1320d–5(b)(2)(B).

[71 FR 8428, Feb. 16, 2006, as amended at 78 FR 34266, June 7, 2013]

§ 160.510 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 160.512 Prehearing conferences.

(a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice, which may not be less than 14 business days, to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this subpart;

(9) The time and place for the hearing;

(10) The potential for the settlement of the case by the parties; and

(11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of privacy of individually identifiable health information that may be submitted into evidence or otherwise used in the proceeding, if appropriate.

(c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 160.514 Authority to settle.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

§ 160.516 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term ''documents'' includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request

for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding; or

(iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

§ 160.518 Exchange of witness lists, witness statements, and exhibits.

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 160.538, not more than 60, and not less than 15, days before the scheduled hearing, except that if a respondent intends to introduce the evidence of a statistical expert, the respondent must provide the Secretarial party with a copy of the statistical expert's report not less than 30 days before the scheduled hearing.

(b)(1) If, at any time, a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief—

(i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party.

(i) If the ALJ finds that there is no substantial prejudice, the evidence may be admitted.

(ii) If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 160.520 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any knowledgeable HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. That motion must—

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

§ 160.522 Fees.

The party requesting a subpoena must pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage must accompany the subpoena when served, except that, when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

§ 160.524 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Board must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

§ 160.526 Computation of time.

(a) In computing any period of time under this subpart or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 160.504.

§ 160.528 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

§ 160.530 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

§ 160.532 Collateral estoppel.

When a final determination that the respondent violated an administrative simplification provision 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.

§ 160.534 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b) (1) The respondent has the burden of going forward and the burden of persuasion with respect to any:

(i) Affirmative defense pursuant to § 160.410 of this part;

(ii) Challenge to the amount of a proposed penalty pursuant to §§ 160.404–160.408 of this part, including any factors raised as mitigating factors; or

(iii) Claim that a proposed penalty should be reduced or waived pursuant to § 160.412 of this part; and

(iv) Compliance with subpart D of part 164, as provided under § 164.414(b).

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability other than with respect to subpart D of part 164, and the existence of any factors considered aggravating factors in determining the amount of the proposed penalty.

(3) The burden of persuasion will be judged by a preponderance of the evidence.

(c) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.

(d)(1) Subject to the 15-day rule under § 160.518(a) and the admissibility of evidence under § 160.540, either party may introduce, during its case in chief, items or information that arose or became known after the date of the issuance of the notice of proposed determination or the request for hearing, as applicable. Such items and information may not be admitted into evidence, if introduced—

(i) By the Secretary, unless they are material and relevant to the acts or omissions with respect to which the penalty is proposed in the notice of proposed determination pursuant to § 160.420 of this part, including circumstances that may increase penalties; or

(ii) By the respondent, unless they are material and relevant to an admission, denial or explanation of a finding of fact in the notice of proposed determination under § 160.420 of this part, or to a specific circumstance or argument expressly stated in the request for hearing under § 160.504, including circumstances that may reduce penalties.

(2) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 160.518.

[71 FR 8428, Feb. 16, 2006, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5692, Jan. 25, 2013]

§ 160.536 Statistical sampling.

(a) In meeting the burden of proof set forth in § 160.534, the Secretary may introduce the results of a statistical sampling study as evidence of the number of violations under § 160.406 of this part, or the factors considered in determining the amount of the civil money penalty under § 160.408 of this part. Such statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitutes prima facie evidence of the number of violations and the existence of factors material to the proposed civil money penalty as described in §§ 160.406 and 160.408.

(b) Once the Secretary has made a prima facie case, as described in paragraph (a) of this section, the burden of going forward shifts to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Secretary will then be given the opportunity to rebut this evidence.

§ 160.538 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to the other party, along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in § 160.518.

(c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses, except that the ALJ may not order to be excluded—

(1) A party who is a natural person;

(2) In the case of a party that is not a natural person, the officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

§ 160.540 Evidence.

(a) The ALJ must determine the admissibility of evidence.

(b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement are inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination under §160.420 of this part.

(h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

§160.542 The record.

(a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ. A party that requests a transcript of hearing proceedings must pay the cost of preparing the transcript unless, for good cause shown by the party, the payment is waived by the ALJ or the Board, as appropriate.

(b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§160.544 Post hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§160.546 ALJ's decision.

(a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.

(c) The ALJ must issue the decision to both parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.

(d) Unless the decision of the ALJ is timely appealed as provided for in §160.548, the decision of the ALJ will be final and binding on the parties 60 days from the date of service of the ALJ's decision.

§160.548 Appeal of the ALJ's decision.

(a) Any party may appeal the decision of the ALJ to the Board by filing a notice of appeal with the Board within 30 days of the date of service of the ALJ decision. The Board may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the Board a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the Board, the ALJ must forward the record of the proceeding to the Board.

(c) A notice of appeal must be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to the exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and the accompanying brief. The Board may permit the parties to file reply briefs.

(d) There is no right to appear personally before the Board or to appeal to the Board any interlocutory ruling by the ALJ.

(e) Except for an affirmative defense under §160.410(a)(1) or (2) of this part,

the Board may not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the Board that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the Board may remand the matter to the ALJ for consideration of such additional evidence.

(g) The Board may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision of the ALJ is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the Board must serve on each party to the appeal a copy of the Board's decision and a statement describing the right of any respondent who is penalized to seek judicial review.

(j)(1) The Board's decision under paragraph (i) of this section, including a decision to decline review of the initial decision, becomes the final decision of the Secretary 60 days after the date of service of the Board's decision, except with respect to a decision to remand to the ALJ or if reconsideration is requested under this paragraph.

(2) The Board will reconsider its decision only if it determines that the decision contains a clear error of fact or error of law. New evidence will not be a basis for reconsideration unless the party demonstrates that the evidence is newly discovered and was not previously available.

(3) A party may file a motion for reconsideration with the Board before the date the decision becomes final under paragraph (j)(1) of this section. A motion for reconsideration must be accompanied by a written brief specifying any alleged error of fact or law and, if the party is relying on additional evidence, explaining why the evidence was not previously available. Any party may file a brief in opposition within 15 days of receiving the motion for reconsideration and the accompanying brief unless this time limit is extended by the Board for good cause shown. Reply briefs are not permitted.

(4) The Board must rule on the motion for reconsideration not later than 30 days from the date the opposition brief is due. If the Board denies the motion, the decision issued under paragraph (i) of this section becomes the final decision of the Secretary on the date of service of the ruling. If the Board grants the motion, the Board will issue a reconsidered decision, after such procedures as the Board determines necessary to address the effect of any error. The Board's decision on reconsideration becomes the final decision of the Secretary on the date of service of the decision, except with respect to a decision to remand to the ALJ.

(5) If service of a ruling or decision issued under this section is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of the date on which the decision of the Board becomes the final decision of the Secretary under paragraph (j) of this section.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging the final decision of the Secretary must be sent by certified mail, return receipt requested, to the General Counsel of HHS. The petition copy must be a copy showing that it has been time-stamped by the clerk of the court when the original was filed with the court.

(3) If the General Counsel of HHS received two or more petitions within 10 days after the final decision of the Secretary, the General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10 day period.

[71 FR 8428, Feb. 16, 2006, as amended at 78 FR 34266, June 7, 2013]

§ 160.550 Stay of the Secretary's decision.

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of the request automatically stays the effective date of the penalty until such time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.

§ 160.552 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Board inconsistent with substantial justice. The ALJ and the Board at every stage of the proceeding must disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 162—ADMINISTRATIVE REQUIREMENTS

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AUTHORITY: 42 U.S.C. 1320d—1320d–9 and secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917.

SOURCE: 65 FR 50367, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 162.100 Applicability.

Covered entities (as defined in § 160.103 of this subchapter) must comply with the applicable requirements of this part.

§ 162.103 Definitions.

For purposes of this part, the following definitions apply:

Code set means any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. A code set includes the codes and the descriptors of the codes.

Code set maintaining organization means an organization that creates and maintains the code sets adopted by the Secretary for use in the transactions for which standards are adopted in this part.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of ''covered entity'' at § 160.103.

Data condition means the rule that describes the circumstances under which a covered entity must use a particular data element or segment.

Data content means all the data elements and code sets inherent to a transaction, and not related to the format of the transaction. Data elements that are related to the format are not data content.

Data element means the smallest named unit of information in a transaction.

Data set means a semantically meaningful unit of information exchanged between two parties to a transaction.

Descriptor means the text defining a code.

Designated standard maintenance organization (DSMO) means an organization designated by the Secretary under § 162.910(a).

Direct data entry means the direct entry of data (for example, using dumb terminals or web browsers) that is immediately transmitted into a health plan's computer.

Format refers to those data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a transaction.

HCPCS stands for the Health [Care Financing Administration] Common Procedure Coding System.

Maintain or *maintenance* refers to activities necessary to support the use of

a standard adopted by the Secretary, including technical corrections to an implementation specification, and enhancements or expansion of a code set. This term excludes the activities related to the adoption of a new standard or implementation specification, or modification to an adopted standard or implementation specification.

Maximum defined data set means all of the required data elements for a particular standard based on a specific implementation specification.

Operating rules means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

Segment means a group of related data elements in a transaction.

Stage 1 payment initiation means a health plan's order, instruction or authorization to its financial institution to make a health care claims payment using an electronic funds transfer (EFT) through the ACH Network.

Standard transaction means a transaction that complies with an applicable standard and associated operating rules adopted under this part.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8374, Feb. 20, 2003; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012; 77 FR 54719, Sept. 5, 2012; 84 FR 57629, Oct. 28, 2019]

Subparts B–C [Reserved]

Subpart D—Standard Unique Health Identifier for Health Care Providers

SOURCE: 69 FR 3468, Jan. 23, 2004, unless otherwise noted.

§ 162.402 [Reserved]

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) *Health care providers.* A covered health care provider must comply with the implementation specifications in § 162.410 no later than May 23, 2007.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.412 no later than one of the following dates:

(1) A health plan that is not a small health plan—May 23, 2007.

(2) A small health plan—May 23, 2008.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the implementation specifications in § 162.414 no later than May 23, 2007.

[69 FR 3468, Jan. 23, 2004, as amended at 77 FR 54719, Sept. 5, 2012]

§ 162.406 Standard unique health identifier for health care providers.

(a) *Standard.* The standard unique health identifier for health care providers is the National Provider Identifier (NPI). The NPI is a 10-position numeric identifier, with a check digit in the 10th position, and no intelligence about the health care provider in the number.

(b) *Required and permitted uses for the NPI.* (1) The NPI must be used as stated in §§ 162.410, 162.412, and 162.414.

(2) The NPI may be used for any other lawful purpose.

§ 162.408 National Provider System.

National Provider System. The National Provider System (NPS) shall do the following:

(a) Assign a single, unique NPI to a health care provider, provided that—

(1) The NPS may assign an NPI to a subpart of a health care provider in accordance with paragraph (g); and

(2) The Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health care provider that has been assigned an NPI and perform tasks necessary to update that information.

(c) If appropriate, deactivate an NPI upon receipt of appropriate information concerning the dissolution of the health care provider that is an organization, the death of the health care provider who is an individual, or other circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated NPI upon receipt of appropriate information.

(e) Not assign a deactivated NPI to any other health care provider.

(f) Disseminate NPS information upon approved requests.

(g) Assign an NPI to a subpart of a health care provider on request if the identifying data for the subpart are unique.

§ 162.410 Implementation specifications: Health care providers.

(a) A covered entity that is a covered health care provider must:

(1) Obtain, by application if necessary, an NPI from the National Provider System (NPS) for itself or for any subpart of the covered entity that would be a covered health care provider if it were a separate legal entity. A covered entity may obtain an NPI for any other subpart that qualifies for the assignment of an NPI.

(2) Use the NPI it obtained from the NPS to identify itself on all standard transactions that it conducts where its health care provider identifier is required.

(3) Disclose its NPI, when requested, to any entity that needs the NPI to identify that covered health care provider in a standard transaction.

(4) Communicate to the NPS any changes in its required data elements in the NPS within 30 days of the change.

(5) If it uses one or more business associates to conduct standard transactions on its behalf, require its business associate(s) to use its NPI and other NPIs appropriately as required by the transactions that the business associate(s) conducts on its behalf.

(6) If it has been assigned NPIs for one or more subparts, comply with the requirements of paragraphs (a)(2) through (a)(5) of this section with respect to each of those NPIs.

(b) An organization covered health care provider that has as a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to—

(1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES); and

(2) To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

(c) A health care provider that is not a covered entity may obtain, by application if necessary, an NPI from the NPS.

[69 FR 3468, Jan. 23, 2004, as amended at 77 FR 54719, Sept. 5, 2012]

§ 162.412 Implementation specifications: Health plans.

(a) A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

(b) A health plan may not require a health care provider that has been assigned an NPI to obtain an additional NPI.

§ 162.414 Implementation specifications: Health care clearinghouses.

A health care clearinghouse must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

Subpart E [Reserved]

Subpart F—Standard Unique Employer Identifier

SOURCE: 67 FR 38020, May 31, 2002, unless otherwise noted.

§ 162.600 Compliance dates of the implementation of the standard unique employer identifier.

(a) *Health care providers.* Health care providers must comply with the requirements of this subpart no later than July 30, 2004.

(b) *Health plans.* A health plan must comply with the requirements of this subpart no later than one of the following dates:

(1) *Health plans other than small health plans*—July 30, 2004.

(2) *Small health plans*—August 1, 2005.

(c) *Health care clearinghouses.* Health care clearinghouses must comply with

the requirements of this subpart no later than July 30, 2004.

§ 162.605 Standard unique employer identifier.

The Secretary adopts the EIN as the standard unique employer identifier provided for by 42 U.S.C. 1320d–2(b).

§ 162.610 Implementation specifications for covered entities.

(a) The standard unique employer identifier of an employer of a particular employee is the EIN that appears on that employee's IRS Form W–2, Wage and Tax Statement, from the employer.

(b) A covered entity must use the standard unique employer identifier (EIN) of the appropriate employer in standard transactions that require an employer identifier to identify a person or entity as an employer, including where situationally required.

(c) Required and permitted uses for the Employer Identifier.

(1) The Employer Identifier must be used as stated in § 162.610(b).

(2) The Employer Identifier may be used for any other lawful purpose.

[67 FR 38020, May 31, 2002, as amended at 69 FR 3469, Jan. 23, 2004]

Subparts G–H [Reserved]

Subpart I—General Provisions for Transactions

§ 162.900 [Reserved]

§ 162.910 Maintenance of standards and adoption of modifications and new standards.

(a) *Designation of DSMOs.* (1) The Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the following functions:

(i) Maintain standards adopted under this subchapter.

(ii) Receive and process requests for adopting a new standard or modifying an adopted standard.

(2) The Secretary designates a DSMO by notice in the FEDERAL REGISTER.

(b) *Maintenance of standards.* Maintenance of a standard by the appropriate DSMO constitutes maintenance of the standard for purposes of this part, if done in accordance with the processes the Secretary may require.

(c) *Process for modification of existing standards and adoption of new standards.* The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

(1) Open public access.

(2) Coordination with other DSMOs.

(3) An appeals process for each of the following, if dissatisfied with the decision on the request:

(i) The requestor of the proposed modification.

(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

§ 162.915 Trading partner agreements.

A covered entity must not enter into a trading partner agreement that would do any of the following:

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

(b) Add any data elements or segments to the maximum defined data set.

(c) Use any code or data elements that are either marked ''not used'' in the standard's implementation specification or are not in the standard's implementation specification(s).

(d) Change the meaning or intent of the standard's implementation specification(s).

[65 FR 50367, Aug. 17, 2000, as amended at 76 FR 40495, July 8, 2011]

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1

CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The materials are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786–6597. The materials are also available from the sources listed below.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3.* The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970–4480; and FAX (703) 970–4488. They are also available through the internet at *http://www.X12.org*. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in §162.1102 and §162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in §162.1102 and §162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in §162.1102 and §162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1 as referenced in §162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in §162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in §162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in §162.1302.

(8) The ASC X12N–276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in §162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company,

004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in §162.1202.

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in §162.1102 and §162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in §162.1102 and §162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1, as referenced in §162.1102 and §162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in §162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in §162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in §162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in §162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in §162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in §162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides.* The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the Internet at *http://www.ncpdp.org*. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in §§162.1102, 162.1202, 162.1302, 162.1602, and 162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in §§162.1102, 162.1202, 162.1302, and 162.1802.

(3) The National Council for Prescription Drug Programs (NCPDP) equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release

0, February 1, 1996, as referenced in §§ 162.1102, 162.1202, 162.1602, and 162.1802.

(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1302, and 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in §§ 162.1102, 162.1202, 162.1302, and 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861–1492; Fax (202) 861- 1454; E-mail *info@CAQH.org*; and Internet at *http://www.caqh.org/benefits.php*.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§ 162.1203, 162.1403, and 162.1603.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

(4) Council for Affordable Quality Healthcare (CAQH) Phase III Committee on Operating Rules for Information Exchange (CORE) EFT & ERA Operating Rule Set, Approved June 2012, as specified in this paragraph and referenced in § 162.1603.

(i) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(ii) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(iii) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(iv) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(v) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(vi) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled ''Health Care Claim Payment/Advice Batch Acknowledgement Requirements''.

(d) The National Automated Clearing House Association (NACHA), The Electronic Payments Association, 1350 Sunrise Valle Drive, Suite 100, Herndon, Virginia 20171 (Phone) (703) 561–1100; (Fax) (703) 713–1641; Email: *info@nacha.org;* and Internet at *http://www.nacha.org*. The implementation specifications are as follows:

(1) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules, Appendix One: ACH File Exchange Specifications (Operating Rule 59) as referenced in §162.1602.

(2) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules Appendix Three: ACH Record Format Specifications (Operating Rule 78), Part 3.1, Subpart 3.1.8 Sequence of Records for CCD Entries as referenced in §162.1602.

[68 FR 8396, Feb. 20, 2003, as amended at 69 FR 18803, Apr. 9, 2004; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§162.923 Requirements for covered entities.

(a) *General rule.* Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

(b) *Exception for direct data entry transactions.* A health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.

(c) *Use of a business associate.* A covered entity may use a business associate, including a health care clearinghouse, to conduct a transaction covered by this part. If a covered entity chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, the covered entity must require the business associate to do the following:

(1) Comply with all applicable requirements of this part.

(2) Require any agent or subcontractor to comply with all applicable requirements of this part.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§162.925 Additional requirements for health plans.

(a) *General rules.* (1) If an entity requests a health plan to conduct a transaction as a standard transaction, the health plan must do so.

(2) A health plan may not delay or reject a transaction, or attempt to adversely affect the other entity or the transaction, because the transaction is a standard transaction.

(3) A health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan (for example, coordination of benefits information).

(4) A health plan may not offer an incentive for a health care provider to conduct a transaction covered by this part as a transaction described under the exception provided for in §162.923(b).

(5) A health plan that operates as a health care clearinghouse, or requires an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan.

(6) During the period from March 17, 2009 through December 31, 2011, a health plan may not delay or reject a standard transaction, or attempt to adversely affect the other entity or the transaction, on the basis that it does

not comply with another adopted standard for the same period.

(b) *Coordination of benefits.* If a health plan receives a standard transaction and coordinates benefits with another health plan (or another payer), it must store the coordination of benefits data it needs to forward the standard transaction to the other health plan (or other payer).

(c) *Code sets.* A health plan must meet each of the following requirements:

(1) Accept and promptly process any standard transaction that contains codes that are valid, as provided in subpart J of this part.

(2) Keep code sets for the current billing period and appeals periods still open to processing under the terms of the health plan's coverage.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§ 162.930 Additional rules for health care clearinghouses.

When acting as a business associate for another covered entity, a health care clearinghouse may perform the following functions:

(a) Receive a standard transaction on behalf of the covered entity and translate it into a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) for transmission to the covered entity.

(b) Receive a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) from the covered entity and translate it into a standard transaction for transmission on behalf of the covered entity.

§ 162.940 Exceptions from standards to permit testing of proposed modifications.

(a) *Requests for an exception.* An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard. For each proposed modification, the organization must meet the following requirements:

(1) *Comparison to a current standard.* Provide a detailed explanation, no more than 10 pages in length, of how the proposed modification would be a significant improvement to the current standard in terms of the following principles:

(i) Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.

(ii) Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.

(iii) Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other private and public sector health data standards.

(iv) Have low additional development and implementation costs relative to the benefits of using the standard.

(v) Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time.

(vi) Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.

(vii) Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.

(viii) Be precise, unambiguous, and as simple as possible.

(ix) Result in minimum data collection and paperwork burdens on users.

(x) Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology.

(2) *Specifications for the proposed modification.* Provide specifications for the proposed modification, including any additional system requirements.

(3) *Testing of the proposed modification.* Provide an explanation, no more than 5 pages in length, of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, geographical areas, and beginning and ending dates of the test.

(4) *Trading partner concurrences.* Provide written concurrences from trading partners who would agree to participate in the test.

(b) *Basis for granting an exception.* The Secretary may grant an initial exception, for a period not to exceed 3 years, based on, but not limited to, the following criteria:

(1) An assessment of whether the proposed modification demonstrates a significant improvement to the current standard.

(2) The extent and length of time of the exception.

(3) Consultations with DSMOs.

(c) *Secretary's decision on exception.* The Secretary makes a decision and notifies the organization requesting the exception whether the request is granted or denied.

(1) *Exception granted.* If the Secretary grants an exception, the notification includes the following information:

(i) The length of time for which the exception applies.

(ii) The trading partners and geographical areas the Secretary approves for testing.

(iii) Any other conditions for approving the exception.

(2) *Exception denied.* If the Secretary does not grant an exception, the notification explains the reasons the Secretary considers the proposed modification would not be a significant improvement to the current standard and any other rationale for the denial.

(d) *Organization's report on test results.* Within 90 days after the test is completed, an organization that receives an exception must submit a report on the results of the test, including a cost-benefit analysis, to a location specified by the Secretary by notice in the FEDERAL REGISTER.

(e) *Extension allowed.* If the report submitted in accordance with paragraph (d) of this section recommends a modification to the standard, the Secretary, on request, may grant an extension to the period granted for the exception.

Subpart J—Code Sets

§ 162.1000 General requirements.

When conducting a transaction covered by this part, a covered entity must meet the following requirements:

(a) *Medical data code sets.* Use the applicable medical data code sets described in §162.1002 as specified in the implementation specification adopted under this part that are valid at the time the health care is furnished.

(b) *Nonmedical data code sets.* Use the nonmedical data code sets as described in the implementation specifications adopted under this part that are valid at the time the transaction is initiated.

§ 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *International Classification of Diseases, 9th Edition, Clinical Modification, (ICD–9–CM), Volumes 1 and 2* (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(2) *International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures* (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

(3) *National Drug Codes* (NDC), as maintained and distributed by HHS, in collaboration with drug manufacturers, for the following:

(i) Drugs

(ii) Biologics.

(4) *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.

(5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth*

Edition (CPT–4), as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

(i) Physician services.

(ii) Physical and occupational therapy services.

(iii) Radiologic procedures.

(iv) Clinical laboratory tests.

(v) Other medical diagnostic procedures.

(vi) Hearing and vision services.

(vii) Transportation services including ambulance.

(6) The *Health Care Financing Administration Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(b) For the period on and after October 16, 2003 through September 30, 2015:

(1) The code sets specified in paragraphs (a)(1), (a)(2),(a)(4), and (a)(5) of this section.

(2) *National Drug Codes (NDC)*, as maintained and distributed by HHS, for reporting the following by retail pharmacies:

(i) Drugs.

(ii) Biologics.

(3) *The Healthcare Common Procedure Coding System (HCPCS)*, as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(c) For the period on and after October 1, 2015:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8397, Feb. 20, 2003; 74 FR 3362, Jan. 16, 2009; 77 FR 54720, Sept. 5, 2012; 79 FR 45134, Aug. 4, 2014]

§ 162.1011 Valid code sets.

Each code set is valid within the dates specified by the organization responsible for maintaining that code set.

Subpart K—Health Care Claims or Equivalent Encounter Information

§ 162.1101 Health care claims or equivalent encounter information transaction.

The health care claims or equivalent encounter information transaction is the transmission of either of the following:

(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.

(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care.

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 1, (Version 1.1), January 2000, supporting Telecomunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in §162.920).

(2) *Dental, health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in §162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010, may 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010x098A1. (Incorporated by reference in §162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in §162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1)(i) The standards identified in paragraph (a) of this section; and

(ii) For retail pharmacy supplies and professional services claims, the following: The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096, October 2002 (Incorporated by reference in §162.920); and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in §162.920.)

(ii) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in §162.920.)

(iii) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in §162.920.)

(iv) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in §162.920.)

(v) *Retail pharmacy supplies and professional services claims.* (A) The Telecommunication Standard, Implementation Guide Version 5, Release 1, September 1999. (Incorporated by reference in §162.920.)

(B) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in §162.920); and

(C) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/

005010X222. (Incorporated by reference in §162.920.)

(c) For the period on and after the January 1, 2012, the standards identified in paragraph (b)(2) of this section, except the standard identified in paragraph (b)(2)(v)(A) of this section.

(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

[68 FR 8397, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3325, Jan. 16, 2009; 85 FR 4242, Jan. 24, 2020]

Subpart L—Eligibility for a Health Plan

§162.1201 Eligibility for a health plan transaction.

The eligibility for a health plan transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan, or from one health plan to another health plan, to obtain any of the following information about a benefit plan for an enrollee:

(1) Eligibility to receive health care under the health plan.

(2) Coverage of health care under the health plan.

(3) Benefits associated with the benefit plan.

(b) A response from a health plan to a health care provider's (or another health plan's) inquiry described in paragraph (a) of this section.

§162.1202 Standards for eligibility for a health plan transaction.

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in §162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1. (Incorporated by reference in §162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in §162.920.)

(ii) *Dental, professional, and institutional health care eligibility benefit inquiry and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279. (Incorporated by reference in §162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8398, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3326, Jan. 16, 2009]

§162.1203 Operating rules for eligibility for a health plan transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH

CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction:

(1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in §162.920).

(2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in §162.920).

(3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in §162.920).

(4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in §162.920).

(5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in §162.920).

(6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in §162.920).

(7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in §162.920).

(8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in §162.920).

(9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in §162.920).

(10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in §162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart M—Referral Certification and Authorization

§162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

[74 FR 3326, Jan. 16, 2009]

§162.1302 Standards for referral certification and authorization transaction.

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug referral certification and authorization.* The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in §162.920).

(2) *Dental, professional, and institutional referral certification and authorization.* The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1. (Incorporated by reference in §162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both—

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs.* The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription

Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional request for review and response.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review-—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

[68 FR 8398, Feb. 20, 2003, as amended at 74 FR 3326, Jan. 16, 2009; 85 FR 4242, Jan. 24, 2020]

Subpart N—Health Care Claim Status

§ 162.1401 Health care claim status transaction.

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

[74 FR 3326, Jan. 16, 2009]

§ 162.1402 Standards for health care claim status transaction.

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N–276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3326, Jan. 16, 2009]

§ 162.1403 Operating rules for health care claim status transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase II operating rules (updated for Version 5010) for the health care claim status transaction:

(1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920).

(2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart O—Enrollment and Disenrollment in a Health Plan

§ 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.

[74 FR 3327, Jan. 16, 2009]

§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.

The Secretary adopts the following standards for enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2003 through March 16, 2009: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220 (Incorporated by reference in § 162.920)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart P—Health Care Electronic Funds Transfers (EFT) and Remittance Advice

§ 162.1601 Health care electronic funds transfers (EFT) and remittance advice transaction.

The health care electronic funds transfers (EFT) and remittance advice transaction is the transmission of either of the following for health care:

(a) The transmission of any of the following from a health plan to a health care provider:

(1) Payment.

(2) Information about the transfer of funds.

(3) Payment processing information.

(b) The transmission of either of the following from a health plan to a health care provider:

(1) Explanation of benefits.

(2) Remittance advice.

[65 FR 50367, Aug. 17, 2000, as amended at 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.1602 Standards for health care electronic funds transfers (EFT) and remittance advice transaction.

The Secretary adopts the following standards:

(a) For the period from October 16, 2003 through March 16, 2009: Health care claims and remittance advice. The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both of the following standards:

(1) The standard identified in paragraph (a) of this section.

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920.)

(c) For the period from January 1, 2012 through December 31, 2013, the standard identified in paragraph (b)(2) of this section.

(d) For the period on and after January 1, 2014, the following standards:

(1) Except when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, for Stage 1 Payment Initiation transmissions described in § 162.1601(a), all of the following standards:

(i) The National Automated Clearing House Association (NACHA) Corporate Credit or Deposit Entry with Addenda

Record (CCD+) implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network as follows (incorporated by reference in § 162.920)—

(A) NACHA Operating Rules, Appendix One: ACH File Exchange Specifications; and

(B) NACHA Operating Rules, Appendix Three: ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries.

(ii) For the CCD Addenda Record (''7''), field 3, of the standard identified in 1602(d)(1)(i), the Accredited Standards Committee (ASC) X12 Standards for Electronic Data Interchange Technical Report Type 3, ''Health Care Claim Payment/Advice (835), April 2006: Section 2.4: 835 Segment Detail: ''TRN Reassociation Trace Number,'' Washington Publishing Company, 005010X221 (Incorporated by reference in § 162.920).

(2) For transmissions described in § 162.1601(b), including when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, ''Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920).

[77 FR 1590, Jan. 10, 2012]

§ 162.1603 Operating rules for health care electronic funds transfers (EFT) and remittance advice transaction.

On and after January 1, 2014, the Secretary adopts the following for the health care electronic funds transfers (EFT) and remittance advice transaction:

(a) The Phase III CORE EFT & ERA Operating Rule Set, Approved June 2012 (Incorporated by reference in § 162.920) which includes the following rules:

(1) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(2) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(3) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(4) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(5) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(6) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled ''Health Care Claim Payment/Advice Batch Acknowledgement Requirements''.

(b) ACME Health Plan, CORE v5010 Master Companion Guide Template, 005010, 1.2, March 2011 (incorporated by reference in § 162.920), as required by the Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012.

[77 FR 48043, Aug. 10, 2012]

Subpart Q—Health Plan Premium Payments

§ 162.1701 Health plan premium payments transaction.

The health plan premium payment transaction is the transmission of any of the following from the entity that is arranging for the provision of health care or is providing health care coverage payments for an individual to a health plan:

(a) Payment.

(b) Information about the transfer of funds.

(c) Detailed remittance information about individuals for whom premiums are being paid.

(d) Payment processing information to transmit health care premium payments including any of the following:

(1) Payroll deductions.

(2) Other group premium payments.

(3) Associated group premium payment information.

§ 162.1702 Standards for health plan premium payments transaction.

The Secretary adopts the following standards for the health plan premium payments transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N 820—Payroll Deducted and Other

Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1. (Incorporated by reference in §162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section, and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218. (Incorporated by reference in §162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart R—Coordination of Benefits

§162.1801 Coordination of benefits transaction.

The coordination of benefits transaction is the transmission from any entity to a health plan for the purpose of determining the relative payment responsibilities of the health plan, of either of the following for health care:

(a) Claims.

(b) Payment information.

§162.1802 Standards for coordination of benefits information transaction.

The Secretary adopts the following standards for the coordination of benefits information transaction.

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in §162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in §162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1. (Incorporated by reference in §162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in §162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in §162.920.)

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in §162.920.)

(iii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in §162.920.)

(iv) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in §162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

[68 FR 8399, Feb. 20, 2003, as amended at 74 FR 3327, Jan. 16, 2009; 85 FR 4242, Jan. 24, 2020]

Subpart S—Medicaid Pharmacy Subrogation

SOURCE: 74 FR 3328, Jan. 16, 2009, unless otherwise noted.

§162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

§162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in §162.1902 (Incorporated by reference at §162.920):

(a) For the period on and after January 1, 2012, for covered entities that are not small health plans;

(b) For the period on and after January 1, 2013 for small health plans.

PART 163 [RESERVED]

PART 164—SECURITY AND PRIVACY

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AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

SOURCE: 65 FR 82802, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104–191, and sections 13400–13424 of Public Law 111–5.

[78 FR 5692, Jan. 25, 2013]

§ 164.103 Definitions.

As used in this part, the following terms have the following meanings:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with §164.105(a)(2)(iii)(D).

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph §164.105(a)(2)(iii)(D).

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 34266, June 7, 2013]

§ 164.104 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this part apply to a business associate.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of this part, other than the requirements of this section, §§ 164.314, and 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*

(i) *Application of other provisions.* In applying a provision of this part, other than the requirements of this section, §§ 164.314, and 164.504, to a hybrid entity:

(A) A reference in such provision to a ''covered entity'' refers to a health care component of the covered entity;

(B) A reference in such provision to a ''health plan,'' ''covered health care provider,'' or ''health care clearinghouse,'' refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;

(C) A reference in such provision to ''protected health information'' refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and

(D) A reference in such provision to ''electronic protected health information'' refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity.

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity.* A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with this part.

(B) The covered entity is responsible for complying with §§ 164.316(a) and 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for complying with §§ 164.314 and 164.504

regarding business associate arrangements and other organizational requirements.

(D) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates one or more health care components, it must include any component that would meet the definition of a covered entity or business associate if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs covered functions.

(b)(1) *Standard: Affiliated covered entities.* Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this part.

(2) *Implementation specifications*—(i) *Requirements for designation of an affiliated covered entity.* (A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements.* An affiliated covered entity must ensure that it complies with the applicable requirements of this part, including, if the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, §§ 164.308(a)(4)(ii)(A) and 164.504(g), as applicable.

(c)(1) *Standard: Documentation.* A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section.

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation as required by paragraph (c)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities and, where provided, business associates, are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

[78 FR 5693, Jan. 25, 2013]

Subpart B [Reserved]

Subpart C—Security Standards for the Protection of Electronic Protected Health Information

AUTHORITY: 42 U.S.C. 1320d–2 and 1320d–4; sec. 13401, Pub. L. 111–5, 123 Stat. 260.

SOURCE: 68 FR 8376, Feb. 20, 2003, unless otherwise noted.

§ 164.302 Applicability.

A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.

[78 FR 5693, Jan. 25, 2013]

§ 164.304 Definitions.

As used in this subpart, the following terms have the following meanings:

Access means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to ''access'' as used in this subpart, not as used in subparts D or E of this part.)

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that information.

Authentication means the corroboration that a person is the one claimed.

Availability means the property that data or information is accessible and useable upon demand by an authorized person.

Confidentiality means the property that data or information is not made available or disclosed to unauthorized persons or processes.

Encryption means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key.

Facility means the physical premises and the interior and exterior of a building(s).

Information system means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

Integrity means the property that data or information have not been altered or destroyed in an unauthorized manner.

Malicious software means software, for example, a virus, designed to damage or disrupt a system.

Password means confidential authentication information composed of a string of characters.

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's or business associate's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

Security or Security measures encompass all of the administrative, physical, and technical safeguards in an information system.

Security incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

Technical safeguards means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

User means a person or entity with authorized access.

Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.

[68 FR 8376, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5693, Jan. 25, 2013]

§ 164.306 Security standards: General rules.

(a) *General requirements.* Covered entities and business associates must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.

(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

(3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.

(4) Ensure compliance with this subpart by its workforce.

(b) *Flexibility of approach.* (1) Covered entities and business associates may use any security measures that allow the covered entity or business associate to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity or business associate must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity or business associate.

(ii) The covered entity's or the business associate's technical infrastructure, hardware, and software security capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to electronic protected health information.

(c) *Standards.* A covered entity or business associate must comply with the applicable standards as provided in this section and in §§ 164.308, 164.310, 164.312, 164.314 and 164.316 with respect

to all electronic protected health information.

(d) *Implementation specifications.* In this subpart:

(1) Implementation specifications are required or addressable. If an implementation specification is required, the word ''Required'' appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word ''Addressable'' appears in parentheses after the title of the implementation specification.

(2) When a standard adopted in §164.308, §164.310, §164.312, §164.314, or §164.316 includes required implementation specifications, a covered entity or business associate must implement the implementation specifications.

(3) When a standard adopted in §164.308, §164.310, §164.312, §164.314, or §164.316 includes addressable implementation specifications, a covered entity or business associate must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting electronic protected health information; and

(ii) As applicable to the covered entity or business associate—

(A) Implement the implementation specification if reasonable and appropriate; or

(B) If implementing the implementation specification is not reasonable and appropriate—

(1) Document why it would not be reasonable and appropriate to implement the implementation specification; and

(2) Implement an equivalent alternative measure if reasonable and appropriate.

(e) *Maintenance.* A covered entity or business associate must review and modify the security measures implemented under this subpart as needed to continue provision of reasonable and appropriate protection of electronic protected health information, and update documentation of such security measures in accordance with §164.316(b)(2)(iii).

[68 FR 8376, Feb. 20, 2003; 68 FR 17153, Apr. 8, 2003; 78 FR 5693, Jan. 25, 2013]

§ 164.308 Administrative safeguards.

(a) A covered entity or business associate must, in accordance with §164.306:

(1)(i) *Standard: Security management process.* Implement policies and procedures to prevent, detect, contain, and correct security violations.

(ii) *Implementation specifications:*

(A) *Risk analysis (Required).* Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

(B) *Risk management (Required).* Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with §164.306(a).

(C) *Sanction policy (Required).* Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity or business associate.

(D) *Information system activity review (Required).* Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate.

(3)(i) *Standard: Workforce security.* Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

(ii) *Implementation specifications:*

(A) *Authorization and/or supervision (Addressable).* Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

(B) *Workforce clearance procedure (Addressable).* Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

(C) *Termination procedures (Addressable).* Implement procedures for terminating access to electronic protected health information when the employment of, or other arrangement with, a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4)(i) *Standard: Information access management.* Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

(ii) *Implementation specifications:*

(A) *Isolating health care clearinghouse functions (Required).* If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

(B) *Access authorization (Addressable).* Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

(C) *Access establishment and modification (Addressable).* Implement policies and procedures that, based upon the covered entity's or the business associate's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

(5)(i) *Standard: Security awareness and training.* Implement a security awareness and training program for all members of its workforce (including management).

(ii) *Implementation specifications.* Implement:

(A) *Security reminders (Addressable).* Periodic security updates.

(B) *Protection from malicious software (Addressable).* Procedures for guarding against, detecting, and reporting malicious software.

(C) *Log-in monitoring (Addressable).* Procedures for monitoring log-in attempts and reporting discrepancies.

(D) *Password management (Addressable).* Procedures for creating, changing, and safeguarding passwords.

(6)(i) *Standard: Security incident procedures.* Implement policies and procedures to address security incidents.

(ii) *Implementation specification: Response and reporting (Required).* Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity or business associate; and document security incidents and their outcomes.

(7)(i) *Standard: Contingency plan.* Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*

(A) *Data backup plan (Required).* Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

(B) *Disaster recovery plan (Required).* Establish (and implement as needed) procedures to restore any loss of data.

(C) *Emergency mode operation plan (Required).* Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

(D) *Testing and revision procedures (Addressable).* Implement procedures for periodic testing and revision of contingency plans.

(E) *Applications and data criticality analysis (Addressable).* Assess the relative criticality of specific applications and data in support of other contingency plan components.

(8) *Standard: Evaluation.* Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule

and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which a covered entity's or business associate's security policies and procedures meet the requirements of this subpart.

(b)(1) *Business associate contracts and other arrangements.* A covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with §164.314(a), that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(2) A business associate may permit a business associate that is a subcontractor to create, receive, maintain, or transmit electronic protected health information on its behalf only if the business associate obtains satisfactory assurances, in accordance with §164.314(a), that the subcontractor will appropriately safeguard the information.

(3) *Implementation specifications: Written contract or other arrangement (Required).* Document the satisfactory assurances required by paragraph (b)(1) or (b)(2) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of §164.314(a).

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§164.310 Physical safeguards.

A covered entity or business associate must, in accordance with §164.306:

(a)(1) *Standard: Facility access controls.* Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(2) *Implementation specifications:*

(i) *Contingency operations (Addressable).* Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

(ii) *Facility security plan (Addressable).* Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

(iii) *Access control and validation procedures (Addressable).* Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

(iv) *Maintenance records (Addressable).* Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks).

(b) *Standard: Workstation use.* Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.

(c) *Standard: Workstation security.* Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users.

(d)(1) *Standard: Device and media controls.* Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.

(2) *Implementation specifications:*

(i) *Disposal (Required).* Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored.

(ii) *Media re-use (Required).* Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.

(iii) *Accountability (Addressable).* Maintain a record of the movements of

hardware and electronic media and any person responsible therefore.

(iv) *Data backup and storage (Addressable).* Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.312 Technical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

(a)(1) *Standard: Access control.* Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).

(2) *Implementation specifications:*

(i) *Unique user identification (Required).* Assign a unique name and/or number for identifying and tracking user identity.

(ii) *Emergency access procedure (Required).* Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

(iii) *Automatic logoff (Addressable).* Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

(iv) *Encryption and decryption (Addressable).* Implement a mechanism to encrypt and decrypt electronic protected health information.

(b) *Standard: Audit controls.* Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.

(c)(1) *Standard: Integrity.* Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

(2) *Implementation specification: Mechanism to authenticate electronic protected health information (Addressable).* Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.

(d) *Standard: Person or entity authentication.* Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

(e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

(2) *Implementation specifications:*

(i) *Integrity controls (Addressable).* Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.

(ii) *Encryption (Addressable).* Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements.* The contract or other arrangement required by § 164.308(b)(3) must meet the requirements of paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section, as applicable.

(2) *Implementation specifications (Required)*—(i) *Business associate contracts.* The contract must provide that the business associate will—

(A) Comply with the applicable requirements of this subpart;

(B) In accordance with § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit electronic protected health information on behalf of the business associate agree to comply with the applicable requirements of this subpart by entering into a contract or other arrangement that complies with this section; and

(C) Report to the covered entity any security incident of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410.

(ii) *Other arrangements.* The covered entity is in compliance with paragraph (a)(1) of this section if it has another arrangement in place that meets the requirements of § 164.504(e)(3).

(iii) *Business associate contracts with subcontractors.* The requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section apply to the contract or other arrangement between a business associate and a subcontractor required by §164.308(b)(4) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(b)(1) *Standard: Requirements for group health plans.* Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to §164.504(f)(1)(ii) or (iii), or as authorized under §164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

(2) *Implementation specifications (Required).* The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to—

(i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan;

(ii) Ensure that the adequate separation required by §164.504(f)(2)(iii) is supported by reasonable and appropriate security measures;

(iii) Ensure that any agent to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

(iv) Report to the group health plan any security incident of which it becomes aware.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013; 78 FR 34266, June 7, 2013]

§164.316 Policies and procedures and documentation requirements.

A covered entity or business associate must, in accordance with §164.306:

(a) *Standard: Policies and procedures.* Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in §164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity or business associate may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

(b)(1) *Standard: Documentation.* (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit (Required).* Retain the documentation required by paragraph (b)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

(ii) *Availability (Required).* Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

(iii) *Updates (Required).* Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5695, Jan. 25, 2013]

§164.318 Compliance dates for the initial implementation of the security standards.

(a) *Health plan.* (1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.

(2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006.

(b) *Health care clearinghouse.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 20, 2005.

(c) *Health care provider.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

APPENDIX A TO SUBPART C OF PART 164—SECURITY STANDARDS: MATRIX

Standards	Sections	Implementation Specifications (R) = Required, (A) = Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R) Risk Management (R) Sanction Policy (R) Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A) Workforce Clearance Procedure Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R) Access Authorization (A) Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A) Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A) Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A) Encryption (A)

Subpart D—Notification in the Case of Breach of Unsecured Protected Health Information

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1) Breach excludes:

(i) Any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of this part.

(ii) Any inadvertent disclosure by a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under subpart E of this part.

(iii) A disclosure of protected health information where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:

(i) The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;

(ii) The unauthorized person who used the protected health information or to whom the disclosure was made;

(iii) Whether the protected health information was actually acquired or viewed; and

(iv) The extent to which the risk to the protected health information has been mitigated.

Unsecured protected health information means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111–5.

[78 FR 5695, Jan. 25, 2013]

§ 164.404 Notification to individuals.

(a) *Standard*—(1) *General rule.* A covered entity shall, following the discovery of a breach of unsecured protected health information, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, used, or disclosed as a result of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (a)(1) of this section, §§164.406(a), and 164.408(a), a breach shall be treated as discovered by a covered entity as of the first day on which such breach is known to the covered entity, or, by exercising reasonable diligence would have been known to the covered entity. A covered entity shall be deemed to have knowledge of a breach if such breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is a workforce member or agent of the covered entity (determined in accordance with the federal common law of agency).

(b) *Implementation specification: Timeliness of notification.* Except as provided in §164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification*—(1) *Elements.* The notification required by paragraph (a)

of this section shall include, to the extent possible:

(A) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;

(B) A description of the types of unsecured protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(C) Any steps individuals should take to protect themselves from potential harm resulting from the breach;

(D) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and

(E) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

(2) *Plain language requirement.* The notification required by paragraph (a) of this section shall be written in plain language.

(d) *Implementation specifications: Methods of individual notification.* The notification required by paragraph (a) of this section shall be provided in the following form:

(1) *Written notice.* (i) Written notification by first-class mail to the individual at the last known address of the individual or, if the individual agrees to electronic notice and such agreement has not been withdrawn, by electronic mail. The notification may be provided in one or more mailings as information is available.

(ii) If the covered entity knows the individual is deceased and has the address of the next of kin or personal representative of the individual (as specified under §164.502(g)(4) of subpart E), written notification by first-class mail to either the next of kin or personal representative of the individual. The notification may be provided in one or more mailings as information is available.

(2) *Substitute notice.* In the case in which there is insufficient or out-of-date contact information that precludes written notification to the individual under paragraph (d)(1)(i) of this section, a substitute form of notice reasonably calculated to reach the individual shall be provided. Substitute notice need not be provided in the case in which there is insufficient or out-of-date contact information that precludes written notification to the next of kin or personal representative of the individual under paragraph (d)(1)(ii).

(i) In the case in which there is insufficient or out-of-date contact information for fewer than 10 individuals, then such substitute notice may be provided by an alternative form of written notice, telephone, or other means.

(ii) In the case in which there is insufficient or out-of-date contact information for 10 or more individuals, then such substitute notice shall:

(A) Be in the form of either a conspicuous posting for a period of 90 days on the home page of the Web site of the covered entity involved, or conspicuous notice in major print or broadcast media in geographic areas where the individuals affected by the breach likely reside; and

(B) Include a toll-free phone number that remains active for at least 90 days where an individual can learn whether the individual's unsecured protected health information may be included in the breach.

(3) *Additional notice in urgent situations.* In any case deemed by the covered entity to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity may provide information to individuals by telephone or other means, as appropriate, in addition to notice provided under paragraph (d)(1) of this section.

§ 164.406 Notification to the media.

(a) *Standard.* For a breach of unsecured protected health information involving more than 500 residents of a State or jurisdiction, a covered entity shall, following the discovery of the breach as provided in §164.404(a)(2), notify prominent media outlets serving the State or jurisdiction.

(b) *Implementation specification: Timeliness of notification.* Except as provided

in §164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* The notification required by paragraph (a) of this section shall meet the requirements of §164.404(c).

[74 FR 42767, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§164.408 Notification to the Secretary.

(a) *Standard.* A covered entity shall, following the discovery of a breach of unsecured protected health information as provided in §164.404(a)(2), notify the Secretary.

(b) *Implementation specifications: Breaches involving 500 or more individuals.* For breaches of unsecured protected health information involving 500 or more individuals, a covered entity shall, except as provided in §164.412, provide the notification required by paragraph (a) of this section contemporaneously with the notice required by §164.404(a) and in the manner specified on the HHS Web site.

(c) *Implementation specifications: Breaches involving less than 500 individuals.* For breaches of unsecured protected health information involving less than 500 individuals, a covered entity shall maintain a log or other documentation of such breaches and, not later than 60 days after the end of each calendar year, provide the notification required by paragraph (a) of this section for breaches discovered during the preceding calendar year, in the manner specified on the HHS web site.

[74 FR 42767, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§164.410 Notification by a business associate.

(a) *Standard*—(1) *General rule.* A business associate shall, following the discovery of a breach of unsecured protected health information, notify the covered entity of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (a)(1) of this section, a breach shall be treated as discovered by a business associate as of the first day on which such breach is known to the business associate or, by exercising reasonable diligence, would have been known to the business associate. A business associate shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the business associate (determined in accordance with the Federal common law of agency).

(b) *Implementation specifications: Timeliness of notification.* Except as provided in §164.412, a business associate shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* (1) The notification required by paragraph (a) of this section shall include, to the extent possible, the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, used, or disclosed during the breach.

(2) A business associate shall provide the covered entity with any other available information that the covered entity is required to include in notification to the individual under §164.404(c) at the time of the notification required by paragraph (a) of this section or promptly thereafter as information becomes available.

[74 FR 42767, Aug. 24, 2009, as amended at 78 FR 5695, Jan. 25, 2013]

§164.412 Law enforcement delay.

If a law enforcement official states to a covered entity or business associate that a notification, notice, or posting required under this subpart would impede a criminal investigation or cause damage to national security, a covered entity or business associate shall:

(a) If the statement is in writing and specifies the time for which a delay is required, delay such notification, notice, or posting for the time period specified by the official; or

(b) If the statement is made orally, document the statement, including the

identity of the official making the statement, and delay the notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.

§ 164.414 Administrative requirements and burden of proof.

(a) *Administrative requirements.* A covered entity is required to comply with the administrative requirements of § 164.530(b), (d), (e), (g), (h), (i), and (j) with respect to the requirements of this subpart.

(b) *Burden of proof.* In the event of a use or disclosure in violation of subpart E, the covered entity or business associate, as applicable, shall have the burden of demonstrating that all notifications were made as required by this subpart or that the use or disclosure did not constitute a breach, as defined at § 164.402.

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: 42 U.S.C. 1320d–2, 1320d–4, and 1320d–9; sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); and secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279.

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) Where provided, the standards, requirements, and implementation specifications adopted under this subpart apply to a business associate with respect to the protected health information of a covered entity.

(d) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5695, Jan. 25, 2013]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political

subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) 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;

(3) Except as prohibited under §164.502(a)(5)(i), underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of §164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy

holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of §164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Marketing:

(1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.

(ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual;

(B) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) *Financial remuneration* means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

Payment means:

(1) The activities undertaken by:

(i) Except as prohibited under §164.502(a)(5)(i), a health plan to obtain premiums or to determine or fulfill its

responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 74 FR 42769, Aug. 24, 2009; 78 FR 5695, Jan. 25, 2013]

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Covered entities: Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this

subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Except for uses and disclosures prohibited under § 164.502(a)(5)(i), pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with any of the following:

(A) This section.

(B) Section 164.512 and, where applicable, § 164.509.

(C) Section 164.514(e), (f), or (g).

(2) *Covered entities: Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subchapter.

(3) *Business associates: Permitted uses and disclosures.* A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e) or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.

(4) *Business associates: Required uses and disclosures.* A business associate is required to disclose protected health information:

(i) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter.

(ii) To the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of protected health information.

(5) *Prohibited uses and disclosures*—(i) *Use and disclosure of genetic information for underwriting purposes:* Notwithstanding any other provision of this subpart, a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan*, shall not use or disclose protected health information that is genetic information for underwriting purposes. For purposes of paragraph (a)(5)(i) of this section, underwriting purposes means, with respect to a health plan:

(A) Except as provided in paragraph (a)(5)(i)(B) of this section:

(*1*) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*2*) The computation of premium or contribution amounts under the plan, coverage, or policy (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*3*) The application of any pre-existing condition exclusion under the plan, coverage, or policy; and

(*4*) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(B) Underwriting purposes does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

(ii) *Sale of protected health information:*

(A) Except pursuant to and in compliance with § 164.508(a)(4), a covered entity or business associate may not sell protected health information.

(B) For purposes of this paragraph, sale of protected health information means:

(*1*) Except as provided in paragraph (a)(5)(ii)(B)(*2*) of this section, a disclosure of protected health information by a covered entity or business associate, if applicable, where the covered entity or business associate directly or indirectly receives remuneration from or on behalf of the recipient of the protected health information in exchange for the protected health information.

(*2*) Sale of protected health information does not include a disclosure of protected health information:

(*i*) For public health purposes pursuant to §164.512(b) or §164.514(e);

(*ii*) For research purposes pursuant to §164.512(i) or §164.514(e), where the only remuneration received by the covered entity or business associate is a reasonable cost-based fee to cover the cost to prepare and transmit the protected health information for such purposes;

(*iii*) For treatment and payment purposes pursuant to §164.506(a);

(*iv*) For the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence as described in paragraph (6)(iv) of the definition of health care operations and pursuant to §164.506(a);

(*v*) To or by a business associate for activities that the business associate undertakes on behalf of a covered entity, or on behalf of a business associate in the case of a subcontractor, pursuant to §§164.502(e) and 164.504(e), and the only remuneration provided is by the covered entity to the business associate, or by the business associate to the subcontractor, if applicable, for the performance of such activities;

(*vi*) To an individual, when requested under §164.524 or §164.528;

(*vii*) Required by law as permitted under §164.512(a); and

(*viii*) For any other purpose permitted by and in accordance with the applicable requirements of this subpart, where the only remuneration received by the covered entity or business associate is a reasonable, cost-based fee to cover the cost to prepare and transmit the protected health information for such purpose or a fee otherwise expressly permitted by other law.

(iii) *Reproductive health care*—(A) *Prohibition.* Subject to paragraphs (a)(5)(iii)(B) and (C) of this section, a covered entity or business associate may not use or disclose protected health information for any of the following activities:

(*1*) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(*2*) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(*3*) To identify any person for any purpose described in paragraphs (a)(5)(iii)(A)(*1*) or (*2*) of this section.

(B) *Rule of applicability.* The prohibition at paragraph (a)(5)(iii)(A) of this section applies only where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for protected health information has reasonably determined that one or more of the following conditions exists:

(*1*) The reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided.

(*2*) The reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.

(*3*) The presumption at paragraph (a)(5)(iii)(C) of this section applies.

(C) *Presumption.* The reproductive health care provided by another person is presumed lawful under paragraph (a)(5)(iii)(B)(*1*) or (*2*) of this section unless the covered entity or business associate has any of the following:

(*1*) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.

(*2*) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific

circumstances in which it was provided.

(D) *Scope.* For the purposes of this subpart, seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

(b) *Standard: Minimum necessary—Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity or business associate, a covered entity or business associate must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under §164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by §164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to §164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in §164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information*—(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under §164.514(a) and (b) is considered not to be individually identifiable health information, *i.e.,* de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of §164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(ii) A business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with §164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information.

(2) *Implementation specification: Documentation.* The satisfactory assurances

required by paragraph (e)(1) of this section must be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of §164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual for a period of 50 years following the death of the individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: Adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: Unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with §164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with §164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under §164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative, provided that the conditions at paragraphs (g)(5)(i) and (ii) of this section are met:

(i) Paragraphs (g)(5)(i)(A) and (B) of this section both apply.

(A) The covered entity has a reasonable belief that any of the following is true:

(*1*) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person.

(*2*) Treating such person as the personal representative could endanger the individual.

(B) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(ii) The covered entity does not have a reasonable belief under paragraph (g)(5)(i)(A) of this section if the basis for their belief is the provision or facilitation of reproductive health care by such person for and at the request of the individual.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of §164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by §164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by §164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in §164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims*—(1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in §164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 78 FR 5696, Jan. 25, 2013; 89 FR 33063, Apr. 26, 2024]

§ 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at §164.514(b)(2)(i) has been deleted, except that the geographic information described in §164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)–(d) [Reserved]

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement required by §164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in §164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(iii) A business associate is not in compliance with the standards in §164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of protected health information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including breaches of unsecured protected health information as required by §164.410;

(D) In accordance with §164.502(e)(1)(ii), ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) To the extent the business associate is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart

that apply to the covered entity in the performance of such obligation.

(I) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(J) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with this paragraph and §164.314(a)(1), if applicable, by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section and §164.314(a)(2), if applicable.

(B) The covered entity may comply with this paragraph and §164.314(a)(1), if applicable, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section and §164.314(a)(2), if applicable.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in §160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph and §164.314(a)(1), if applicable, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(2) of this section and §164.314(a)(1), if applicable, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(iv) A covered entity may comply with this paragraph and §164.314(a)(1) if the covered entity discloses only a limited data set to a business associate for the business associate to carry out a health care operations function and the covered entity has a data use agreement with the business associate that complies with §§164.514(e)(4) and 164.314(a)(1), if applicable.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the protected health information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the protected health information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and

used or further disclosed only as required by law or for the purposes for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(5) *Implementation specifications: Business associate contracts with subcontractors.* The requirements of §164.504(e)(2) through (e)(4) apply to the contract or other arrangement required by §164.502(e)(1)(ii) between a business associate and a business associate that is a subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under §164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) Except as prohibited by §164.502(a)(5)(i), the group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for purposes of:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with §164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with §164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with §164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by §164.520(b)(1)(iii)(C) is included in the appropriate notice; and (iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.* (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5697, Jan. 25, 2013]

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under §164.508(a)(2) through (4) or that are prohibited under §164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under §164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.* (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

[67 FR 53268, Aug. 14, 2002, as amended at 78 FR 5698, Jan. 25, 2013]

§164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: Authorizations for uses and disclosures*—(1) *Authorization required: General rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: Psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by §164.502(a)(2)(ii) or permitted by §164.512(a); §164.512(d) with respect to the oversight of the originator of the psychotherapy notes; §164.512(g)(1); or §164.512(j)(1)(i).

(3) *Authorization required: Marketing.* (i) Notwithstanding any provision of this subpart, other than the transition provisions in §164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves financial remuneration, as defined in paragraph (3) of the definition of marketing at §164.501, to the covered entity from a third party, the authorization must state that such remuneration is involved.

(4) *Authorization required: Sale of protected health information.* (i) Notwithstanding any provision of this subpart,

other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any disclosure of protected health information which is a sale of protected health information, as defined in § 164.501 of this subpart. (ii) Such authorization must state that the disclosure will result in remuneration to the covered entity.

(b) *Implementation specifications: General requirements*—(1) *Valid authorizations.* (i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (a)(4)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same or another research study. This exception includes combining an authorization for the use or disclosure of protected health information for a research study with another authorization for the same research study, with an authorization for the creation or maintenance of a research database or repository, or with a consent to participate in research. Where a covered health care provider has conditioned the provision of research-related treatment on the provision of one of the authorizations, as permitted under paragraph (b)(4)(i) of this section, any compound authorization created under this paragraph must clearly differentiate between the conditioned and unconditioned components and provide the individual with an opportunity to opt in to the research activities described in the unconditioned authorization.

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes.

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations. The prohibition in this paragraph on combining authorizations where one authorization conditions the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits under paragraph (b)(4) of this section does not apply to a compound authorization created in accordance with paragraph (b)(3)(i) of this section.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health

plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation.* A covered entity must document and retain any signed authorization under this section as required by §164.530(j).

(c) *Implementation specifications: Core elements and requirements*—(1) *Core elements.* A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement ''end of the research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements.* In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by §164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization

to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement.* The authorization must be written in plain language.

(4) *Copy to the individual.* If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

[67 FR 53268, Aug. 14, 2002, as amended at 78 FR 5699, Jan. 25, 2013]

§ 164.509 Uses and disclosures for which an attestation is required.

(a) *Standard: Attestations for certain uses and disclosures of protected health information to persons other than covered entities or business associates.* (1) A covered entity or business associate may not use or disclose protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), without obtaining an attestation that is valid under paragraph (b)(1) of this section from the person requesting the use or disclosure and complying with all applicable conditions of this part.

(2) A covered entity or business associate that uses or discloses protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), in reliance on an attestation that is defective under paragraph (b)(2) of this section, is not in compliance with this section.

(b) *Implementation specifications: General requirements*—(1) *Valid attestations.* (i) A valid attestation is a document that meets the requirements of paragraph (c)(1) of this section.

(ii) A valid attestation verifies that the use or disclosure is not otherwise prohibited by § 164.502(a)(5)(iii).

(iii) A valid attestation may be electronic, provided that it meets the requirements in paragraph (c)(1) of this section, as applicable.

(2) *Defective attestations.* An attestation is not valid if the document submitted has any of the following defects:

(i) The attestation lacks an element or statement required by paragraph (c) of this section.

(ii) The attestation contains an element or statement not required by paragraph (c) of this section

(iii) The attestation violates paragraph (b)(3) of this section.

(iv) The covered entity or business associate has actual knowledge that material information in the attestation is false.

(v) A reasonable covered entity or business associate in the same position would not believe that the attestation is true with respect to the requirement at paragraph (c)(1)(iv) of this section.

(3) *Compound attestation.* An attestation may not be combined with any other document except where such other document is needed to satisfy the requirements at paragraph (c)(iv) of this section or at § 164.502(a)(5)(iii)(C), as applicable.

(c) *Implementation specifications: Content requirements and other obligations*—(1) *Required elements.* A valid attestation under this section must contain the following elements:

(i) A description of the information requested that identifies the information in a specific fashion, including one of the following:

(A) The name of any individual(s) whose protected health information is sought, if practicable.

(B) If including the name(s) of any individual(s) whose protected health information is sought is not practicable, a description of the class of individuals whose protected health information is sought.

(ii) The name or other specific identification of the person(s), or class of persons, who are requested to make the use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity is to make the requested use or disclosure.

(iv) A clear statement that the use or disclosure is not for a purpose prohibited under § 164.502(a)(5)(iii).

(v) A statement that a person may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if that person knowingly and in violation of HIPAA obtains individually identifiable health information relating to an individual or discloses individually identifiable health information to another person.

(vi) Signature of the person requesting the protected health information, which may be an electronic signature, and date. If the attestation is signed by a representative of the person requesting the information, a description of such representative's authority to act for the person must also be provided.

(2) *Plain language requirement.* The attestation must be written in plain language.

(d) *Material misrepresentations.* If, during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity or business associate discovers information reasonably showing that any representation made in the attestation was materially false, leading to a use or disclosure for a purpose prohibited under §164.502(a)(5)(iii), the covered entity or business associate must cease such use or disclosure.

[89 FR 33063, Apr. 26, 2024]

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) *Standard: Use and disclosure for facility directories*—(1) *Permitted uses and disclosure.* Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Use or disclose for directory purposes such information:

(A) To members of the clergy; or

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) *Standard: Uses and disclosures for involvement in the individual's care and notification purposes*—(1) *Permitted uses and disclosures.* (i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5699, Jan. 25, 2013]

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Except as provided by § 164.502(a)(5)(iii), a covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given verbally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may

use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: Uses and disclosures for public health activities*—(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or

(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(vi) A school, about an individual who is a student or prospective student of the school, if:

(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and

(C) The covered entity obtains and documents the agreement to the disclosure from either:

(*1*) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or

(*2*) The individual, if the individual is an adult or emancipated minor.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect, or domestic violence*—(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(3) *Rule of construction.* Nothing in this section shall be construed to permit disclosures prohibited by §164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.

(d) *Standard: Uses and disclosures for health oversight activities*—(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity

does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings*—(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(*1*) No objections were filed; or

(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties

to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Notwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(v) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(*3*) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other

than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents*—(1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes*—(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by

§ 164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or

expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*—(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in §164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered

entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions*—(1) *Military and veterans activities*—(i) *Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12968;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations*—(i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; or

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(7) *National Instant Criminal Background Check System.* A covered entity may use or disclose protected health information for purposes of reporting to the National Instant Criminal Background Check System the identity of an individual who is prohibited from possessing a firearm under 18 U.S.C. 922(g)(4), provided the covered entity:

(i) Is a State agency or other entity that is, or contains an entity that is:

(A) An entity designated by the State to report, or which collects information for purposes of reporting, on behalf of the State, to the National Instant Criminal Background Check System; or

(B) A court, board, commission, or other lawful authority that makes the commitment or adjudication that causes an individual to become subject to 18 U.S.C. 922(g)(4); and

(ii) Discloses the information only to:

(A) The National Instant Criminal Background Check System; or

(B) An entity designated by the State to report, or which collects information for purposes of reporting, on behalf of the State, to the National Instant Criminal Background Check System; and

(iii)(A) Discloses only the limited demographic and certain other information needed for purposes of reporting to the National Instant Criminal Background Check System; and

(B) Does not disclose diagnostic or clinical information for such purposes.

(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5699, Jan. 25, 2013; 78 FR 34266, June 7, 2013; 81 FR 395, Jan. 6, 2016; 89 FR 33064, Apr. 26, 2024]

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

(a) *Standard: De-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify

an individual is not individually identifiable health information.

(b) *Implementation specifications: Requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) *Implementation specifications: Re-identification.* A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) *Derivation.* The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) *Security.* The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) *Standard: minimum necessary requirements.* In order to comply with §164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: Minimum necessary uses of protected health information.* (i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce

who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers

of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f) *Fundraising communications*—(1) *Standard: Uses and disclosures for fundraising.* Subject to the conditions of paragraph (f)(2) of this section, a covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of §164.508:

(i) Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth;

(ii) Dates of health care provided to an individual;

(iii) Department of service information;

(iv) Treating physician;

(v) Outcome information; and

(vi) Health insurance status.

(2) *Implementation specifications: Fundraising requirements.* (i) A covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by §164.520(b)(1)(iii)(A) is included in the covered entity's notice of privacy practices.

(ii) With each fundraising communication made to an individual under this paragraph, a covered entity must provide the individual with a clear and conspicuous opportunity to elect not to receive any further fundraising communications. The method for an individual to elect not to receive further fundraising communications may not cause the individual to incur an undue burden or more than a nominal cost.

(iii) A covered entity may not condition treatment or payment on the individual's choice with respect to the receipt of fundraising communications.

(iv) A covered entity may not make fundraising communications to an individual under this paragraph where the individual has elected not to receive such communications under paragraph (f)(2)(ii) of this section.

(v) A covered entity may provide an individual who has elected not to receive further fundraising communications with a method to opt back in to receive such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected health information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may only use or disclose such protected health information for such purpose or as may be required by law, subject to the prohibition at §164.502(a)(5)(i) with respect to genetic information included in the protected health information.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under §164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification*—(i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in §164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by §164.512(i)(2) may be satisfied by one or more written statements, provided

that each is appropriately dated and signed in accordance with §164.512(i)(2)(i) and (v).

(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with §164.510 or acts on a good faith belief in making a disclosure in accordance with §164.512(j).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5700, Jan. 25, 2013; 78 FR 34266, June 7, 2013]

§164.520 Notice of privacy practices for protected health information.

(a) *Standard: Notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(3) or (4) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Notice requirements for covered entities creating or maintaining records subject to 42 U.S.C. 290dd-2.* As provided in 42 CFR 2.22, an individual who is the subject of records protected under 42 CFR part 2 has a right to adequate notice of the uses and disclosures of such records, and of the individual's rights and the covered entity's legal duties with respect to such records.

(3) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in §164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an

insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in §164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(4) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) *Implementation specifications: Content of notice*—(1) *Required elements.* The covered entity, including any covered entity receiving or maintaining records subject to 42 U.S.C. 290dd-2, must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed:

''THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.''

(ii) *Uses and disclosures.* The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, such as 42 CFR part 2, the description of such use or disclosure must reflect the more stringent law as defined in §160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law, such as 42 CFR part 2.

(E) A description of the types of uses and disclosures that require an authorization under §164.508(a)(2)–(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by §164.508(b)(5).

(F) A description, including at least one example, of the types of uses and disclosures prohibited under §164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.

(G) A description, including at least one example, of the types of uses and disclosures for which an attestation is required under §164.509.

(H) A statement adequate to put the individual on notice of the potential for information disclosed pursuant to this subpart to be subject to redisclosure by the recipient and no longer protected by this subpart

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) or (B) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with §164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with §164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan;

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* intends to use or disclose

protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes;

(D) Substance use disorder treatment records received from programs subject to 42 CFR part 2, or testimony relaying the content of such records, shall not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in 42 CFR part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed; or

(E) If a covered entity that creates or maintains records subject to 42 CFR part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, the individual must first be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by §164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under §164.522(a)(1)(vi);

(B) The right to receive confidential communications of protected health information as provided by §164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by §164.524;

(D) The right to amend protected health information as provided by §164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by §164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) *Covered entity's duties.* The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices, and to notify affected individuals following a breach of unsecured protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by §164.530(a)(1)(ii).

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity

elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.

(1) *Specific requirements for health plans.* (i) A health plan must provide the notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(v) If there is a material change to the notice:

(A) A health plan that posts its notice on its web site in accordance with paragraph (c)(3)(i) of this section must prominently post the change or its revised notice on its web site by the effective date of the material change to the notice, and provide the revised notice, or information about the material change and how to obtain the revised notice, in its next annual mailing to individuals then covered by the plan.

(B) A health plan that does not post its notice on a web site pursuant to paragraph (c)(3)(i) of this section must provide the revised notice, or information about the material change and how to obtain the revised notice, to individuals then covered by the plan within 60 days of the material revision to the notice.

(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

(iii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.

(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(4) The permission in paragraph (d) of this section for covered entities that participate in an organized health care arrangement to issue a joint notice may not be construed to remove any obligations or duties of entities creating or maintaining records subject to 42 U.S.C. 290dd-2, or to remove any rights of patients who are the subjects of such records.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by §164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such

written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002; 78 FR 5701, Jan. 25, 2013; 89 FR 33064, Apr. 26, 2024]

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.* (i) A covered entity must permit an individual to request that the covered entity restrict:

(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and

(B) Disclosures permitted under § 164.510(b).

(ii) Except as provided in paragraph (a)(1)(vi) of this section, a covered entity is not required to agree to a restriction.

(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under § 164.502(a)(2)(ii), § 164.510(a) or § 164.512.

(vi) A covered entity must agree to the request of an individual to restrict disclosure of protected health information about the individual to a health plan if:

(A) The disclosure is for the purpose of carrying out payment or health care operations and is not otherwise required by law; and

(B) The protected health information pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate a restriction, if:

(i) The individual agrees to or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented; or

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is:

(A) Not effective for protected health information restricted under paragraph (a)(1)(vi) of this section; and

(B) Only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity must document a restriction in accordance with § 160.530(j) of this subchapter.

(b)(1) *Standard: Confidential communications requirements.* (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.

(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.

(2) *Implementation specifications: Conditions on providing confidential communications.* (i) A covered entity may require the individual to make a request

for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002; 78 FR 5701, Jan. 25, 2013]

§ 164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information*—(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes; and

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: Requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable hard copy form or such other form and format as agreed to by the covered entity and the individual.

(ii) Notwithstanding paragraph (c)(2)(i) of this section, if the protected health information that is the subject of a request for access is maintained in one or more designated record sets electronically and if the individual requests an electronic copy of such information, the covered entity must provide the individual with access to the protected health information in the electronic form and format requested by the individual, if it is readily producible in such form and format; or, if not, in a readable electronic form and format as agreed to by the covered entity and the individual.

(iii) The covered entity may provide the individual with a summary of the

protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* (i) The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(ii) If an individual's request for access directs the covered entity to transmit the copy of protected health information directly to another person designated by the individual, the covered entity must provide the copy to the person designated by the individual. The individual's request must be in writing, signed by the individual, and clearly identify the designated person and where to send the copy of protected health information.

(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Labor for copying the protected health information requested by the individual, whether in paper or electronic form;

(ii) Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;

(iii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iv) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(iii) of this section.

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial.* The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in §164.530(d) or to the Secretary pursuant to the procedures in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).

(3) *Other responsibility.* If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) *Review of denial requested.* If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access

requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 78 FR 5701, Jan. 25, 2013; 78 FR 34266, June 7, 2013; 79 FR 7316, Feb. 6, 2014]

§164.526 Amendment of protected health information.

(a) *Standard: Right to amend.* (1) *Right to amend.* An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment.* A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under §164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: Requests for amendment and timely action—*(1) *Individual's request for amendment.* The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity.* (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) *Implementation specifications: Accepting the amendment.* If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Making the amendment.* The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual.* In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to

have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) *Informing others.* The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) *Implementation specifications: Denying the amendment.* If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Denial.* The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in §164.530(d) or to the Secretary pursuant to the procedures established in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).

(2) *Statement of disagreement.* The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) *Rebuttal statement.* The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

(4) *Recordkeeping.* The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) *Future disclosures.* (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required

by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) *Implementation specification: Actions on notices of amendment.* A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) *Implementation specification: Documentation.* A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by §164.530(j).

§164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information.* (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in §164.506;

(ii) To individuals of protected health information about them as provided in §164.502;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in §164.502;

(iv) Pursuant to an authorization as provided in §164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in §164.510;

(vi) For national security or intelligence purposes as provided in §164.512(k)(2);

(vii) To correctional institutions or law enforcement officials as provided in §164.512(k)(5);

(viii) As part of a limited data set in accordance with §164.514(e); or

(ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in §164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §164.502(a)(2)(ii) or §164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §164.502(a)(2)(ii) or §164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by §164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that

are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.530 Administrative requirements.

(a)(1) *Standard: Personnel designations.* (i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.

(2) *Implementation specification: Personnel designations.* A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) *Standard: Training.* A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart and subpart D of this part, as necessary and appropriate for the members of the workforce to carry out their functions within the covered entity.

(2) *Implementation specifications: Training.* (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart or subpart D of this part, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) *Standard: Safeguards.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2)(i) *Implementation specification: Safeguards.* A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

(d)(1) *Standard: Complaints to the covered entity.* A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart and subpart D of this part or its compliance with such policies and procedures or the requirements of this subpart or subpart D of this part.

(2) *Implementation specification: Documentation of complaints.* As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) *Standard: Sanctions.* A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart or subpart D of this part. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.

(2) *Implementation specification: Documentation.* As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) *Standard: Mitigation.* A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) *Standard: Refraining from intimidating or retaliatory acts.* A covered entity—

(1) May not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process provided for, by this subpart or subpart D of this part, including the filing of a complaint under this section; and

(2) Must refrain from intimidation and retaliation as provided in § 160.316 of this subchapter.

(h) *Standard: Waiver of rights.* A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter, this subpart, or subpart D of this part, as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) *Standard: Policies and procedures.* A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart and subpart D of this part. The policies and procedures must be reasonably designed, taking into account the size and the type of activities that relate to protected health information undertaken by a covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) *Standard: Changes to policies and procedures.* (i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart or subpart D of this part.

(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) *Implementation specification: Changes in law.* Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) *Implementation specifications: Changes to privacy practices stated in the notice.* (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by § 164.520(b)(3) to state the changed practice and make the revised notice available as required by § 164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under §164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation specifications in paragraphs (i)(4)(i)(A)–(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) *Implementation specification: Changes to other policies or procedures.* A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by §164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(iv) Maintain documentation sufficient to meet its burden of proof under §164.414(b).

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) *Standard: Group health plans.* (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in §164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with §164.504(f).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 71 FR 8433, Feb. 16, 2006; 74 FR 42769, Aug. 24, 2009]

§164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, a waiver of informed consent by an IRB, or a waiver of authorization in accordance with §164.512(i)(1)(i).

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in §164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of

this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research;

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research; or

(4) A waiver of authorization in accordance with § 164.512(i)(1)(i).

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this part, a covered entity, or business associate with respect to a subcontractor, may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), only in accordance with paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance*—(1) *Qualification.* Notwithstanding other sections of this part, a covered entity, or business associate with respect to a subcontractor, is deemed to be in compliance with the documentation and contract requirements of §§ 164.308(b), 164.314(a), 164.502(e), and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to January 25, 2013, such covered entity, or business associate with respect to a subcontractor, has entered into and is operating pursuant to a written contract or other written arrangement with the business associate that complies with the applicable provisions of § 164.314(a) or § 164.504(e) that were in effect on such date; and

(ii) The contract or other arrangement is not renewed or modified from March 26, 2013, until September 23, 2013.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after September 23, 2013; or

(ii) September 22, 2014.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

(f) *Effect of prior data use agreements.* If, prior to January 25, 2013, a covered entity has entered into and is operating pursuant to a data use agreement with a recipient of a limited data set that complies with § 164.514(e), notwithstanding § 164.502(a)(5)(ii), the covered entity may continue to disclose a limited data set pursuant to such agreement in exchange for remuneration from or on behalf of the recipient of the protected health information until the earlier of:

(1) The date such agreement is renewed or modified on or after September 23, 2013; or

(2) September 22, 2014.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 78 FR 5702, Jan. 25, 2013; 78 FR 34266, June 7, 2013]

§ 164.534 Compliance dates for initial implementation of the privacy standards.

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 14, 2003.

(b) *Health plans.* A health plan must comply with the applicable requirements of this subpart no later than the following as applicable:

(1) *Health plans other than small health plans.* April 14, 2003.

(2) *Small health plans.* April 14, 2004.

(c) *Health clearinghouses.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 14, 2003.

[66 FR 12434, Feb. 26, 2001]

§ 164.535 Severability.

If any provision of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[89 FR 33066, Apr. 26, 2024]

PARTS 165–169 [RESERVED]

SUBCHAPTER D—HEALTH INFORMATION TECHNOLOGY

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

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AUTHORITY: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

SOURCE: 75 FR 2042, Jan. 13, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 170.100 Statutory basis and purpose.

The provisions of this subchapter implement sections 3001(c)(5) and 3004 of the Public Health Service Act.

[75 FR 36203, June 24, 2010]

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria

adopted in this part apply to health information technology and the testing and certification of Health IT Modules.

[85 FR 70082, Nov. 4, 2020]

§ 170.102 Definitions.

For the purposes of this part:

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to healthcare quality;

(iv) To exchange electronic health information with, and integrate such information from other sources; and

(3) Has been certified to the certification criteria adopted by the Secretary in—

(i) Section 170.315(a)(1), (2), or (3); (a)(5) and (14), (b)(1), (c)(1), and (g)(7), (9), (10); and (h)(1) or (2);

(ii) Section 170.315(a)(9) or (b)(11) for the period up to and including December 31, 2024; and

(iii) Section 170.315(b)(11) on and after January 1, 2025.

Certification criteria means criteria:

(1) To establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or

(2) That are used to test and certify that health information technology includes required capabilities.

Common Clinical Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) Patient name.

(2) *Sex:* The standard specified in §170.207(n)(1).

(3) Date of birth.

(4) *Race:*

(i) The standard specified in §170.207(f)(2); and

(ii) The standard specified in §170.207(f)(1) for each race identified in accordance §170.207(f)(2).

(5) *Ethnicity:*

(i) The standard specified in §170.207(f)(2); and

(ii) The standard specified in §170.207(f)(1) for each ethnicity identified in accordance §170.207(f)(2).

(6) *Preferred language:* The standard specified in §170.207(g)(2).

(7) Smoking status.

(8) *Problems:* At a minimum, the standard specified in §170.207(a)(4).

(9) *Medications:* At a minimum, the standard specified in §170.207(d)(3).

(10) *Medication allergies:* At a minimum, the standard specified in §170.207(d)(3).

(11) *Laboratory test(s):* At a minimum, the standard specified in §170.207(c)(3).

(12) Laboratory value(s)/result(s).

(13) *Vital signs:*

(i) The patient's diastolic blood pressure, systolic blood pressure, body height, body weight, heart rate, respiratory rate, body temperature, pulse oximetry, and inhaled oxygen concentration must be exchanged in numerical values only; and

(ii) In accordance with the standard specified in §170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in §170.207(m)(1).

(iii) *Optional:* The patient's BMI percentile per age and sex for youth 2–20 years of age, weight for age per length and sex for children less than 3 years of age, and head occipital-frontal circumference for children less than 3 years of age must be recorded in numerical values only in accordance with the standard specified in §170.207(c)(3) and with the associated applicable unit of measure for the vital sign measurement in the standard specified in §170.207(m)(1). For BMI percentile per age and sex for youth 2–20 years of age and weight for age per length and sex for children less than 3 years of age, the reference range/scale or growth curve should be included as appropriate.

(14) *Procedures:*

(i) At a minimum, the version of the standard specified in §170.207(a)(4) or §170.207(b)(2); or

(ii) For technology primarily developed to record dental procedures, the standard specified in §170.207(b)(3).

(iii) *Optional:* The standard specified in §170.207(b)(4).

(15) Care team member(s).

(16) *Immunizations:* In accordance with, at a minimum, the standards specified in § 170.207(e)(3) and (4).

(17) Unique device identifier(s) for a patient's implantable device(s): In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4).

(18) *Assessment and plan of treatment:*

(i) In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4); or

(ii) In accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4).

(19) *Goals:* In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4).

(20) *Health concerns:* In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4).

Day or Days means a calendar day or calendar days.

Device identifier is defined as it is in 21 CFR 801.3.

Disclosure is defined as it is in 45 CFR 160.103.

Electronic health information (EHI) is defined as it is in § 171.102.

Fee is defined as it is in § 171.102 of this subchapter.

Global Unique Device Identification Database (GUDID) is defined as it is in 21 CFR 801.3.

Health information technology means hardware, software, integrated technologies or related licenses, IP, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information.

Health IT Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

Implantable device is defined as it is in 21 CFR 801.3.

Implementation specification means specific requirements or instructions for implementing a standard.

Interoperability is, with respect to health information technology, such health information technology that—

(1) Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(3) Does not constitute information blocking as defined in § 171.103 of this subchapter.

Interoperability element is defined as it is in § 171.102 of this subchapter.

ONC certification criteria for health IT means the certification criteria in § 170.315.

Predictive Decision Support Intervention or Predictive DSI means technology that supports decision-making based on algorithms or models that derive relationships from training data and then produces an output that results in prediction, classification, recommendation, evaluation, or analysis.

Production identifier is defined as it is in 21 CFR 801.3.

Provide means the action or actions taken by a developer of certified Health IT Modules to make the certified health IT available to its customers.

Qualified EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists; and

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality; and

(iv) To exchange electronic health information with, and integrate such information from other sources.

Revised certification criterion (or criteria) means a certification criterion

that meets at least one of the following:

(1) Has added or changed the capabilities described in the existing criterion in this part;

(2) Has an added or changed standard or implementation specification referenced in the existing criterion in this part; or

(3) Is specified through notice and comment rulemaking as an iterative or replacement version of an existing criterion in this part.

Standard means a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

Unique device identifier is defined as it is in 21 CFR 801.3.

[75 FR 2042, Jan. 13, 2010, as amended at 75 FR 36203, June 24, 2010; 75 FR 44649, July 28, 2010; 77 FR 54283, Sept. 4, 2012; 78 FR 65887, Nov. 4, 2013; 79 FR 52933, Sept. 4, 2014; 79 FR 54477, 54478, Sept. 11, 2014; 80 FR 62741, Oct. 16, 2015; 80 FR 76871, Dec. 11, 2015; 85 FR 25939, May 1, 2020; 85 FR 70082, Nov. 4, 2020; 89 FR 1426, Jan. 9, 2024]

Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Health Information technology.

[85 FR 70082, Nov. 4, 2020]

§ 170.202 Transport standards and other protocols.

The Secretary adopts the following transport standards:

(a) *Direct Project*. (1) [Reserved]

(2) *Standard*. ONC Applicability Statement for Secure Health Transport, Version 1.2 (incorporated by reference in § 170.299).

(b) *Standard*. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).

(c) *Standard*. ONC Transport and Security Specification (incorporated by reference in § 170.299).

(d) *Standard*. ONC Implementation Guide for Direct Edge Protocols (incorporated by reference in § 170.299).

(e) *Delivery notification*—(1) *Standard*. ONC Implementation Guide for Delivery Notification in Direct (incorporated by reference in § 170.299).

(2) [Reserved]

[77 FR 54284, Sept. 4, 2012, as amended at 79 FR 54478, Sept. 11, 2014; 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020]

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility*—(1) *Standard*. Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(2) *Standard*. Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance (incorporated by reference in § 170.299).

(b) *Reference source*. *Standard*. HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299).

(1)–(2) [Reserved]

(3) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (''Infobutton''), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1 (incorporated by reference in § 170.299).

(4) *Standard*. HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application (''Infobutton''), Knowledge Request, Release 2 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4 (incorporated by reference in § 170.299).

[77 FR 54284, Sept. 4, 2012, as amended at 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020]

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) *Patient summary record.* (1) [Reserved]

(2) [Reserved]

(3) *Standard.* HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the ''unstructured document'' document-level template is prohibited.

(4) *Standard.* HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1 and HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1 (incorporated by reference in § 170.299).

(5) *Standard.* HL7 CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2026.

(6) *Standard.* HL7® CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes STU Companion Guide, Release 4.1—US Realm (incorporated by reference, see § 170.299).

(b) *Electronic prescribing*—(1) *Standard.* National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299). The Secretary's adoption of this standard expires on January 1, 2028.

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 2023011 (incorporated by reference in § 170.299).

(c) *Real-time prescription benefit*—(1) *Standard.* NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13 (incorporated by reference in § 170.299).

(2) [Reserved]

(d) *Electronic submission to public health agencies for surveillance or reporting.* (1) [Reserved]

(2) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299).

(3) [Reserved]

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015 (incorporated by reference in § 170.299) and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings (incorporated by reference in § 170.299).

(e) *Electronic submission to immunization registries.* (1) [Reserved]

(2)–(3) [Reserved]

(4) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 (incorporated by reference in § 170.299) and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015 (incorporated by reference in § 170.299).

(f) [Reserved]

(g) *Electronic transmission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (incorporated by reference in § 170.299).

(h) *Clinical quality measure data import, export and reporting.* (1) [Reserved]

(2) *Standard.* HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material and HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting

Material (incorporated by reference in §170.299).

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2020 (incorporated by reference in §170.299).

(i) *Cancer information.* (1) [Reserved]

(2) *Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in §170.299). *Implementation specifications.* HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1, Volume 1—Introductory Material and HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material (incorporated by reference in §170.299).

(j) [Reserved]

(k) *Clinical quality measure aggregate reporting*—(1) *Standard.* Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in §170.299).

(2) *Standard.* Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014 (incorporated by reference in §170.299).

(3) *Standard.* CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2020 (incorporated by reference in §170.299).

(l)–(n) [Reserved]

(o) *Data segmentation for privacy*—(1) *Standard.* HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 (incorporated by reference in §170.299).

(2) [Reserved]

(p) *XDM package processing*—(1) *Standard.* IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b) (incorporated by reference in §170.299).

(2) [Reserved]

(q) [Reserved]

(r) *Public health—antimicrobial use and resistance information*—(1) *Standard.* The following sections of HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm (incorporated by reference in §170.299). Technology is only required to conform to the following sections of the implementation guide:

(i) HAI Antimicrobial Use and Resistance (AUR) Antimicrobial Resistance Option (ARO) Report (Numerator) specific document template in Section 2.1.2.1 (pages 69–72);

(ii) Antimicrobial Resistance Option (ARO) Summary Report (Denominator) specific document template in Section 2.1.1.1 (pages 54–56); and

(iii) Antimicrobial Use (AUP) Summary Report (Numerator and Denominator) specific document template in Section 2.1.1.2 (pages 56–58).

(2) [Reserved]

(s) *Public health—health care survey information*—(1) *Standard.* HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material and HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material (incorporated by reference in §170.299).

(2) [Reserved]

(t) *Public health—electronic case reporting*—(1) *Standard.* HL7® FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm 2.1.0—STU 2 US (HL7 FHIR eCR IG) (incorporated by reference, see §170.299).

(2) *Standard.* HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG) (incorporated by reference, see §170.299).

(3) *Standard.* HL7® CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG) (incorporated by reference, see §170.299).

(4) *Standard.* Reportable Conditions Trigger Codes Value Set for Electronic

Case Reporting. (incorporated by reference, see § 170.299).

(u) *Formulary and benefit*—(1) *Standard.* NCPDP Formulary and Benefit Standard Version 60 (incorporated by reference in § 170.299).

(2) [Reserved]

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010; 77 FR 54284, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62743, Oct. 16, 2015; 85 FR 25940, May 1, 2020; 85 FR 70082, Nov. 4, 2020; 89 FR 1426, Jan. 9, 2024; 89 FR 51265, June 17, 2024]

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) *Problems.*

(1) *Standard.* SNOMED CT®, U.S. Edition, March 2022 Release (incorporated by reference, see § 170.299).

(2)–(3) [Reserved]

(4) *Standard.* IHTSDO SNOMED CT®, U.S. Edition, September 2015 Release (incorporated by reference in § 170.299).

(b) *Procedures.* (1) [Reserved]

(2) *Standard.* The code set specified at 45 CFR 162.1002(a)(5).

(3) *Standard.* The code set specified at 45 CFR 162.1002(a)(4).

(4) *Standard.* The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.

(c) *Laboratory tests.*

(1) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, a universal code system for identifying health measurements, observations, and documents produced by the Regenstrief Institute, Inc., February 16, 2022 (incorporated by reference, see § 170.299).

(2) [Reserved]

(3) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).

(d) *Medications.*

(1) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, July 5, 2022 (incorporated by reference, see § 170.299).

(2) [Reserved]

(3) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release (incorporated by reference in § 170.299).

(4) *Standard.* The code set specified at 45 CFR 162.1002(b)(2) as referenced in 45 CFR 162.1002(c)(1) for the time period on or after October 1, 2015.

(e) *Immunizations.*

(1) *Standard.* HL7® Standard Code Set CVX—Vaccines Administered, dated through June 15, 2022 (incorporated by reference, see § 170.299).

(2) *Standard.* National Drug Code Directory (NDC)—Vaccine NDC Linker, dated July 19, 2022 (incorporated by reference, see § 170.299).

(3) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015 (incorporated by reference in § 170.299).

(4) *Standard.* National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015 (incorporated by reference in § 170.299).

(f) *Race and Ethnicity*—(1) *Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (incorporated by reference in § 170.299).

(2) *Standard.* CDC Race and Ethnicity Code Set Version 1.0 (March 2000) (incorporated by reference in § 170.299).

(3) *Standard.* CDC Race and Ethnicity Code Set Version 1.2 (July 08, 2021) (incorporated by reference, see § 170.299).

(g) *Preferred language.* (1) [Reserved]

(2) *Standard.* Request for Comments (RFC) 5646 (incorporated by reference in § 170.299).

(h) [Reserved]

(i) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(j)–(l) [Reserved]

(m) *Numerical references*—(1) *Standard.* The Unified Code of Units of Measure, Revision 1.9 (incorporated by reference in § 170.299).

(2) *Standard.* The Unified Code for Units of Measure, Version 2.1, November 21, 2017 (incorporated by reference, see §170.299).

(n) *Sex*—(1) *Standard.* Birth sex must be coded in accordance with HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see §170.299), up until the adoption of this standard expires January 1, 2026, attributed as follows:

(i) Male. M;

(ii) Female. F;

(iii) Unknown. NullFlavor UNK.

(2) *Standard.* Sex must be coded in accordance with, at a minimum, the version of SNOMED CT ® U.S. Edition codes specified in paragraph (a)(1) of this section.

(3) *Standard.* Sex Parameter for Clinical Use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section.

(o) *Sexual orientation and gender information*—(1) *Standard.* Sexual orientation must be coded in accordance with, at a minimum, the version of SNOMED–CT® U.S. Edition codes specified in paragraph (a)(4) of this section for paragraphs (o)(1)(i) through (iii) of this section and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference, see §170.299), up until the adoption of this standard expires on January 1, 2026, for paragraphs (o)(1)(iv) through (vi) of this section, attributed as follows:

(i) *Lesbian, gay or homosexual.* 38628009

(ii) *Straight or heterosexual.* 20430005

(iii) *Bisexual.* 42035005

(iv) *Something else, please describe.* NullFlavor OTH

(v) *Don't know.* NullFlavor UNK

(vi) *Choose not to disclose.* NullFlavor ASKU

(2) *Standard.* Gender identity must be coded in accordance with, at a minimum, the version of SNOMED–CT® codes specified in paragraph (a)(4) of this section for paragraphs (o)(2)(i) through (v) of this section and HL7® Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor (incorporated by reference in §170.299), up until the adoption of this standard expires January 1, 2026, for paragraphs (o)(2)(vi) and (vii) of this section, attributed as follows:

(i) *Male.* 446151000124109

(ii) *Female.* 446141000124107

(iii) *Female-to-Male (FTM)/Transgender Male/Trans Man.* 407377005

(iv) *Male-to-Female (MTF)/Transgender Female/Trans Woman.* 407376001

(v) *Genderqueer, neither exclusively male nor female.* 446131000124102

(vi) *Additional gender category or other, please specify.* NullFlavor OTH

(vii) *Choose not to disclose.* NullFlavor ASKU

(3) *Standard.* Sexual Orientation and Gender Identity must be coded in accordance with, at a minimum, the version of SNOMED CT® codes specified in paragraph (a)(1) of this section.

(4) *Standard.* Pronouns must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section.

(p) *Social, psychological, and behavioral data*—(1) *Financial resource strain.* Financial resource strain must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with the LOINC® code 76513–1 and LOINC® answer list ID LL3266–5.

(2) *Education.* Education must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with LOINC® code 63504–5 and LOINC® answer list ID LL1069–5.

(3) *Stress.* Stress must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with the LOINC® code 76542–0 and LOINC® answer list LL3267–3.

(4) *Depression.* Depression must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with LOINC® codes 55757–9, 44250–9 (with LOINC® answer list ID LL361–7), 44255–8 (with LOINC® answer list ID LL361–7), and 55758–7 (with the answer coded with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section).

(5) *Physical activity.* Physical activity must be coded in accordance with, at a

minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with LOINC® codes 68515–6 and 68516–4. The answers must be coded with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section.

(6) *Alcohol use.* Alcohol use must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with LOINC® codes 72109–2, 68518–0 (with LOINC® answer list ID LL2179–1), 68519–8 (with LOINC® answer list ID LL2180–9), 68520–6 (with LOINC® answer list ID LL2181–7), and 75626–2 (with the answer coded with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section).

(7) *Social connection and isolation.* Social connection and isolation must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with the LOINC® codes 76506–5, 63503–7 (with LOINC® answer list ID LL1068–7), 76508–1 (with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section), 76509–9 (with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section), 76510–7 (with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section), 76511–5 (with LOINC answer list ID LL963–0), and 76512–3 (with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section).

(8) *Exposure to violence (intimate partner violence).* Exposure to violence: Intimate partner violence must be coded in accordance with, at a minimum, the version of LOINC® codes specified in paragraph (c)(1) of this section and attributed with the LOINC® code 76499–3, 76500–8 (with LOINC® answer list ID LL963–0), 76501–6 (with LOINC® answer list ID LL963–0), 76502–4 (with LOINC® answer list ID LL963–0), 76503–2 (with LOINC® answer list ID LL963–0), and 76504–0 (with the associated applicable unit of measure in the standard specified in paragraph (m)(2) of this section).

(q) *Patient matching*—(1) *Phone number standard.* ITU–T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, email addresses and web addresses (incorporated by reference in §170.299); and ITU–T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service: The international public telecommunication numbering plan (incorporated by reference in §170.299).

(2) [Reserved]

(r) *Provider type*—(1) *Standard.* Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015 (incorporated by reference in §170.299).

(2) *Standard.* Medicare Provider and Supplier Taxonomy Crosswalk, 2021 (incorporated by reference, see §170.299).

(s) *Patient insurance*—(1) *Standard.* Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011) (incorporated by reference in §170.299).

(2) *Standard.* Public Health Data Standards Consortium Users Guide for Source of Payment Typology, Version 9.2 (incorporated by reference, see §170.299).

[75 FR 44649, July 28, 2010, as amended at 77 FR 54284, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62744, Oct. 16, 2015; 80 FR 76871, Dec. 11, 2015; 85 FR 25940, May 1, 2020; 89 FR 1426, Jan. 9, 2024]

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

(a) *Encryption and decryption of electronic health information.* (1) [Reserved]

(2) *General.* Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS)

Publication 140–2, October 8, 2014 (incorporated by reference in § 170.299).

(b) [Reserved]

(c) *Hashing of electronic health information.* (1) [Reserved]

(2) *Standard.* A hashing algorithm with a security strength equal to or greater than SHA–2 as specified by NIST in FIPS Publication 180–4 (August 2015) (incorporated by reference in § 170.299).

(d) *Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

(e) *Record actions related to electronic health information, audit log status, and encryption of end-user devices.* (1)(i) The audit log must record the information specified in sections 7.1.1 and 7.1.2 and 7.1.6 through 7.1.9 of the standard specified in § 170.210(h) and changes to user privileges when health IT is in use.

(ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g).

(2)(i) The audit log must record the information specified in sections 7.1.1 and 7.1.7 of the standard specified at § 170.210(h) when the audit log status is changed.

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(3) The audit log must record the information specified in sections 7.1.1 and 7.1.7 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by health IT on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(f) *Encryption and hashing of electronic health information.* Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140–2 (incorporated by reference in § 170.299).

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized using any Network Time Protocol (NTP) standard.

(h) *Audit log content.* ASTM E2147–18, (incorporated by reference in § 170.299).

[75 FR 44649, July 28, 2010, as amended at 77 FR 54285, Sept. 4, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62745, Oct. 16, 2015; 85 FR 25940, May 1, 2020; 85 FR 70082, Nov. 4, 2020; 89 FR 1428, Jan. 9, 2024]

§ 170.213 United States Core Data for Interoperability.

The Secretary adopts the following versions of the United States Core Data for Interoperability standard:

(a) *Standard.* United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2026.

(b) *Standard.* United States Core Data for Interoperability Version 3 (USCDI v3) (incorporated by reference, see § 170.299).

[89 FR 1428, Jan. 9, 2024]

§ 170.215 Application Programming Interface Standards.

The Secretary adopts the following standards and associated implementation specifications as the available standards for application programming interfaces (API):

(a) *API base standard.* The following are applicable for purposes of standards-based APIs.

(1) *Standard.* HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 (incorporated by reference, see § 170.299).

(2) [Reserved]

(b) *API constraints and profiles.* The following are applicable for purposes of constraining and profiling data standards.

(1) *United States Core Data Implementation Guides*—(i) *Implementation specification.* HL7® FHIR® US Core Implementation Guide STU 3.1.1 (incorporated by reference in § 170.299). The adoption of this standard expires on January 1, 2026.

(ii) *Implementation Specification.* HL7® FHIR® US Core Implementation Guide STU 6.1.0 (incorporated by reference, see § 170.299).

(2) [Reserved]

(c) *Application access and launch.* The following are applicable for purposes of enabling client applications to access and integrate with data systems.

(1) *Implementation specification.* HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the ''SMART Core Capabilities'' (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2026.

(2) *Implementation specification.* HL7® SMART App Launch Implementation Guide Release 2.0.0, including mandatory support for the ''Capability Sets'' of ''Patient Access for Standalone Apps'' and ''Clinician Access for EHR Launch''; all ''Capabilities'' as defined in ''8.1.2 Capabilities,'' excepting the ''permission-online'' capability; ''Token Introspection'' as defined in ''7 Token Introspection'' (incorporated by reference, see § 170.299).

(d) *Bulk export and data transfer standards.* The following are applicable for purposes of enabling access to large volumes of information on a group of individuals.

(1) *Implementation specification.* FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), including mandatory support for the ''group-export'' ''OperationDefinition'' (incorporated by reference, see § 170.299).

(2) [Reserved]

(e) *API authentication, security, and privacy.* The following are applicable for purposes of authorizing and authenticating client applications.

(1) *Standard.* OpenID Connect Core 1.0, incorporating errata set 1 (incorporated by reference, see § 170.299).

(2) [Reserved]

[89 FR 1428, Jan. 9, 2024]

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(b) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the U.S. Department of Health and Human Services (HHS) and at the National Archives and Records Administration (NARA). Contact HHS at: U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201; call ahead to arrange for inspection at 202–690–7151. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the sources in the following paragraphs of this section.

(b) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org.*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/.*

(1) ASTM E2147–18 Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved May 1, 2018, IBR approved for § 170.210(h).

(2)–(3) [Reserved]

(d) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333; phone: (800) 232–4636); website: *www.cdc.gov/cdc-info/index.html*

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) [Reserved]

(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7)Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08,

HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for §170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT MESSAGES A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for §170.205.

(7)–(8) [Reserved]

(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for §170.205.

(10) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0, April 21, 2015, IBR approved for §170.205(d).

(11) Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, IBR approved for §170.205(d).

(12) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, October 1, 2014, IBR approved for §170.205(e).

(13) HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015, IBR approved for §170.205(e).

(14) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015, IBR approved for §170.207(e).

(15) National Drug Code Directory (NDC)—Vaccine NDC Linker, updates through August 17, 2015, IBR approved for §170.207(e).

(16) CDC Race and Ethnicity Code Set Version 1.0 (March 2000), IBR approved for §170.207(f).

(17) HL7® Standard Code Set CVX—Vaccines Administered, dated June 15, 2022; IBR approved for §170.207(e).

(18) National Drug Code Directory (NDC)—Vaccine NDC Linker, dated July 19, 2022; IBR approved for §170.207(e).

(19) CDC Race and Ethnicity Code Set version 1.2 (July 08, 2021); IBR approved for §170.207(f).

(e) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786–3000; website: *www.cms.gov*.

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for §170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for §170.205.

(3) Crosswalk: Medicare Provider/Supplier to Healthcare Provider Taxonomy, April 2, 2015, IBR approved for §170.207(r).

(4) CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting Implementation Guide for 2020; published December 3, 2019, IBR approved for §170.205(h).

(5) CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs Implementation Guide for 2020; published April 30, 2020, IBR approved for §170.205(k).

(6) Medicare Provider and Supplier Taxonomy Crosswalk, 2021; IBR approved for §170.207(r).

(f) Council of State and Territorial Epidemiologists, 2635 Century Parkway NE, Suite 700, Atlanta, GA 30345; phone: (770) 458–3811; website: *www.cste.org/*

(1) Reportable Conditions Trigger Codes Value Set for Electronic Case Reporting. RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022; IBR approved for §170.205(t).

(2) [Reserved]

(g) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; phone: (734) 677–7777; website: *www.hl7.org/*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for §170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for §170.205.

(3) [Reserved]

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton); Release 1, July 2010, IBR approved for § 170.204.

(6)–(7) [Reserved]

(8) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012, IBR approved for § 170.205.

(9) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005, IBR approved for § 170.205.

(10)–(11) [Reserved]

(12) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DTSU Release 2 (Universal Realm), Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for § 170.205.

(14) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm) Draft Standard for Trial Use, November 2012, IBR approved for § 170.205.

(15) HL7 Version 3 Standard: Context Aware Retrieval Application (''Infobutton''), Knowledge Request, Release 2, 2014 Release, IBR approved for § 170.204(b).

(16) HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1, August 9, 2013, IBR approved for § 170.204(b).

(17) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4, June 13, 2014, IBR approved for § 170.204(b).

(18) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 1—Introductory Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(19) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, Release 2.1, August 2015, IBR approved for § 170.205(a).

(20) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 1—Introductory Material, June 2015, IBR approved for § 170.205(h).

(21) HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture—Category I (QRDA I); Release 1, DSTU Release 3 (US Realm), Volume 2—Templates and Supporting Material, June 2015, IBR approved for § 170.205(h).

(22) HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 1—Introductory Material, April 2015, IBR approved for § 170.205(i).

(23) HL7 CDA© Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1; DSTU Release 1.1 (US Realm), Volume 2—Templates and Supporting Material, April 2015, IBR approved for § 170.205(i).

(24) Errata to the HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture—Category III, DSTU Release 1 (US Realm), September 2014, IBR approved for § 170.205(k).

(25) HL7 Version 3 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1, Part 1: CDA R2 and Privacy Metadata Reusable Content Profile, May 16, 2014, IBR approved for § 170.205(o).

(26) HL7 Implementation Guide for CDA® Release 2—Level 3: Healthcare Associated Infection Reports, Release 1 (U.S. Realm), August 9, 2013, IBR approved for § 170.205(r).

(27) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 1—Introductory Material, December 2014, IBR approved for § 170.205(s).

(28) HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1—US Realm, HL7 Draft Standard for Trial Use, Volume 2—Templates and Supporting Material, December 2014, IBR approved for §170.205(s).

(29) HL7 Version 3 (V3) Standard, Value Sets for AdministrativeGender and NullFlavor, published August 1, 2013, IBR approved for §170.207(n) and (o).

(30) HL7® CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2–US Realm, October 2019, IBR approved for §170.205(a).

(31) HL7 FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), August 22, 2019, IBR approved for §170.215(a).

(32) HL7 FHIR SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018, IBR approved for §170.215(a).

(33) HL7 Fast Healthcare Interoperability Resources Specification (FHIR®) Release 4, Version 4.0.1: R4, October 30, 2019, including Technical Correction #1, November 1, 2019, IBR approved for §170.215(a).

(34) HL7 FHIR® US Core Implementation Guide STU3 Release 3.1.1, August 28, 2020, IBR approved for §170.215(a).

(35) HL7 CDA® R2 Implementation Guide: C–CDA Templates for Clinical Notes STU Companion Guide, Release 4.1 (US Realm) Standard for Trial Use, Specification Version: 4.1.1, June 2023 (including appendices A and B); IBR approved for §170.205(a).

(36) HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR)—US Realm, Version 2.1.0—STU 2 US (HL7 FHIR eCR IG), August 31, 2022; IBR approved for §170.205(t).

(37) HL7 CDA® R2 Implementation Guide: Public Health Case Report—the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1—US Realm (HL7 CDA eICR IG), July 2022, volumes 1 and 2; IBR approved for §170.205(t).

(38) HL7 CDA® R2 Implementation Guide: Reportability Response, Release 1, STU Release 1.1—US Realm (HL7 CDA RR IG), July 2022, volumes 1 through 4; IBR approved for §170.205(t).

(39) HL7 FHIR US Core Implementation Guide Version 6.1.0—STU 6, June 19, 2023; IBR approved for §170.215(b).

(40) HL7 FHIR® SMART App Launch [Implementation Guide], 2.0.0—Standard for Trial Use, November 26, 2021; IBR approved for §170.215(c).

(h) Integrating the Healthcare Enterprise (IHE), 820 Jorie Boulevard, Oak Brook, IL, Telephone (630) 481–1004, *http://www.ihe.net/*.

(1) IHE IT Infrastructure Technical Framework Volume 2b (ITI TF–2b), Transactions Part B—Sections 3.29—2.43, Revision 7.0, August 10, 2010, IBR approved for §170.205(p).

(2) [Reserved]

(i) Internet Engineering Task Force (IETF) Secretariat, c/o Association Management Solutions, LLC (AMS), 48377 Fremont Blvd., Suite 117, Fremont, CA, 94538, Telephone (510) 492–4080, *http://www.ietf.org/rfc.html*.

(1) [Reserved]

(2) Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010, IBR approved for §170.210.

(3) Request for Comment (RFC) 5646, ''Tags for Identifying Languages, September 2009,'' copyright 2009, IBR approved for §170.207(g).

(j) International Telecommunication Union (ITU), Place des Nations, 1211 Geneva 20 Switzerland, Telephone (41) 22 730 511, *http://www.itu.int/en/pages/default.aspx*.

(1) ITU–T E.123, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—General provisions concerning users: Notation for national and international telephone numbers, e-mail addresses and web addresses, February 2001, IBR approved for §170.207(q).

(2) ITU–T E.164, Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors, International operation—Numbering plan of the international telephone service, The international public telecommunication numbering plan, November 2010, IBR approved for §170.207(q).

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E Raintree Drive, Scottsdale, AZ 85260–7518; phone (480) 477–1000; fax: (480) 767–1042: website: *www.ncpdp.org*.

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071,

ANSI-approved July 28, 2017; IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, ANSI-approved January 17, 2023; IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, ANSI-approved May 19, 2022; IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, ANSI-approved April 12, 2023; IBR approved for § 170.205(u).

(l) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, May 30, 2012, IBR approved for § 170.210.

(3) [Reserved]

(4) FIPS PUB 180–4, Secure Hash Standard (August 2015), IBR approved for § 170.210(c).

(m) Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW, Washington, DC 20201; phone: (202) 690–7151; website: *https://healthit.gov*.

(1) Applicability Statement for Secure Health Transport, Version 1.1, July 10, 2012, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338*.

(2) XDR and XDM for Direct Messaging Specification, Version 1, March 9, 2011, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__direct_project/3338*.

(3) Transport and Security Specification, Version 1.0, June 19, 2012, IBR approved for § 170.202.

(4) ONC Implementation Guide for Direct Edge Protocols, Version 1.1, June 25, 2014, IBR approved for § 170.202; available at *http://www.healthit.gov/sites/default/files/implementationguidefordirectedgeprotocolsv1_1.pdf*.

(5) United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata, IBR approved for § 170.213; available at *https://www.healthit.gov/USCDI*.

(6) United States Core Data for Interoperability (USCDI), Version 3 (v3), October 2022 Errata; IBR approved for § 170.213(b).

(n) OpenID Foundation, 2400 Camino Ramon, Suite 375, San Ramon, CA 94583, Telephone +1 925–275–6639, *http://openid.net/*.

(1) OpenID Connect Core 1.0 Incorporating errata set 1, November 8, 2014, IBR approved for § 170.215(b).

(2) [Reserved]

(o) Public Health Data Standards Consortium, 111 South Calvert Street, Suite 2700, Baltimore, MD 21202; phone: (801) 532–2299; website: *www.Ph.D.sc.org/*.

(1) Public Health Data Standards Consortium Source of Payment Typology Code Set Version 5.0 (October 2011), IBR approved for § 170.207(s).

(2) Users Guide for Source of Payment Typology, Version 9.2, December 2020; IBR approved for § 170.207(s).

(p) Regenstrief Institute, Inc., LOINC® c/o Regenstrief Center for Biomedical Informatics, Inc., 410 West 10th Street, Suite 2000, Indianapolis, IN 46202–3012; phone: (317) 274–9000; website: *https://loinc.org/* and *https://ucum.org/ucum*.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released June 2012, IBR approved for § 170.207.

(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, IBR approved for § 170.207(c).

(4) The Unified Code of Units for Measure, Revision 1.9, October 23, 2013, IBR approved for § 170.207.

(5) Logical Observation Identifiers Names and Codes (LOINC®) Database Version 2.72, February 2022; IBR approved for § 170.207(c).

(6) The Unified Code for Units of Measure, Version 2.1, November 21, 2017; IBR approved for §170.207(m).

(q) The Direct Project, c/o the Office of the National Coordinator for Health Information Technology (ONC), 330 C Street SW., Washington, DC 20201, *http://healthit.hhs.gov*.

(1) Applicability Statement for Secure Health Transport, Version 1.2, August 2015, IBR approved for §170.202(a).

(2) Implementation Guide for Delivery Notification in Direct, Version 1.0, June 29, 2012, IBR approved for §170.202(e).

(r) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; phone (301) 594–5983; website: *www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for §170.207.

(2) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012, IBR approved for §170.207.

(3) US Extension to SNOMED CT® March 2012 Release, IBR approved for §170.207.

(4)–(5) [Reserved]

(6) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) U.S. Edition, September 2015 Release, IBR approved for §170.207(a).

(7) RxNorm, September 8, 2015 Full Release Update, IBR approved for §170.207(d).

(8) SNOMED CT® [Systematized Nomenclature of Medicine Clinical Terms] U.S. Edition, March 2022 Release; IBR approved for §170.207(a).

(9) RxNorm, Full Update Release, July 5, 2022; IBR approved for §170.207(d).

(s) World Wide Web Consortium (W3C)/MIT, 32 Vassar Street, Room 32–G515, Cambridge, MA 02139 USA, *http://www.w3.org/standards/*

(1) Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008, IBR approved for §170.204.

(2) [Reserved]

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010; 77 FR 54285, Sept. 4, 2012; 77 FR 72991, Dec. 7, 2012; 79 FR 54478, Sept. 11, 2014; 80 FR 62745, Oct. 16, 2015; 81 FR 72463, Oct. 19, 2016; 85 FR 25941, May 1, 2020; 85 FR 70082, Nov. 4, 2020; 89 FR 1428, Jan. 9, 2024; 89 FR 51265, June 17, 2024]

Subpart C—Certification Criteria for Health Information Technology

SOURCE: 75 FR 44651, July 28, 2010, unless otherwise noted.

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Health IT Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.

(c) Health Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In §170.315, all certification criteria and all capabilities specified within a certification criterion have general applicability (*i.e.*, apply to any health care setting) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

[75 FR 44649, July 28, 2010, as amended at 77 FR 54286, Sept. 4, 2012; 80 FR 62747, Oct. 16, 2015; 85 FR 25941, May 1, 2020; 85 FR 70083, Nov. 4, 2020]

§§ 170.302–170.306 [Reserved]

§ 170.314 [Reserved]

§ 170.315 ONC certification criteria for Health IT.

The Secretary adopts the following certification criteria for health IT. Health IT must be able to electronically perform the following capabilities in accordance with applicable standards and implementation specifications adopted in this part. For all criteria in this section, a health IT developer with a Health IT Module certified to any revised certification criterion, as defined in §170.102, shall update the Health IT Module and shall provide such update

to their customers in accordance with the dates identified for each revised certification criterion and for each applicable standard in 45 CFR part 170 subpart B.

(a) *Clinical*—(1) *Computerized provider order entry—medications.* (i) Enable a user to record, change, and access medication orders.

(ii) *Optional.* Include a ''reason for order'' field.

(2) *Computerized provider order entry—laboratory.* (i) Enable a user to record, change, and access laboratory orders.

(ii) *Optional.* Include a ''reason for order'' field.

(3) *Computerized provider order entry—diagnostic imaging.* (i) Enable a user to record, change, and access diagnostic imaging orders.

(ii) *Optional.* Include a ''reason for order'' field.

(4) *Drug-drug, drug-allergy interaction checks for CPOE*—(i) *Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) *Adjustments.* (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels in at least one of these two ways:

(*1*) To a specific set of identified users.

(*2*) As a system administrative function.

(5) *Patient demographics and observations.* (i) Enable a user to record, change, and access patient demographic and observations data including race, ethnicity, preferred language, sex, sex parameter for clinical use, sexual orientation, gender identity, name to use, pronouns, and date of birth.

(A) *Race and ethnicity.* (*1*) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(3) and whether a patient declines to specify race.

(*2*) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in §170.207(f)(3) and whether a patient declines to specify ethnicity.

(*3*) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(*1*) and (*2*) of this section to the categories in the standard specified in §170.207(f)(1).

(B) *Preferred language.* Enable preferred language to be recorded in accordance with the standard specified in §170.207(g)(2) and whether a patient declines to specify a preferred language.

(C) *Sex.* Enable sex to be recorded in accordance with the standard specified in §170.207(n)(1) for the period up to and including December 31, 2025; or §170.207(n)(2).

(D) *Sexual orientation.* Enable sexual orientation to be recorded in accordance with, at a minimum, the version of the standard specified in §170.207(o)(1) for the period up to and including December 31, 2025; or §170.207(o)(3), as well as whether a patient declines to specify sexual orientation.

(E) *Gender identity.* Enable gender identity to be recorded in accordance with, at a minimum, the version of the standard specified in §170.207(o)(2) for the period up to and including December 31, 2025; or §170.207(o)(3), as well as whether a patient declines to specify gender identity.

(F) *Sex Parameter for Clinical Use.* Enable at least one sex parameter for clinical use to be recorded in accordance with, at a minimum, the version of the standard specified in §170.207(n)(3). Conformance with this paragraph is required by January 1, 2026.

(G) *Name to Use.* Enable at least one preferred name to use to be recorded. Conformance with this paragraph is required by January 1, 2026.

(H) *Pronouns.* Enable at least one pronoun to be recorded in accordance with, at a minimum, the version of the standard specified in §170.207(o)(4). Conformance with this paragraph is required by January 1, 2026.

(ii) *Inpatient setting only.* Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

(6)–(8) [Reserved]

(9) *Clinical decision support (CDS)*—(i) *CDS intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *CDS configuration.* (A) Enable interventions and reference resources specified in paragraphs (a)(9)(iii) and (iv) of this section to be configured by a limited set of identified users (*e.g.*, system administrator) based on a user's role.

(B) Enable interventions:

(*1*) Based on the following data:

(*i*) Problem list;

(*ii*) Medication list;

(*iii*) Allergy and intolerance list;

(*iv*) At least one demographic specified in paragraph (a)(5)(i) of this section;

(*v*) Laboratory tests; and

(*vi*) Vital signs.

(*2*) When a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(iii) *Evidence-based decision support interventions.* Enable a limited set of identified users to select (*i.e.*, activate) electronic CDS interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(*1*)(*i*) through (*vi*) of this section.

(iv) *Linked referential CDS.* (A) Identify for a user diagnostic and therapeutic reference information in accordance at least one of the following standards and implementation specifications:

(*1*) The standard and implementation specifications specified in §170.204(b)(3).

(*2*) The standard and implementation specifications specified in §170.204(b)(4).

(B) For paragraph (a)(9)(iv)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(9)(ii)(B)(*1*)(*i*), (*ii*), and (*iv*) of this section.

(v) *Source attributes.* Enable a user to review the attributes as indicated for all CDS resources:

(A) For evidence-based decision support interventions under paragraph (a)(9)(iii) of this section:

(*1*) Bibliographic citation of the intervention (clinical research/guideline);

(*2*) Developer of the intervention (translation from clinical research/guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential CDS in paragraph (a)(9)(iv) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) *Expiration of criterion.* The adoption of this criterion for purposes of the ONC Health IT Certification Program expires on January 1, 2025.

(10) *Drug-formulary and preferred drug list checks.* The requirements specified in one of the following paragraphs (that is, paragraphs (a)(10)(i) and (a)(10)(ii) of this section) must be met to satisfy this certification criterion:

(i) *Drug formulary checks.* Automatically check whether a drug formulary exists for a given patient and medication.

(ii) *Preferred drug list checks.* Automatically check whether a preferred drug list exists for a given patient and medication.

(11) [Reserved]

(12) *Family health history.* Enable a user to record, change, and access a patient's family health history in accordance with the familial concepts or expressions included in, at a minimum, the version of the standard in §170.207(a)(1).

(13) *Patient-specific education resources.* (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with at least one of the following standards and implementation specifications:

(A) The standard and implementation specifications specified in §170.204(b)(3).

(B) The standard and implementation specifications specified in § 170.204(b)(4).

(ii) *Optional.* Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).

(14) *Implantable device list.* (i) Record Unique Device Identifiers associated with a patient's Implantable Devices.

(ii) Parse the following identifiers from a Unique Device Identifier:

(A) Device Identifier; and

(B) The following identifiers that compose the Production Identifier:

(*1*) The lot or batch within which a device was manufactured;

(*2*) The serial number of a specific device;

(*3*) The expiration date of a specific device;

(*4*) The date a specific device was manufactured; and

(*5*) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

(iii) Obtain and associate with each Unique Device Identifier:

(A) A description of the implantable device referenced by at least one of the following:

(*1*) The ''GMDN PT Name'' attribute associated with the Device Identifier in the Global Unique Device Identification Database.

(*2*) The ''SNOMED CT® Description'' mapped to the attribute referenced in in paragraph (a)(14)(iii)(A)(*1*) of this section.

(B) The following Global Unique Device Identification Database attributes:

(*1*) ''Brand Name'';

(*2*) ''Version or Model'';

(*3*) ''Company Name'';

(*4*) ''What MRI safety information does the labeling contain?''; and

(*5*) ''Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).''

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for the patient;

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section; and

(C) A method to access all Unique Device Identifiers recorded for a patient.

(v) For each Unique Device Identifier recorded for a patient, enable a user to access:

(A) The Unique Device Identifier;

(B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;

(C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section; and

(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

(vi) Enable a user to change the status of a Unique Device Identifier recorded for a patient.

(15) *Social, psychological, and behavioral data.* Enable a user to record, change, and access the following patient social, psychological, and behavioral data:

(i) *Financial resource strain.* Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(p)(1) and whether a patient declines to specify financial resource strain.

(ii) *Education.* Enable education to be recorded in accordance with the standard specified in § 170.207(p)(2) and whether a patient declines to specify education.

(iii) *Stress.* Enable stress to be recorded in accordance with the standard specified in § 170.207(p)(3) and whether a patient declines to specify stress.

(iv) *Depression.* Enable depression to be recorded in accordance with the standard specified in § 170.207(p)(4) and whether a patient declines to specify depression.

(v) *Physical activity.* Enable physical activity to be recorded in accordance with the standard specified in § 170.207(p)(5) and whether a patient declines to specify physical activity.

(vi) *Alcohol use.* Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(p)(6) and whether a patient declines to specify alcohol use.

(vii) *Social connection and isolation.* Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(p)(7) and

whether a patient declines to specify social connection and isolation.

(viii) *Exposure to violence (intimate partner violence)*. Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in §170.207(p)(8) and whether a patient declines to specify exposure to violence (intimate partner violence).

(b) *Care coordination*—(1) *Transitions of care*—(i) *Send and receive via edge protocol*. (A) Send transition of care/referral summaries through a method that conforms to the standard specified in §170.202(d) and that leads to such summaries being processed by a service that has implemented the standard specified in §170.202(a)(2); and

(B) Receive transition of care/referral summaries through a method that conforms to the standard specified in §170.202(d) from a service that has implemented the standard specified in §170.202(a)(2).

(C) *XDM processing*. Receive and make available the contents of a XDM package formatted in accordance with the standard adopted in §170.205(p)(1) when the technology is also being certified using an SMTP-based edge protocol.

(ii) *Validate and display*—(A) *Validate C–CDA conformance—system performance*. Demonstrate the ability to detect valid and invalid transition of care/referral summaries received and formatted in accordance with the standards specified in §170.205(a)(3), (4), and (5) for the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates. This includes the ability to:

(*1*) Parse each of the document types.

(*2*) Detect errors in corresponding ''document-templates,'' ''section-templates,'' and ''entry-templates,'' including invalid vocabulary standards and codes not specified in the standards adopted in §170.205(a)(3), (4), and (5).

(*3*) Identify valid document-templates and process the data elements required in the corresponding section-templates and entry-templates from the standards adopted in §170.205(a)(3), (4), and (5).

(*4*) Correctly interpret empty sections and null combinations.

(*5*) Record errors encountered and allow a user through at least one of the following ways to:

(*i*) Be notified of the errors produced.

(*ii*) Review the errors produced.

(B) *Display*. Display in human readable format the data included in transition of care/referral summaries received and formatted according to the standards specified in §170.205(a)(3), (4), and (5).

(C) *Display section views*. Allow for the individual display of each section (and the accompanying document header information) that is included in a transition of care/referral summary received and formatted in accordance with the standards adopted in §170.205(a)(3), (4), and (5) in a manner that enables the user to:

(*1*) Directly display only the data within a particular section;

(*2*) Set a preference for the display order of specific sections; and

(*3*) Set the initial quantity of sections to be displayed.

(iii) *Create*. Enable a user to create a transition of care/referral summary formatted in accordance with the standard specified in §170.205(a)(3), (4), and (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates that includes, at a minimum:

(A)(*1*) The data classes expressed in the standards in §170.213 and in accordance with §170.205(a)(4), (5), and paragraphs (b)(1)(iii)(A)(*3*)(*i*) through (*iii*) of this section for the time period up to and including December 31, 2025, or

(*2*) The data classes expressed in the standards in §170.213 and in accordance with §170.205(a)(4), (6), and paragraphs (b)(1)(iii)(A)(*3*)(*i*) through (*iii*) of this section, and

(*3*) The following data classes:

(*i*) *Assessment and plan of treatment*. In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in §170.205(a)(4); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in §170.205(a)(4).

(*ii*) *Goals*. In accordance with the ''Goals Section'' of the standard specified in §170.205(a)(4).

(*iii*) *Health concerns.* In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4).

(*iv*) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in § 170.205(a)(4).

(B) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(*1*) The standard specified in § 170.207(i).

(*2*) At a minimum, the version of the standard specified in § 170.207(a)(1).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only.* Discharge instructions.

(G) *Patient matching data.* First name, last name, previous name, middle name (including middle initial), suffix, date of birth, current address, phone number, and sex. The following constraints apply:

(*1*) *Date of birth constraint.* (*i*) The year, month and day of birth must be present for a date of birth. The technology must include a null value when the date of birth is unknown.

(*ii*) *Optional.* When the hour, minute, and second are associated with a date of birth the technology must demonstrate that the correct time zone offset is included.

(*2*) *Phone number constraint.* Represent phone number (home, business, cell) in accordance with the standards adopted in § 170.207(q)(1). All phone numbers must be included when multiple phone numbers are present.

(*3*) *Sex Constraint:* Represent sex with the standard adopted in § 170.207(n)(1) up to and including December 31, 2025; or with the standard adopted in § 170.207(n)(2).

(2) *Clinical information reconciliation and incorporation*—(i) *General requirements.* Paragraphs (b)(2)(ii) and (iii) of this section must be completed based on the receipt of a transition of care/referral summary formatted in accordance with the standards adopted in § 170.205(a)(3) through (5) using the Continuity of Care Document, Referral Note, and (inpatient setting only) Discharge Summary document templates, for time period up to and including December 31, 2025; or in accordance with the standards adopted in § 170.205(a)(3), (4), (6).

(ii) *Correct patient.* Upon receipt of a transition of care/referral summary formatted according to the standards adopted § 170.205(a)(3) through (5) for the period up to and including December 31, 2025; or according to the standards adopted § 170.205(a)(3), (4), and (6), technology must be able to demonstrate that the transition of care/referral summary received can be properly matched to the correct patient.

(iii) *Reconciliation.* Enable a user to reconcile the data that represent a patient's active medication list, allergies and intolerance list, and problem list as follows. For each list type:

(A) Simultaneously display (*i.e.*, in a single view) the data from at least two sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(B) Enable a user to create a single reconciled list of each of the following: Medications; Allergies and Intolerances; and problems.

(C) Enable a user to review and validate the accuracy of a final set of data.

(D) Upon a user's confirmation, automatically update the list, and incorporate the following data expressed according to the specified standards:

(*1*) *Medications.* At a minimum, the version of the standard specified in § 170.213;

(*2*) *Allergies and intolerance.* At a minimum, the version of the standard specified in § 170.213; and

(*3*) *Problems.* At a minimum, the version of the standard specified in § 170.213.

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file formatted according to the standard specified in § 170.205(a)(4) using the Continuity of Care Document template and the standard specified in § 170.205(a)(5) on and after December 31, 2022.

(iv) *System verification.* Based on the data reconciled and incorporated, the technology must be able to create a file

formatted according to the standard specified in §170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(5) of this section for the time period up to and including December 31, 2025; or according to the standard specified in §170.205(a)(4) using the Continuity of Care Document template and the standard specified in paragraph (a)(6) of this section.

(3) *Electronic prescribing.* (i) For technology certified prior to June 30, 2020, subject to the real world testing provisions at §170.405(b)(5),

(A) Enable a user to perform the following prescription-related electronic transactions in accordance with, at a minimum, the version of the standard specified in §170.207(d)(3) as follows:

(*1*) Create new prescriptions (NEWRX).

(*2*) Change prescriptions (RXCHG, CHGRES).

(*3*) Cancel prescriptions (CANRX, CANRES).

(*4*) Refill prescriptions (REFREQ, REFRES).

(*5*) Receive fill status notifications (RXFILL).

(*6*) Request and receive medication history information (RXHREQ, RXHRES).

(B) For each transaction listed in paragraph (b)(3)(i)(A) of this section, the technology must be able to receive and transmit the reason for the prescription using the diagnosis elements in the DRU Segment.

(C) *Optional:* For each transaction listed in paragraph (b)(3)(i)(A) of this section, the technology must be able to receive and transmit the reason for prescription using the indication elements in the SIG Segment.

(D) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.,* not cc).

(E) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(ii) For technology certified subsequent to June 30, 2020:

(A) Enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in §170.205(b)(1) and, at a minimum, the version of the standard specified in §170.207(d)(1) as follows:

(*1*) Create new prescriptions (NewRx).

(*2*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(*3*) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).

(*4*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(*5*) Receive fill status notifications (RxFill).

(*6*) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).

(*7*) Relay acceptance of a transaction back to the sender (Status).

(*8*) Respond that there was a problem with the transaction (Error).

(*9*) Respond that a transaction requesting a return receipt has been received (Verify).

(B) Optionally, enable a user to perform the following prescription-related electronic transactions in accordance with the standard specified in §170.205(b)(1) and, at a minimum, the version of the standard specified in §170.207(d)(3) as follows:

(*1*) Create and respond to new prescriptions (NewRxRequest, NewRxResponseDenied).

(*2*) Send fill status notifications (RxFillIndicatorChange).

(*3*) Ask the Mailbox if there are any transactions (GetMessage).

(*4*) Request to send an additional supply of medication (Resupply).

(*5*) Communicate drug administration events (DrugAdministration).

(*6*) Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse, RxTransferConfirm).

(*7*) Recertify the continued administration of a medication order (Recertification).

(*8*) Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

(*9*) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest,

PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse).

(C) For the following prescription-related transactions, the technology must be able to receive and transmit the reason for prescription using the diagnosis elements: <Diagnosis> <Primary> or <Secondary>:

(*1*) *Required transactions:*

(*i*) Create new prescriptions (NewRx).

(*ii*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(*iii*) Cancel prescriptions (CancelRx).

(*iv*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(*v*) Receive fill status notifications (RxFill).

(*vi*) Receive medication history (RxHistoryResponse).

(*2*) *Optional transactions:*

(*i*) Request to send an additional supply of medication (Resupply)

(*ii*) Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse)

(*iii*) Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

(*iv*) Electronic prior authorization (ePA) transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse).

(D) *Optional:* For each transaction listed in paragraph (b)(3)(ii)(C) of this section, the technology must be able to receive and transmit reason for prescription using the <IndicationforUse> element in the SIG segment.

(E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (*i.e.*, not cc).

(F) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(4)–(5) [Reserved]

(6) *Data export*—(i) *General requirements for export summary configuration.* (A) Enable a user to set the configuration options specified in paragraphs (b)(6)(iii) and (iv) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(B) Limit the ability of users who can create export summaries in at least one of these two ways:

(*1*) To a specific set of identified users.

(*2*) As a system administrative function.

(ii) *Creation.* Enable a user to create export summaries formatted in accordance with the standard specified in §170.205(a)(4) using the Continuity of Care Document document template that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(*1*) The standard specified in §170.207(i).

(*2*) At a minimum, the version of the standard specified in §170.207(a)(1).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only.* Discharge instructions.

(iii) *Timeframe configuration.* (A) Enable a user to set the date and time period within which data would be used to create the export summaries. This must include the ability to enter in a start and end date and time range.

(B) Consistent with the date and time period specified in paragraph (b)(6)(iii)(A) of this section, enable a user to do each of the following:

(*1*) Create export summaries in real-time;

(*2*) Create export summaries based on a relative date and time (*e.g.*, the first of every month at 1:00 a.m.); and

(*3*) Create export summaries based on a specific date and time (*e.g.*, on 10/24/2015 at 1:00 a.m.).

(iv) *Location configuration.* Enable a user to set the storage location to

which the export summary or export summaries are intended to be saved.

(7) *Security tags—summary of care—send.* Enable a user to create a summary record formatted in accordance with the standard adopted in §170.205(a)(4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in §170.205(o)(1) at the:

(i) Document, section, and entry (data element) level; or

(ii) Document level for the period before December 31, 2022.

(8) *Security tags—summary of care—receive.* (i) Enable a user to receive a summary record that is formatted in accordance with the standard adopted in §170.205(a)(4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in §170.205(o)(1) at the:

(A) Document, section, and entry (data element) level; or

(B) Document level for the period before December 31, 2022; and

(ii) Preserve privacy markings to ensure fidelity to the tagging based on consent and with respect to sharing and re-disclosure restrictions.

(9) *Care plan.* Enable a user to record, change, access, create, and receive care plan information in accordance with:

(i) The Care Plan document template, including the Health Status Evaluations and Outcomes Section and Interventions Section (V2), in the standard specified in §170.205(a)(4); and

(ii) The standard in §170.205(a)(5) for the time period up to and including December 31, 2025; or §170.205(a)(6).

(10) *Electronic Health Information export*—(i) *Single patient electronic health information export.* (A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part.

(B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(C) Limit the ability of users who can create export file(s) in at least one of these two ways:

(*1*) To a specific set of identified users

(*2*) As a system administrative function.

(D) The export file(s) created must be electronic and in a computable format.

(E) The publicly accessible hyperlink of the export's format must be included with the exported file(s).

(ii) *Patient population electronic health information export.* Create an export of all the electronic health information that can be stored at the time of certification by the product, of which the Health IT Module is a part.

(A) The export created must be electronic and in a computable format.

(B) The publicly accessible hyperlink of the export's format must be included with the exported file(s).

(iii) *Documentation.* The export format(s) used to support paragraphs (b)(10)(i) and (ii) of this section must be kept up-to-date.

(11) Decision support interventions—

(i) *Decision support intervention interaction.* Interventions provided to a user must occur when a user is interacting with technology.

(ii) *Decision support configuration.* (A) Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role.

(B) Enable interventions when a patient's medications, allergies and intolerance, and problems are incorporated from a transition of care or referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.

(C) Enable a user to provide electronic feedback data for evidence-based decision support interventions selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location.

(iii) *Decision support intervention selection.* Enable a limited set of identified users to select (*i.e.*, activate) electronic decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) that are:

(A) Evidence-based decision support interventions and use any data based on the following data expressed in the standards in §170.213:

(*1*) Problems;
(*2*) Medications;
(*3*) Allergies and Intolerances;
(*4*) At least one demographic specified in paragraph (a)(5)(i) of this section;
(*5*) Laboratory;
(*6*) Vital Signs;
(*7*) Unique Device Identifier(s) for a Patient's Implantable Device(s); and
(*8*) Procedures.
(B) Predictive Decision Support Interventions and use any data expressed in the standards in § 170.213.
(iv) *Source attributes.* Source attributes listed in paragraphs (b)(11)(iv)(A) and (B) of this section must be supported.
(A) For evidence-based decision support interventions:
(*1*) Bibliographic citation of the intervention (clinical research or guideline);
(*2*) Developer of the intervention (translation from clinical research or guideline);
(*3*) Funding source of the technical implementation for the intervention(s) development;
(*4*) Release and, if applicable, revision dates of the intervention or reference source;
(*5*) Use of race as expressed in the standards in § 170.213;
(*6*) Use of ethnicity as expressed in the standards in § 170.213;
(*7*) Use of language as expressed in the standards in § 170.213;
(*8*) Use of sexual orientation as expressed in the standards in § 170.213;
(*9*) Use of gender identity as expressed in the standards in § 170.213;
(*10*) Use of sex as expressed in the standards in § 170.213;
(*11*) Use of date of birth as expressed in the standards in § 170.213;
(*12*) Use of social determinants of health data as expressed in the standards in § 170.213; and
(*13*) Use of health status assessments data as expressed in the standards in § 170.213.
(B) For Predictive Decision Support Interventions:
(*1*) Details and output of the intervention, including:
(*i*) Name and contact information for the intervention developer;
(*ii*) Funding source of the technical implementation for the intervention(s) development;
(*iii*) Description of value that the intervention produces as an output; and
(*iv*) Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.
(*2*) Purpose of the intervention, including:
(*i*) Intended use of the intervention;
(*ii*) Intended patient population(s) for the intervention's use;
(*iii*) Intended user(s); and
(*iv*) Intended decision-making role for which the intervention was designed to be used/for (*e.g.*, informs, augments, replaces clinical management).
(*3*) Cautioned out-of-scope use of the intervention, including:
(*i*) Description of tasks, situations, or populations where a user is cautioned against applying the intervention; and
(*ii*) Known risks, inappropriate settings, inappropriate uses, or known limitations.
(*4*) Intervention development details and input features, including at a minimum:
(*i*) Exclusion and inclusion criteria that influenced the training data set;
(*ii*) Use of variables in paragraphs (b)(11)(iv)(A)(*5*) through (*13*) of this section as input features;
(*iii*) Description of demographic representativeness according to variables in paragraphs (b)(11)(iv)(A)(*5*) through (*13*) of this section including, at a minimum, those used as input features in the intervention;
(*iv*) Description of relevance of training data to intended deployed setting; and
(*5*) Process used to ensure fairness in development of the intervention, including:
(*i*) Description of the approach the intervention developer has taken to ensure that the intervention's output is fair; and
(*ii*) Description of approaches to manage, reduce, or eliminate bias.
(*6*) External validation process, including:
(*i*) Description of the data source, clinical setting, or environment where an intervention's validity and fairness

has been assessed, other than the source of training and testing data

(*ii*) Party that conducted the external testing;

(*iii*) Description of demographic representativeness of external data according to variables in paragraph (b)(11)(iv)(A)(*5*)–(*13*) including, at a minimum, those used as input features in the intervention; and

(*iv*) Description of external validation process.

(*7*) Quantitative measures of performance, including:

(*i*) Validity of intervention in test data derived from the same source as the initial training data;

(*ii*) Fairness of intervention in test data derived from the same source as the initial training data;

(*iii*) Validity of intervention in data external to or from a different source than the initial training data;

(*iv*) Fairness of intervention in data external to or from a different source than the initial training data;

(*v*) References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes;

(*8*) Ongoing maintenance of intervention implementation and use, including:

(*i*) Description of process and frequency by which the intervention's validity is monitored over time;

(*ii*) Validity of intervention in local data;

(*iii*) Description of the process and frequency by which the intervention's fairness is monitored over time;

(*iv*) Fairness of intervention in local data; and

(*9*) Update and continued validation or fairness assessment schedule, including:

(*i*) Description of process and frequency by which the intervention is updated; and

(*ii*) Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.

(v) *Source attribute access and modification*—(A) *Access.* (*1*) For evidence-based decision support interventions and Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attribute information specified in paragraphs (b)(11)(iv)(A) and (B) of this section.

(*2*) For Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must indicate when information is not available for review for source attributes in paragraphs (b)(11)(iv)(B)(*6*); (b)(11)(iv)(B)(*7*)(*iii*), (*iv*), and (*v*); (b)(11)(iv)(B)(*8*)(*ii*) and (*iv*); and (b)(11)(iv)(B)(*9*) of this section.

(B) *Modify.* (*1*) For evidence-based decision support interventions and Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access source attributes in paragraphs (b)(11)(iv)(A) and (B) of this section.

(*2*) For Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access additional source attributes not specified in paragraph (b)(11)(iv)(B) of this section.

(vi) *Intervention risk management.* Intervention risk management practices must be applied for each Predictive Decision Support Intervention supplied by the health IT developer as part of its Health IT Module.

(A) *Risk analysis.* The Predictive Decision Support Intervention(s) must be subject to analysis of potential risks and adverse impacts associated with the following characteristics: validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy.

(B) *Risk mitigation.* The Predictive Decision Support Intervention (s) must be subject to practices to mitigate risks, identified in accordance with paragraph (b)(11)(vi)(A) of this section; and

(C) *Governance.* The Predictive Decision Support Intervention(s) must be subject to policies and implemented controls for governance, including how data are acquired, managed, and used.

(c) *Clinical quality measures*—(1) *Clinical quality measures—record and export*—(i) *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of ''patient reason,'' ''system reason,'' or ''medical reason.''

(ii) *Export.* A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:

(A) Formatted in accordance with the standard specified in §170.205(h)(2);

(B) Ranging from one to multiple patients; and

(C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate*—(i) *Import.* Enable a user to import a data file in accordance with the standard specified in §170.205(h)(2) for one or multiple patients and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(ii) Calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—report.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), category I, for inpatient measures in §170.205(h)(3) and CMS implementation guide for QRDA, category III for ambulatory measures in §170.205 (k)(3); or

(ii) In accordance with the standards specified in §170.205(h)(2) and §170.205(k)(1) and (2) for the period before December 31, 2022.

(4) *Clinical quality measures—filter.* (i) Record the data listed in paragraph (c)(4)(iii) of this section in accordance with the identified standards, where specified.

(ii) Filter CQM results at the patient and aggregate levels by each one and any combination of the data listed in paragraph (c)(4)(iii) of this section and be able to:

(A) Create a data file of the filtered data in accordance with the standards adopted in §170.205(h)(2) and §170.205(k)(1) and (2); and

(B) Display the filtered data results in human readable format.

(iii) *Data.*

(A) Taxpayer Identification Number.

(B) National Provider Identifier.

(C) Provider type in accordance with, at a minimum, the standard specified in §170.207(r)(2).

(D) Practice site address.

(E) Patient insurance in accordance with the standard specified in §170.207(s)(2).

(F) Patient age.

(G) Patient sex in accordance with the version of the standard specified in §170.207(n)(2).

(H) Patient race and ethnicity in accordance with, at a minimum, the version of the standard specified in §170.207(f)(3).

(I) Patient problem list data in accordance with, at a minimum, the version of the standard specified in §170.207(a)(1).

(d) *Privacy and security*—(1) *Authentication, access control, and authorization.* (i) Verify against a unique identifier(s) (*e.g.*, username or number) that a user seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the technology.

(2) *Auditable events and tamper-resistance*—(i) *Record actions.* Technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in §170.210(e)(1);

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in §170.210(e)(2) unless it cannot be disabled by any user; and

(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by technology in accordance with the standard specified in §170.210(e)(3) unless the technology prevents electronic health information from being locally stored on end-user devices (see paragraph (d)(7) of this section).

(ii) *Default setting.* Technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) and (d)(2)(i)(C) of this section.

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that technology permits to be disabled, the ability to do so must be restricted to a limited set of users.

(iv) *Audit log protection.* Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the technology.

(v) *Detection.* Technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards in §170.210(e).

(4) *Amendments.* Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request in at least one of the following ways:

(A) To the affected record.

(B) Include a link that indicates this information's location.

(5) *Automatic access time-out.* (i) Automatically stop user access to health information after a predetermined period of inactivity.

(ii) Require user authentication in order to resume or regain the access that was stopped.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* The requirements specified in one of the following paragraphs (that is, paragraphs (d)(7)(i) and (d)(7)(ii) of this section) must be met to satisfy this certification criterion.

(i) Technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of the technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in §170.210(a)(2).

(B) *Default setting.* Technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) Technology is designed to prevent electronic health information from being locally stored on end-user devices after use of the technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in §170.210(c)(2).

(ii) Verify in accordance with the standard specified in §170.210(c)(2) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Trusted connection.* Establish a trusted connection using one of the following methods:

(i) *Message-level.* Encrypt and integrity protect message contents in accordance with the standards specified in §170.210(a)(2) and (c)(2).

(ii) *Transport-level.* Use a trusted connection in accordance with the standards specified in §170.210(a)(2) and (c)(2).

(10) *Auditing actions on health information.* (i) By default, be set to record actions related to electronic health information in accordance with the standard specified in § 170.210(e)(1).

(ii) If technology permits auditing to be disabled, the ability to do so must be restricted to a limited set of users.

(iii) Actions recorded related to electronic health information must not be capable of being changed, overwritten, or deleted by the technology.

(iv) Technology must be able to detect whether the audit log has been altered.

(11) *Accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(12) *Encrypt authentication credentials.* Health IT developers must make one of the following attestations and may provide the specified accompanying information, where applicable:

(i) Yes—the Health IT Module encrypts stored authentication credentials in accordance with standards adopted in § 170.210(a)(2).

(ii) No—the Health IT Module does not encrypt stored authentication credentials. When attesting ''no,'' the health IT developer may explain why the Health IT Module does not support encrypting stored authentication credentials.

(13) *Multi-factor authentication.* Health IT developers must make one of the following attestations and, as applicable, provide the specified accompanying information:

(i) Yes—the Health IT Module supports the authentication, through multiple elements, of the user's identity with the use of industry-recognized standards. When attesting ''yes,'' the health IT developer must describe the use cases supported.

(ii) No—the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry-recognized standards. When attesting ''no,'' the health IT developer may explain why the Health IT Module does not support authentication, through multiple elements, of the user's identity with the use of industry-recognized standards.

(e) *Patient engagement*—(1) *View, download, and transmit to 3rd party.* (i) Patients (and their authorized representatives) must be able to use internet-based technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Such access must be consistent and in accordance with the standard adopted in § 170.204(a)(1) and may alternatively be demonstrated in accordance with the standard specified in § 170.204(a)(2).

(A) *View.* Patients (and their authorized representatives) must be able to use health IT to view, at a minimum, the following data:

(*1*) The data classes expressed in the standards in § 170.213 (which should be in their English (*i.e.,* non-coded) representation if they associate with a vocabulary/code set), and in accordance with § 170.205(a)(4) and (a)(5), and paragraphs (e)(1)(i)(A)(*3*)(*i*) through (*iii*) of this section for the time period up to and including December 31, 2025, or

(*2*) The data classes expressed in the standards in § 170.213 (which should be in their English (*i.e.,* non-coded) representation if they associate with a vocabulary/code set), and in accordance with § 170.205(a)(4) and (a)(6), and paragraphs (e)(1)(i)(A)(*3*)(*i*) through (*iii*) of this section.

(*3*) The following data classes:

(*i*) *Assessment and plan of treatment.* In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in § 170.205(a)(4); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in § 170.205(a)(4).

(*ii*) *Goals.* In accordance with the ''Goals Section'' of the standard specified in § 170.205(a)(4).

(*iii*) *Health concerns.* In accordance with the ''Health Concerns Section'' of the standard specified in § 170.205(a)(4).

(*iv*) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standards specified in § 170.205(a)(4).

(*4*) Ambulatory setting only. Provider's name and office contact information.

(*5*) Inpatient setting only. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(*6*) Laboratory test report(s). Laboratory test report(s), including:

(*i*) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(1) through (7);

(*ii*) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

(*iii*) The information for corrected reports as specified in 42 CFR 493.1291(k)(2).

(*7*) Diagnostic image report(s).

(B) *Download.* (*1*) Patients (and their authorized representatives) must be able to use technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in the following formats:

(*i*) Human readable format; and

(*ii*) The format specified in accordance with the standard specified in §170.205(a)(4) and (5) for the time period up to and including December 31, 2025, or §170.205(a)(4) and (6), and following the CCD document template.

(*2*) When downloaded according to the standard specified in §170.205(a)(4) through (6) following the CCD document template, the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(*i*) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(*1*), (*2*), (*4*), and (*5*) of this section.

(*ii*) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(*1*), and (*3*) through (*5*) of this section.

(*3*) *Inpatient setting only.* Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion specified in paragraph (b)(1) of this section).

(C) *Transmit to third party.* Patients (and their authorized representatives) must be able to:

(*1*) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(*2*) of this section in accordance with both of the following ways:

(*i*) Email transmission to any email address; and

(*ii*) An encrypted method of electronic transmission.

(*2*) *Inpatient setting only.* Transmit transition of care/referral summaries (as a result of a transition of care/referral as referenced by (e)(1)(i)(B)(*3*)) of this section selected by the patient (or their authorized representative) in both of the ways referenced (e)(1)(i)(C)(*1*)(*i*) and (*ii*) of this section).

(D) *Timeframe selection.* With respect to the data available to view, download, and transmit as referenced paragraphs (e)(1)(i)(A), (B), and (C) of this section, patients (and their authorized representatives) must be able to:

(*1*) Select data associated with a specific date (to be viewed, downloaded, or transmitted); and

(*2*) Select data within an identified date range (to be viewed, downloaded, or transmitted).

(ii) *Activity history log.* (A) When any of the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section are used, the following information must be recorded and made accessible to the patient (or his/her authorized representative):

(*1*) The action(s) (*i.e.*, view, download, transmission) that occurred;

(*2*) The date and time each action occurred in accordance with the standard specified in §170.210(g);

(*3*) The user who took the action; and

(*4*) Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) [Reserved]

(iii) *Request for restrictions.* Patients (and their authorized representatives) must be able to use an internet-based method to request a restriction to be applied for any data expressed in the standards in §170.213. Conformance with this paragraph is required by January 1, 2026.

(2) *Secure messaging.* Enable a user to send messages to, and receive messages from, a patient in a secure manner.

(3) *Patient health information capture.* Enable a user to:

(i) Identify, record, and access information directly and electronically shared by a patient (or authorized representative).

(ii) Reference and link to patient health information documents.

(f) *Public health*—(1) *Transmission to immunization registries.* (i) Create immunization information for electronic transmission in accordance with:

(A) The standard and applicable implementation specifications specified in § 170.205(e)(4).

(B) At a minimum, the version of the standard specified in § 170.207(e)(1) for historical vaccines.

(C) At a minimum, the version of the standard specified in § 170.207(e)(2) for administered vaccines.

(ii) Enable a user to request, access, and display a patient's evaluated immunization history and the immunization forecast from an immunization registry in accordance with the standard at § 170.205(e)(4).

(2) *Transmission to public health agencies—syndromic surveillance.* Create syndrome-based public health surveillance information for electronic transmission in accordance with the standard (and applicable implementation specifications) specified in § 170.205(d)(4).

(3) *Transmission to public health agencies—reportable laboratory tests and values/results.* Create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(1) and (c)(1).

(4) *Transmission to cancer registries.* Create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2).

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(1) and (c)(1).

(5) *Transmission to public health agencies—electronic case reporting.* Enable a user to create a case report for electronic transmission meeting the requirements described in paragraphs (f)(5)(i) of this section for the time period up to and including December 31, 2025; or the requirements described in paragraph (f)(5)(ii) of this section.

(i) *Functional electronic case reporting.* A Health IT Module must enable a user to create a case report for electronic transmission in accordance with the following:

(A) Consume and maintain a table of trigger codes to determine which encounters may be reportable.

(B) Match a patient visit or encounter to the trigger code based on the parameters of the trigger code table.

(C) *Case report creation.* Create a case report for electronic transmission:

(*1*) Based on a matched trigger from paragraph (f)(5)(i)(B).

(*2*) That includes, at a minimum:

(*i*) The data classes expressed in the standards in § 170.213.

(*ii*) Encounter diagnoses formatted according to at least one of the standards specified in § 170.207(i) or § 170.207(a)(1).

(*iii*) The provider's name, office contact information, and reason for visit.

(*iv*) An identifier representing the row and version of the trigger table that triggered the case report.

(ii) *Standards-based electronic case reporting.* A Health IT Module must enable a user to create a case report for electronic transmission in accordance with the following:

(A) Consume and process case reporting trigger codes and identify a reportable patient visit or encounter based on a match from the Reportable Conditions Trigger Code value set in § 170.205(t)(4).

(B) Create a case report consistent with at least one of the following standards:

(*1*) The eICR profile of the HL7 FHIR eCR IG in § 170.205(t)(1); or

(*2*) The HL7 CDA eICR IG in § 170.205(t)(2).

(C) Receive, consume, and process a case report response that is formatted

to either the reportability response profile of the HL7 FHIR eCR IG in §170.205(t)(1) or the HL7 CDA RR IG in §170.205(t)(3) as determined by the standard used in (f)(5)(ii)(B) of this section.

(D) Transmit a case report electronically to a system capable of receiving a case report.

(6) *Transmission to public health agencies—antimicrobial use and resistance reporting.* Create antimicrobial use and resistance reporting information for electronic transmission in accordance with the standard specified in §170.205(r)(1).

(7) *Transmission to public health agencies—health care surveys.* Create health care survey information for electronic transmission in accordance with the standard specified in §170.205(s)(1).

(g) *Design and performance*—(1) *Automated numerator recording.* For each Promoting Interoperability Programs percentage-based measure, technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation.* For each Promoting Interoperability Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.

(3) *Safety-enhanced design.* (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (5), (9) (until the criterion's expiration date), and (14) and (b)(2), (3), and (11) of this section.

(ii) *Number of test participants.* A minimum of 10 test participants must be used for the testing of each capability identified in paragraph (g)(3)(i) of this section.

(iii) One of the following must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard.

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

(iv) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and product version; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: Sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) The specific metrics captured during the testing of each user task performed in (g)(3)(iv)(C) of this section, which must include: Task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy) or an alternative acceptable user satisfaction measure;

(E) Test results for each task using the metrics identified above in paragraph (g)(3)(iv)(D) of this section; and

(F) Results and data analysis narrative, including: Major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(v) Submit test scenarios used in summative usability testing.

(4) *Quality management system.* (i) For each capability that a technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in

the development, testing, implementation, and maintenance of that capability must be identified that satisfies one of the following ways:

(A) The QMS used is established by the Federal government or a standards developing organization.

(B) The QMS used is mapped to one or more QMS established by the Federal government or standards developing organization(s).

(ii) When a single QMS was used for applicable capabilities, it would only need to be identified once.

(iii) When different QMS were applied to specific capabilities, each QMS applied would need to be identified.

(5) *Accessibility-centered design.* For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) When a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) When different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) When no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

(6) *Consolidated CDA creation performance.* The following technical and performance outcomes must be demonstrated related to Consolidated CDA creation. The capabilities required under paragraphs (g)(6)(i) through (v) of this section can be demonstrated in tandem and do not need to be individually addressed in isolation or sequentially.

(i) This certification criterion's scope includes:

(A) The data classes expressed in the standards in §170.213 in accordance with §170.205(a)(4) and (a)(5) and paragraphs (g)(6)(i)(C)(*1*) through (*4*) of this section for the time period up to and including December 31, 2025; or

(B) The data classes expressed in the standards in §170.213, and in accordance with §170.205(a)(4) and (6) and paragraphs (g)(6)(i)(C)(*1*) through (*3*) of this section.

(C) The following data classes:

(*1*) *Assessment and plan of treatment.* In accordance with the ''Assessment and Plan Section (V2)'' of the standard specified in §170.205(a)(4); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standard specified in §170.205(a)(4).

(*2*) *Goals.* In accordance with the ''Goals Section'' of the standard specified in §170.205(a)(4).

(*3*) *Health concerns.* In accordance with the ''Health Concerns Section'' of the standard specified in §170.205(a)(4).

(*4*) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standard specified in §170.205(a)(4).

(ii) *Reference C–CDA match.* (A) For health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) and (5) that matches a gold-standard, reference data file.

(B) For health IT certified to (g)(6)(i)(B) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that matches a gold-standard, reference data file.

(iii) *Document-template conformance.* (A) For health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) and (5) that demonstrates a valid implementation of each document template applicable to the certification criterion or criteria within the scope of the certificate sought.

(B) For health IT certified to (g)(6)(i)(B) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that demonstrates a valid implementation of each document template applicable

to the certification criterion or criteria within the scope of the certificate sought.

(iv) *Vocabulary conformance.* (A) For health IT certified to (g)(6)(i)(A) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) and (5) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(B) For health IT certified to (g)(6)(i)(B) of this section, create a data file formatted in accordance with the standard adopted in §170.205(a)(4) that demonstrates the required vocabulary standards (and value sets) are properly implemented.

(v) *Completeness verification.* Create a data file for each of the applicable document templates referenced in paragraph (g)(6)(iii) of this section without the omission of any of the data included in either paragraph (g)(6)(i)(A) or (B) of this section, as applicable.

(7) *Application access—patient selection.* The following technical outcome and conditions must be met through the demonstration of an application programming interface (API).

(i) *Functional requirement.* The technology must be able to receive a request with sufficient information to uniquely identify a patient and return an ID or other token that can be used by an application to subsequently execute requests for that patient's data.

(ii) *Documentation.* (A) The API must include accompanying documentation that contains, at a minimum:

(*1*) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(*2*) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(B) The documentation used to meet paragraph (g)(7)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(8) *Application access—data category request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A) Respond to requests for patient data (based on an ID or other token) for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in a computable format.

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation*—(A) The API must include accompanying documentation that contains, at a minimum:

(*1*) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(*2*) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(B) The documentation used to meet paragraph (g)(8)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(9) *Application access—all data request.* The following technical outcome and conditions must be met through the demonstration of an application programming interface.

(i) *Functional requirements.* (A)(*1*) Respond to requests for patient data (based on an ID or other token) for all of the data classes expressed in the standards in §170.213 at one time and return such data (according to the specified standards, where applicable) in a summary record formatted in accordance with §170.205(a)(4) and (5) following the CCD document template, and as specified in paragraphs (g)(9)(i)(A)(*3*)(*i*) through (*iv*) of this section for the time period up to and including December 31, 2025; or

(*2*) Respond to requests for patient data (based on an ID or other token) for all of the data classes expressed in the standards in §170.213 at one time and return such data (according to the specified standards, where applicable)

in a summary record formatted in accordance with §170.205(a)(4) and (6) following the CCD document template, and as specified in paragraphs (g)(9)(i)(A)(*3*)(*i*) through (*iv*) of this section.

(*3*) The following data classes:

(*i*) *Assessment and plan of treatment.* In accordance with the ''Assessment and Plan Section (V2)'' of the standards specified in §170.205(a)(4); or in accordance with the ''Assessment Section (V2)'' and ''Plan of Treatment Section (V2)'' of the standards specified in §170.205(a)(4).

(*ii*) *Goals.* In accordance with the ''Goals Section'' of the standards specified in §170.205(a)(4).

(*iii*) *Health concerns.* In accordance with the ''Health Concerns Section'' of the standards specified in §170.205(a)(4).

(*iv*) *Unique device identifier(s) for a patient's implantable device(s).* In accordance with the ''Product Instance'' in the ''Procedure Activity Procedure Section'' of the standards specified in §170.205(a)(4).

(B) Respond to requests for patient data associated with a specific date as well as requests for patient data within a specified date range.

(ii) *Documentation*—(A) The API must include accompanying documentation that contains, at a minimum:

(*1*) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(*2*) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(B) The documentation used to meet paragraph (g)(9)(ii)(A) of this section must be available via a publicly accessible hyperlink.

(10) *Standardized API for patient and population services.* The following technical outcomes and conditions must be met through the demonstration of application programming interface technology.

(i) *Data response.* (A) Respond to requests for a single patient's data according to the standards and implementation specifications adopted in §170.215(a) and in §170.215(b)(1), including the mandatory capabilities described in ''US Core Server CapabilityStatement,'' for each of the data included in the standards adopted in §170.213. All data elements indicated as ''mandatory'' and ''must support'' by the standards and implementation specifications must be supported.

(B) Respond to requests for multiple patients' data as a group according to the standards and implementation specifications adopted in §170.215(a), (b)(1), and (d), for each of the data included in the standards adopted in §170.213. All data elements indicated as ''mandatory'' and ''must support'' by the standards and implementation specifications must be supported.

(ii) *Supported search operations.* (A) Respond to search requests for a single patient's data consistent with the search criteria included in the implementation specifications adopted in §170.215(b)(1), specifically the mandatory capabilities described in ''US Core Server CapabilityStatement.''

(B) Respond to search requests for multiple patients' data consistent with the search criteria included in the implementation specification adopted in §170.215(d).

(iii) *Application registration.* Enable an application to register with the Health IT Module's ''authorization server.''

(iv) *Secure connection.* (A) Establish a secure and trusted connection with an application that requests data for patient and user scopes in accordance with the implementation specifications adopted in §170.215(b)(1) and (c).

(B) Establish a secure and trusted connection with an application that requests data for system scopes in accordance with the implementation specification adopted in §170.215(d).

(v) *Authentication and authorization*—(A) *Authentication and authorization for patient and user scopes*—(*1*) *First time connections.* (*i*) Authentication and authorization must occur during the process of granting access to patient data in accordance with the implementation specification adopted in §170.215(c) and standard adopted in §170.215(e).

(*ii*) A Health IT Module's authorization server must issue a refresh token

valid for a period of no less than three months to applications using the ''confidential app'' profile according to an implementation specification adopted in §170.215(c).

(*iii*) A Health IT Module's authorization server must issue a refresh token for a period of no less than three months to native applications capable of securing a refresh token

(*2*) *Subsequent connections.* (*i*) Access must be granted to patient data in accordance with the implementation specification adopted in §170.215(c) without requiring re-authorization and re-authentication when a valid refresh token is supplied by the application.

(*ii*) A Health IT Module's authorization server must issue a refresh token valid for a new period of no less than three months to applications using the ''confidential app'' profile according to an implementation specification adopted in §170.215(c).

(B) Authentication and authorization for system scopes. Authentication and authorization must occur during the process of granting an application access to patient data in accordance with the ''SMART Backend Services: Authorization Guide'' section of the implementation specification adopted in §170.215(d) and the application must be issued a valid access token.

(vi) *Patient authorization revocation.* A Health IT Module's authorization server must be able to revoke and must revoke an authorized application's access at a patient's direction within 1 hour of the request.

(vii) *Token introspection.* A Health IT Module's authorization server must be able to receive and validate tokens it has issued in accordance with an implementation specification in §170.215(c).

(viii) *Documentation.* (A) The API(s) must include complete accompanying documentation that contains, at a minimum:

(*1*) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(*2*) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(*3*) All applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server.

(B) The documentation used to meet paragraph (g)(10)(viii)(A) of this section must be available via a publicly accessible hyperlink without any preconditions or additional steps.

(h) *Transport methods and other protocols*—(1) *Direct Project*—(i) *Applicability Statement for Secure Health Transport.* Able to send and receive health information in accordance with the standard specified in §170.202(a)(2), including formatted only as a ''wrapped'' message.

(ii) *Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

(2) *Direct Project, Edge Protocol, and XDR/XDM.* (i) Able to send and receive health information in accordance with:

(A) The standard specified in §170.202(a)(2), including formatted only as a ''wrapped'' message;

(B) The standard specified in §170.202(b), including support for both limited and full XDS metadata profiles; and

(C) Both edge protocol methods specified by the standard in §170.202(d).

(ii) *Delivery Notification in Direct.* Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

[80 FR 62747, Oct. 16, 2015, as amended at 80 FR 76871, Dec. 11, 2015; 85 FR 25941, May 1, 2020; 85 FR 47099, Aug. 4, 2020; 85 FR 70083, Nov. 4, 2020; 85 FR 78236, Dec. 4, 2020; 89 FR 1429, Jan. 9, 2024; 89 FR 8548, Feb. 8, 2024; 89 FR 16470, Mar. 7, 2024]

Subpart D—Conditions and Maintenance of Certification Requirements for Health IT Developers

SOURCE: 85 FR 25945, May 1, 2020, unless otherwise noted.

§ 170.400 Basis and scope.

This subpart implements section 3001(c)(5)(D) of the Public Health Service Act by setting forth certain Conditions and Maintenance of Certification requirements for health IT developers participating in the ONC Health IT Certification Program.

§ 170.401 Information blocking.

(a) *Condition of Certification requirement.* A health IT developer must not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103 on or after April 5, 2021.

(b) [Reserved]

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020]

§ 170.402 Assurances.

(a) *Condition of Certification requirement.* (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj–52 and § 171.103 of this chapter on and after April 5, 2021, unless for legitimate purposes as specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information.

(2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria.

(3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the full scope of the technology's certification.

(4) A health IT developer of a certified Health IT Module that is part of a health IT product which electronically stores EHI must certify to the certification criterion in § 170.315(b)(10).

(5) A health IT developer must not inhibit its customer's timely access to interoperable health IT certified under the Program.

(b) *Maintenance of Certification requirements.* (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for:

(i) A period of 10 years beginning from the date a developer's Health IT Module(s) is first certified under the Program; or

(ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations.

(2)(i) By December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

(ii) On and after December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in § 170.315(b)(10).

(3)(i) *Update.* A health IT developer must update a Health IT Module, once certified to a certification criterion adopted in § 170.315, to all applicable revised certification criteria, including the most recently adopted capabilities and standards included in the revised certification criterion.

(ii) *Provide.* A health IT developer must provide all Health IT Modules certified to a revised certification criterion, including the most recently adopted capabilities and standards included in the revised certification criterion, to its customers of such certified health IT.

(iii) *Timeliness.* A health IT developer must complete the actions specified in paragraphs (b)(3)(i) and (ii) of this section:

(A) Consistent with the timeframes specified in part 170; or

(B) If the developer obtains new customers of health IT certified to the revised criterion after the effective date of the final rule adopting the revised criterion or criteria, then the health IT developer must provide the health IT certified to the revised criterion to such customers within whichever of the following timeframes that expires last:

(*1*) The timeframe provided in paragraph (b)(3)(iii)(A) of this section; or

(*2*) No later than 12 months after the purchasing or licensing relationship has been established between the health IT developer and the new customer for the health IT certified to the revised criterion.

(4) For developers of Health IT Modules certified to §170.315(b)(11), starting January 1, 2025, and on an ongoing basis thereafter, review and update as necessary source attribute information in §170.315(b)(11)(iv)(A) and (B), intervention risk management practices described in §170.315(b)(11)(vi), and summary information provided through §170.523(f)(1)(xxi).

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020; 85 FR 70084, Nov. 4, 2020; 89 FR 1433, Jan. 9, 2024]

§ 170.403 Communications.

(a) *Condition of Certification requirements.* (1) A health IT developer may not prohibit or restrict any communication regarding—

(i) The usability of its health IT;

(ii) The interoperability of its health IT;

(iii) The security of its health IT;

(iv) Relevant information regarding users' experiences when using its health IT;

(v) The business practices of developers of health IT related to exchanging electronic health information; and

(vi) The manner in which a user of the health IT has used such technology.

(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.

(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes:

(A) Making a disclosure required by law;

(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;

(C) Communicating information about cybersecurity threats and incidents to government agencies;

(D) Communicating information about information blocking and other unlawful practices to government agencies; or

(E) Communicating information about a health IT developer's failure to comply with a Condition of Certification requirement, or with any other requirement of this part, to ONC or an ONC–ACB.

(ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (E) of this section.

(A) *Developer employees and contractors.* (*1*) A health IT developer may prohibit or restrict the communications of the developer's employees or contractors.

(*2*) A self-developer must not prohibit or restrict communications of users of their health IT who are also employees or contractors.

(B) *Non-user-facing aspects of health IT.* A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT.

(C) *Intellectual property.* A health IT developer may prohibit or restrict communications that involve the use or disclosure of intellectual property existing in the developer's health IT (including third-party intellectual property), provided that any prohibition or restriction imposed by a developer must be no broader than necessary to protect the developer's legitimate intellectual property interests

and consistent with all other requirements of paragraph (a)(2)(ii) of this section. A restriction or prohibition is deemed broader than necessary and inconsistent with the requirements of paragraph (a)(2)(ii) of this section if it would restrict or preclude a public display of a portion of a work subject to copyright protection (without regard to whether the copyright is registered) that would reasonably constitute a ''fair use'' of that work.

(D) *Screenshots and video.* A health IT developer may require persons who communicate screenshots or video to—

(*1*) Not alter the screenshots or video, except to annotate the screenshots or video or resize the screenshots or video;

(*2*) Limit the sharing of screenshots to the relevant number of screenshots needed to communicate about the health IT regarding one or more of the six subject areas in paragraph (a)(1) of this section; and

(*3*) Limit the sharing of video to:

(*i*) The relevant amount of video needed to communicate about the health IT regarding one or more of the six subject areas in paragraph (a)(1) of this section; and

(*ii*) Only videos that address temporal matters that cannot be communicated through screenshots or other forms of communication.

(E) *Pre-market testing and development.* A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section.

(b) *Maintenance of Certification requirements*—(1) *Notice.* Health IT developers must issue a written notice to all customers and those with which it has contracts or agreements containing provisions that contravene paragraph (a) of this section annually, beginning in calendar year 2021, until paragraph (b)(2)(ii) of this section is fulfilled, stating that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.

(2) *Contracts and agreements.* (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.

(ii) If a health IT developer has a contract or agreement in existence as of June 30, 2020, that contravenes paragraph (a) of this section, then the developer must amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section whenever the contract is next modified for other reasons or renewed.

(c) *Communication, defined.* ''Communication'' as used in this section means any communication, irrespective of the form or medium. The term includes visual communications, such as screenshots and video.

[85 FR 25945, May 1, 2020, as amended at 85 FR 43711, July 20, 2020; 85 FR 70084, Nov. 4, 2020]

§ 170.404 Application programming interfaces.

The following Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (10).

(a) *Condition of certification requirements*—(1) *General.* A Certified API Developer must publish APIs and allow electronic health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.

(2) *Transparency conditions*—(i) *Complete business and technical documentation.* A Certified API Developer must publish complete business and technical documentation, including the

documentation described in paragraph (a)(2)(ii) of this section, via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(ii) *Terms and conditions*—(A) *Material information.* A Certified API Developer must publish all terms and conditions for its certified API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be:

(*1*) Needed to develop software applications to interact with the certified API technology;

(*2*) Needed to distribute, deploy, and enable the use of software applications in production environments that use the certified API technology;

(*3*) Needed to use software applications, including to access, exchange, and use electronic health information by means of the certified API technology;

(*4*) Needed to use any electronic health information obtained by means of the certified API technology;

(*5*) Used to verify the authenticity of API Users; and

(*6*) Used to register software applications.

(B) *API fees.* Any and all fees charged by a Certified API Developer for the use of its certified API technology must be described in detailed, plain language. The description of the fees must include all material information, including but not limited to:

(*1*) The persons or classes of persons to whom the fee applies;

(*2*) The circumstances in which the fee applies; and

(*3*) The amount of the fee, which for variable fees must include the specific variable(s) and methodology(ies) that will be used to calculate the fee.

(3) *Fees conditions*—(i) *General conditions*—(A) *All fees.* All fees related to certified API technology not otherwise permitted by this section are prohibited from being imposed by a Certified API Developer. The permitted fees in paragraphs (a)(3)(ii) and (iv) of this section may include fees that result in a reasonable profit margin in accordance with §171.302.

(B) *Permitted fees requirements.* For all permitted fees, a Certified API Developer must:

(*1*) Ensure that such fees are based on objective and verifiable criteria that are uniformly applied to all similarly situated API Information Sources and API Users;

(*2*) Ensure that such fees imposed on API Information Sources are reasonably related to the Certified API Developer's costs to supply certified API technology to, and if applicable, support certified API technology for, API Information Sources;

(*3*) Ensure that such fees to supply and, if applicable, support certified API technology are reasonably allocated among all similarly situated API Information Sources; and

(*4*) Ensure that such fees are not based on whether API Information Sources or API Users are competitors, potential competitors, or will be using the certified API technology in a way that facilitates competition with the Certified API Developer.

(C) *Prohibited fees.* A Certified API Developer is prohibited from charging fees for the following:

(*1*) Costs associated with intangible assets other than actual development or acquisition costs of such assets;

(*2*) Opportunity costs unrelated to the access, exchange, or use of electronic health information; and

(*3*) The permitted fees in this section cannot include any costs that led to the creation of intellectual property if the actor charged a royalty for that intellectual property pursuant to §171.303 and that royalty included the development costs for the creation of the intellectual property.

(D) *Record-keeping requirements.* A Certified API Developer must keep for inspection detailed records of any fees charged with respect to the certified API technology, the methodology(ies) used to calculate such fees, and the specific costs to which such fees are attributed.

(ii) *Permitted fee—development, deployment, and upgrades.* A Certified API Developer is permitted to charge fees to an API Information Source to recover the costs reasonably incurred by the

Certified API Developer to develop, deploy, and upgrade certified API technology.

(iii) *Permitted fee—recovering API usage costs.* A Certified API Developer is permitted to charge fees to an API Information Source related to the use of certified API technology. The fees must be limited to the recovery of incremental costs reasonably incurred by the Certified API Developer when it hosts certified API technology on behalf of the API Information Source.

(iv) *Permitted fee—value-added services.* A Certified API Developer is permitted to charge fees to an API User for value-added services related to certified API technology, so long as such services are not necessary to efficiently and effectively develop and deploy production-ready software that interacts with certified API technology.

(4) *Openness and pro-competitive conditions; general condition.* A Certified API Developer must grant an API Information Source the independent ability to permit an API User to interact with the certified API technology deployed by the API Information Source.

(*i*) *Non-discrimination.* (A) A Certified API Developer must provide certified API technology to an API Information Source on terms that are no less favorable than it provides to itself and its own customers, suppliers, partners, and other persons with whom it has a business relationship.

(B) The terms on which a Certified API Developer provides certified API technology must be based on objective and verifiable criteria that are uniformly applied to all substantially similar or similarly situated classes of persons and requests.

(C) A Certified API Developer must not offer different terms or services based on:

(*1*) Whether a competitive relationship exists or would be created;

(*2*) The revenue or other value that another party may receive from using the API technology.

(ii) *Rights to access and use certified API technology*—(A) *Rights that must be granted.* A Certified API Developer must have and, upon request, must grant to API Information Sources and API Users all rights that may be reasonably necessary to:

(*1*) Access and use the Certified API Developer's certified API technology in a production environment;

(*2*) Develop products and services that are designed to interact with the Certified API Developer's certified API technology; and

(*3*) Market, offer, and distribute products and services associated with the Certified API Developer's certified API technology.

(B) *Prohibited conduct.* A Certified API Developer is prohibited from conditioning the receipt of the rights described in paragraph (a)(4)(ii)(A) of this section on:

(*1*) Receiving a fee, including but not limited to a license fee, royalty, or revenue-sharing arrangement;

(*2*) Agreeing to not compete with the Certified API Developer in any product, service, or market;

(*3*) Agreeing to deal exclusively with the Certified API Developer in any product, service, or market;

(*4*) Obtaining additional licenses, products, or services that are not related to or can be unbundled from the certified API technology;

(*5*) Licensing, granting, assigning, or transferring any intellectual property to the Certified API Developer;

(*6*) Meeting any Certified API Developer-specific testing or certification requirements; and.

(*7*) Providing the Certified API Developer or its technology with reciprocal access to application data.

(iii) *Service and support obligations.* A Certified API Developer must provide all support and other services reasonably necessary to enable the effective development, deployment, and use of certified API technology by API Information Sources and API Users in production environments.

(A) *Changes and updates to* certified *API technology.* A Certified API Developer must make reasonable efforts to maintain the compatibility of its certified API technology and to otherwise avoid disrupting the use of certified API technology in production environments.

(B) *Changes to terms and conditions.* Except as exigent circumstances require, prior to making changes to its

certified API technology or to the terms and conditions thereof, a Certified API Developer must provide notice and a reasonable opportunity for API Information Sources and API Users to update their applications to preserve compatibility with certified API technology and to comply with applicable terms and conditions.

(b) *Maintenance of certification requirements*—(1) *Authenticity verification and registration for production use.* The following apply to a Certified API Developer with a Health IT Module certified to the certification criterion adopted in §170.315(g)(10):

(i) *Authenticity verification.* A Certified API Developer is permitted to institute a process to verify the authenticity of API Users so long as such process is objective and the same for all API Users and completed within ten business days of receipt of an API User's request to register their software application for use with the Certified API Developer's Health IT Module certified to §170.315(g)(10).

(ii) *Registration for production use.* A Certified API Developer must register and enable all applications for production use within five business days of completing its verification of an API User's authenticity, pursuant to paragraph (b)(1)(i) of this section.

(2) *Service base URL publication.* For all Health IT Modules certified to §170.315(g)(10), a Certified API Developer must publish, at no charge, the service base URLs and related organization details that can be used by patients to access their electronic health information, by December 31, 2024. This includes all customers regardless of whether the Health IT Modules certified to §170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source. These service base URLs and organization details must conform to the following:

(i) Service base URLs must be publicly published in Endpoint resource format according to the standard adopted in §170.215(a).

(ii) Organization details for each service base URL must be publicly published in Organization resource format according to the standard adopted in §170.215(a). Each Organization resource must contain:

(A) A reference, in the Organization.endpoint element, to the Endpoint resources containing service base URLs managed by this organization.

(B) The organization's name, location, and facility identifier.

(iii) Endpoint and Organization resources must be:

(A) Collected into a Bundle resource formatted according to the standard adopted in §170.215(a) for publication; and

(B) Reviewed quarterly and, as necessary, updated.

(3) *Rollout of (g)(10)-certified APIs.* A Certified API Developer with certified API technology previously certified to the certification criterion in §170.315(g)(8) must provide all API Information Sources with such certified API technology deployed with certified API technology certified to the certification criterion in §170.315(g)(10) by no later than December 31, 2022.

(4) *Compliance for existing certified API technology.* By no later than April 5, 2021, a Certified API Developer with Health IT Module(s) certified to the certification criteria in §170.315(g)(7), (8), or (9) must comply with paragraph (a) of this section, including revisions to their existing business and technical API documentation and make such documentation available via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(c) *Definitions.* The following definitions apply to this section:

API Information Source means an organization that deploys certified API technology created by a ''Certified API Developer;''

API User means a person or entity that creates or uses software applications that interact with the ''certified API technology'' developed by a ''Certified API Developer'' and deployed by an ''API Information Source;''

Certified API Developer means a health IT developer that creates the ''certified API technology'' that is certified to any of the certification criteria adopted in §170.315(g)(7) through (10); and

Certified API technology means the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria adopted in §170.315(g)(7) through (10).

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020; 89 FR 1433, Jan. 9, 2024]

§ 170.405 Real world testing.

(a) *Condition of Certification requirement.* A health IT developer with one or more Health IT Module(s) certified to any one or more of the ONC Certification Criteria for Health IT in §170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h) must successfully test the real world use of those Health IT Module(s) for interoperability (as defined in 42 U.S.C. 300jj(9) and §170.102) in the type of setting in which such Health IT Module(s) would be/is marketed.

(b) *Maintenance of Certification requirements*—(1) *Real world testing plan submission.* A health IT developer with Health IT Module(s) certified to any one or more of the criteria referenced in paragraph (a) of this section must submit to its ONC–ACB an annual real world testing plan addressing each of those certified Health IT Modules by a date determined by the ONC–ACB that enables the ONC–ACB to publish a publicly available hyperlink to the plan on CHPL no later than December 15 of each calendar year, beginning in 2021.

(i) The plan must be approved by a health IT developer authorized representative capable of binding the health IT developer for execution of the plan and include the representative's contact information.

(ii) The plan must include all health IT certified to any one or more of the criteria referenced in paragraph (a) of this section as of August 31 of the year in which the plan is submitted, and address the real world testing to be conducted in the calendar year immediately following plan submission.

(iii) The plan must address the following for each of the certification criteria identified in paragraph (a) of this section that are included in each Health IT Module's scope of certification:

(A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the full scope of the certification criterion's requirements, including scenario- and use case-focused testing;

(B) The care setting(s) that will be tested for real world interoperability and an explanation for the health IT developer's choice of care setting(s) to test;

(C) For any standards and implementation specifications referenced by the criterion that the developer has chosen to certify to National Coordinator-approved newer versions pursuant to paragraph (b)(8) or (9) of this section, a description of how the developer will test and demonstrate conformance to all requirements of the criterion using all versions of the adopted standards to which each Health IT Module was certified as of August 31 of the year in which the real world testing plan is due.

(D) A schedule of key real world testing milestones;

(E) A description of the expected outcomes of real world testing;

(F) At least one measurement/metric associated with the real world testing; and

(G) A justification for the health IT developer's real world testing approach.

(2) *Real world testing results reporting.* (i) If in the course of conducting real world testing the developer discovers one or more non-conformities with the full scope of any certification criterion under the Program, the developer must report that non-conformity to the ONC–ACB within 30 days.

(ii) For real world testing activities conducted during the immediately preceding calendar year, a health IT developer must submit to its ONC–ACB an annual real world testing results report addressing each of its certified Health IT Modules that include certification criteria referenced in paragraph (a) of this section by a date determined by the ONC–ACB that enables the ONC–ACB to publish a publicly available hyperlink to the results report on CHPL no later than March 15 of each calendar year, beginning in 2023. For certified Health IT Modules included in paragraph (a) of this section that are updated using Inherited Certified Status after August 31 of the year in which

the plan is submitted, a health IT developer must include the newer version of the certified Health IT Module(s) in its annual real world testing results report. The real world testing results must report the following for each of the certification criteria identified in paragraph (a) of this section that are included in the Health IT Module's scope of certification:

(A) The method(s) that was used to demonstrate real world interoperability;

(B) The care setting(s) that was tested for real world interoperability;

(C) The voluntary updates to standards and implementation specifications that the National Coordinator has approved through the Standards Version Advancement Process;

(D) A list of the key milestones met during real world testing;

(E) The outcomes of real world testing including a description of any challenges encountered during real world testing; and

(F) At least one measurement/metric associated with the real world testing.

(3)–(7) [Reserved]

(8) *Standards Version Advancement Process—voluntary updates of certified health IT to newer versions of standards and implementation specifications.* A health IT developer subject to this paragraph (b) is permitted to update Health IT Module(s) certified to any one or more of the certification criteria referenced in paragraph (a) of this section to a newer version of any adopted standard or implementation specification included in the criterion, provided that newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. A developer that pursues such updates to its certified Health IT Module(s) must:

(i) Provide advance notice to all affected customers and its ONC–ACB—

(A) Expressing its intent to update the certified Health IT Module(s) to the National Coordinator-approved advanced version of the standard implementation specification;

(B) The developer's expectations for how the update(s) will affect real world interoperability for the Health IT Module(s);

(C) Whether the developer intends to continue to support the certificate(s) for the existing certified Health IT Module(s) version(s) for some period of time and how long or if the existing certified Health IT Module(s) version(s) will be deprecated; and

(ii) Successfully demonstrate conformance with approved more recent versions of the standard(s) or implementation specification(s) included in each certification criterion under which the developer chooses to update its certified Health IT Module(s).

(iii) Maintain the updated certified Health IT Module(s) in full conformance with all applicable Program requirements.

(9) *Standards Version Advancement Process—voluntary certification to newer versions of standards and implementation specifications.* A Health IT developer is permitted to seek certification for its Health IT Module(s) to any one or more of the certification criteria referenced in paragraph (a) of this section using a newer version of any adopted standard(s) or implementation specification(s) included in the criterion without first obtaining certification to the version of that adopted standard or implementation specification that is incorporated by reference in §170.299, provided that the newer version is approved by the National Coordinator for use in certifications issued under the ONC Health IT Certification Program. Developers may, for each standard and implementation specification included in each criterion, choose on an itemized basis whether to seek certification to the version incorporated by reference in §170.299, or to one or more newer version(s) approved by the National Coordinator for use in Health IT Module certifications issued pursuant to section 3001(c)(5) of the Public Health Service Act, or to both.

(10) [Reserved]

[85 FR 25945, May 1, 2020, as amended at 85 FR 43711, July 20, 2020; 85 FR 70084, Nov. 4, 2020; 85 FR 78236, Dec. 4, 2020; 89 FR 1434, Jan. 9, 2024]

§ 170.406 Attestations.

(a) *Condition of Certification requirement.* A health IT developer, or its authorized representative that is capable of binding the health IT developer,

must provide the Secretary an attestation of compliance with the following Conditions and Maintenance of Certification requirements:

(1) Section 170.401;

(2) Section 170.402, but only for §170.402(a)(4) and (b)(2) if the health IT developer certified a Health IT Module(s) that is part of a health IT product which can store electronic health information;

(3) Section 170.403;

(4) Section 170.404 if the health IT developer has a Health IT Module(s) certified to any of the certification criteria adopted in §170.315(g)(7) through (10); and such health IT developer must also ensure that health IT allows for health information to be exchanged, accessed, and used, in the manner described in §170.404; and

(5) Section 170.405 if a health IT developer has a Health IT Module(s) certified to any one or more ONC Certification Criteria for Health IT in §170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h).

(b) *Maintenance of Certification requirement*. (1) A health IT developer, or its authorized representative that is capable of binding the health IT developer, must provide the attestation specified in paragraph (a) of this section semiannually for any Health IT Modules that have or have had an active certification at any time under the ONC Health IT Certification Program during the prior six months.

(2) [Reserved][85 FR 25945, May 1, 2020, as amended at 89 FR 8549, Feb. 8, 2024]

§170.407 Insights Condition and Maintenance of Certification.

(a) *Condition of Certification*—(1) *Measure responses*. A health IT developer must submit (to the independent entity designated by the Secretary) for each reporting period pursuant to paragraph (b) of this section:

(i) Responses for the measures specified in this section, which must include:

(A) Data aggregated at the product level (across versions);

(B) Documentation related to the data sources and methodology used to generate measures; and

(C) Percentage of total customers (*e.g.*, hospital sites, individual clinician users) represented in provided data; or

(ii) A response (attestation) that it does not:

(A) Meet the minimum reporting qualifications requirement in paragraph (a)(2) of this section; or

(B) Have health IT certified to the certification criteria specified in each measure in paragraphs (a)(3)(i) through (vii) of this section; or

(C) Have any users using the certified health IT specified in each measure in paragraphs (a)(3)(i) through (vii) of this section during the reporting period.

(2) *Minimum reporting qualifications requirement*. At least 50 hospital sites or 500 individual clinician users across the developer's certified health IT.

(3) *Measures*—(i) *Individuals' access to electronic health information through certified health IT*. If a health IT developer has a Health IT Module certified to §170.315(e)(1) or (g)(10) or both, then the health IT developer must submit responses for the number of unique individuals who access electronic health information (EHI) overall and by different methods of access through certified health IT.

(ii) *Consolidated clinical document architecture (C–CDA) problems, medications, and allergies reconciliation and incorporation through certified health IT*. If a health IT developer has a Health IT Module certified to §170.315(b)(2), then the health IT developer must submit responses for:

(A) Encounters;

(B) Unique patients with an encounter;

(C) C–CDA documents obtained (unique and overall); and

(D) C–CDA documents reconciled and incorporated both through manual and automated processes.

(iii) *Applications supported through certified health IT*. If a health IT developer has a Health IT Module certified to §170.315(g)(10), then the health IT developer must submit responses on how their certified health IT is supporting the application ecosystem, by providing the following information for applications that are connected to their certified health IT including:

(A) Application Name(s);

(B) Application Developer Name(s);

(C) Intended Purpose(s) of Application;

(D) Intended Application User(s); and

(E) Application Status.

(iv) *Use of FHIR in apps through certified health IT.* If a health IT developer has a Health IT Module certified to §170.315(g)(10), then the health IT developer must submit responses on the number of requests made to distinct certified health IT deployments that returned FHIR resources, number of distinct certified health IT deployments active at any time, the number of distinct deployments active at any time that returned FHIR resources in response to API calls from apps connected to certified health IT, including stratifying responses by the following:

(A) User type;

(B) FHIR resource; and

(C) US Core Implementation Guide version.

(v) *Use of FHIR bulk data access through certified health IT.* If a health IT developer has a Health IT Module certified to §170.315(g)(10), then the health IT developer must submit responses for the total number of FHIR bulk data access requests completed through the certified health IT, and the number of distinct deployments of the certified health IT active at any time overall, and by whether at least one bulk data download request was completed.

(vi) *Immunization administrations electronically submitted to immunization information systems through certified health IT.* If a health IT developer has a Health IT Module certified to §170.315(f)(1), then the health IT developer must submit responses for the use of certified health IT to electronically send immunizations administered to immunization information systems (IIS), including stratifying responses based on the following subgroups:

(A) IIS; and

(B) Age group.

(vii) *Immunization history and forecasts through certified health IT.* If a health IT developer has a Health IT Module certified to §170.315(f)(1), then the health IT developer must submit responses for the use of certified health IT to query immunization history and forecast information from immunization information systems (IIS), including stratifying responses based on the following subgroup:

(A) IIS.

(B) [Reserved]

(b) *Maintenance of Certification.* (1) A health IT developer must provide responses to the Insights Condition of Certification specified in paragraph (a) of this section annually for any Health IT Module that has or has had an active certification at any time under the ONC Health IT Certification Program during the prior six months:

(i) A health IT developer must provide responses for measures specified in:

(A) Paragraphs (a)(3)(i), (iii), (iv)(A) and (B), and (vi) of this section beginning July 2027;

(B) Paragraphs (a)(3)(ii)(A) through (C), (iv)(C), (v), (vi)(A) and (B), and (vii) of this section beginning July 2028; and

(C) Paragraph (a)(3)(ii)(D), (vii)(A) of this section beginning July 2029.

(ii) [Reserved]

(2) [Reserved]

[89 FR 1434, Jan. 9, 2024; 89 FR 16470, Mar. 7, 2024]

Subpart E—ONC Health IT Certification Program

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart E of part 170 appear at 80 FR 62755, Oct. 16, 2015.

§170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the ONC Health IT Certification Program for health information technology (health IT) administered by the National Coordinator for Health Information Technology.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012]

§170.501 Applicability.

(a) This subpart establishes the processes that applicants for ONC–ACB status must follow to be granted ONC–ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC–ACB status;

the requirements that ONC–ACBs must follow to maintain ONC–ACB status; and the requirements of ONC–ACBs for certifying Health IT Module(s), and other types of health IT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

(b) This subpart establishes the processes that applicants for ONC–ATL status must follow to be granted ONC–ATL status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC–ATL status; the requirements that ONC–ATLs must follow to maintain ONC–ATL status; and the requirements of ONC–ATLs for testing Health IT Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

(c) [Reserved]

(d) This subpart establishes the processes the National Coordinator will follow when exercising direct review of certified health IT and related requirements for ONC–ACBs, ONC–ATLs, and developers of health IT certified under the ONC Health IT Certification Program.

[81 FR 72464, Oct. 19, 2016, as amended at 85 FR 25950, May 1, 2020]

§ 170.502 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ACB or ONC–ATL by submitting an application to the National Coordinator for such status.

Deployment site means the physical location where a Health IT Module(s) or other type of health IT resides or is being or has been implemented.

Development site means the physical location where a Health IT Module(s) or other type of health IT was developed.

Gap certification means the certification of a previously certified Health IT Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on test results issued by a NVLAP-accredited testing laboratory under the ONC Health IT Certification Program or an ONC–ATL; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or Health IT Module(s) under the ONC Health IT Certification Program.

ONC–Authorized Certification Body or ONC–ACB means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Health IT Module(s), and/or other types of health IT under the ONC Health IT Certification Program.

ONC-Authorized Testing Lab or ONC–ATL means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing of Health IT Modules to certification criteria adopted by the Secretary at subpart C of this part.

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified Health IT Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the Health IT Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the Health IT Module(s).

Remote certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ACB to be physically present at the development or deployment site to conduct certification.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012; 81 FR 72464, Oct. 19, 2016; 85 FR 25950, May 1, 2020]

§§ 170.503–170.504 [Reserved]

§ 170.505 Correspondence.

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified.

(1) Consideration for providing notice beyond email, such as by regular, express, or certified mail, will be based on, but not limited to, whether: The party requests use of correspondence beyond email; the party has responded via email to our communications; we have sufficient information from the party to ensure appropriate delivery of any other method of notice; and the matter involves an alleged violation within ONC's purview under §170.580 that indicates a serious violation under the ONC Health IT Certification Program with potential consequences of suspension, certification termination, or a certification ban.

(2) The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC–ACB status, an applicant for ONC–ATL status, an ONC–ACB, an ONC–ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC–ACB status, an applicant for ONC–ATL status, an ONC–ACB, an ONC–ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.

[85 FR 25950, May 1, 2020]

§ 170.510 Authorization scope for ONC–ACB status.

Applicants for ONC–ACB status may seek authorization from the National Coordinator to perform the following types of certification:

(a) Health IT Module certification; and/or

(b) Certification of other types of health IT for which the Secretary has adopted certification criteria under subpart C of this part.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72464, Oct. 19, 2016; 85 FR 25950, May 1, 2020]

§ 170.511 Authorization scope for ONC–ATL status.

Applicants may seek authorization from the National Coordinator to perform the testing of Complete EHRs or Health IT Modules to a portion of a certification criterion, one certification criterion, or many or all certification criteria adopted by the Secretary under subpart C of this part.

[81 FR 72464, Oct. 19, 2016]

§ 170.520 Application.

(a) *ONC–ACB application.* Applicants must include the following information in an application for ONC–ACB status and submit it to the National Coordinator for the application to be considered complete.

(1) The type of authorization sought pursuant to §170.510. For authorization to perform Health IT Module certification, applicants must indicate the specific type(s) of Health IT Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of Health IT Module(s) for which they seek authorization.

(2) General identifying, information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and email address of the person who will serve as the applicant's point of contact.

(3) Documentation that confirms that the applicant has been accredited to ISO/IEC 17065 (for availability, see §170.599), with an appropriate scope, by any accreditation body that is a signatory to the Multilateral Recognition Arrangement (MLA) with the International Accreditation Forum (IAF).

(4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ACBs.

(b) *ONC–ATL application.* Applicants must include the following information in an application for ONC–ATL status and submit it to the National Coordinator for the application to be considered complete.

(1) The authorization scope sought pursuant to §170.511.

(2) General identifying, information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and email address of the person who will serve as the applicant's point of contact.

(3) Documentation that confirms that the applicant has been accredited by NVLAP to the ONC Health IT Certification Program, including to ISO/IEC 17025 (incorporated by reference, *see* § 170.599).

(4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ATLs.

[81 FR 72464, Oct. 19, 2016, as amended at 85 FR 25950, May 1, 2020]

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

(a) *Accreditation.* Maintain its accreditation in good standing to ISO/IEC 17065 (incorporated by reference in § 170.599).

(b) *Mandatory training.* Attend all mandatory ONC training and program update sessions;

(c) *Training program.* Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify health IT;

(d) *Reporting.* Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to certify health IT.

(e) *Onsite observation.* Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the ONC Health IT Certification Program;

(f) *Certified product listing.* Provide ONC, no less frequently than weekly, a current list of Health IT Modules, and/or EHR Modules that have been certified that includes, at a minimum:

(1) For the ONC Certification Criteria for Health IT:

(i) The Health IT Module developer name; product name; product version; developer Web site, physical address, email, phone number, and contact name;

(ii) The ONC–ACB Web site, physical address, email, phone number, and contact name, contact function/title;

(iii) The ATL Web site, physical address, email, phone number, and contact name, contact function/title;

(iv) Location and means by which the testing was conducted (*e.g.*, remotely with health IT developer at its headquarters location);

(v) The date(s) the Health IT Module was tested;

(vi) The date the Health IT Module was certified;

(vii) The unique certification number or other specific product identification;

(viii) The certification criterion or criteria to which the Health IT Module has been certified, including the test procedure and test data versions used, test tool version used, and whether any test data was altered (*i.e.*, a yes/no) and for what purpose;

(ix) The way in which each privacy and security criterion was addressed for the purposes of certification;

(x) The standard or mapping used to meet the quality management system certification criterion;

(xi) The standard(s) or lack thereof used to meet the accessibility-centered design certification criterion;

(xii) *Where applicable,* the hyperlink to access an application programming interface (API)'s documentation and terms of use;

(xiii) *Where applicable,* which certification criteria were gap certified;

(xiv) *Where applicable,* if a certification issued was a result of an inherited certified status request;

(xv) *Where applicable,* the clinical quality measures to which the Health IT Module has been certified;

(xvi) *Where applicable,* any additional software a Health IT Module relied upon to demonstrate its compliance

with a certification criterion or criteria adopted by the Secretary;

(xvii) *Where applicable*, the standard(s) used to meet a certification criterion where more than one is permitted;

(xviii) *Where applicable*, any optional capabilities within a certification criterion to which the Health IT Module was tested and certified;

(xix) *Where applicable*, and for each applicable certification criterion, all of the information required to be submitted by Health IT Module developers to meet the safety-enhanced design certification criterion. Each user-centered design element required to be reported must be at a granular level (*e.g.*, task success/failure));

(xx) A hyperlink to the disclosures required by §170.523(k)(1) for the Health IT Module;

(xxi) Where applicable, summary information of the intervention risk management practices listed in §170.315(b)(11)(vi) is submitted by the health IT developer via publicly accessible hyperlink that allows any person to access the summary information directly without any preconditions or additional steps.

(xxii) *When applicable*, for each instance in which a Health IT Module failed to conform to its certification and for which corrective action was instituted under §170.556 (provided no provider or practice site is identified):

(A) The specific certification requirements to which the technology failed to conform, as determined by the ONC–ACB;

(B) A summary of the deficiency or deficiencies identified by the ONC–ACB as the basis for its determination of non-conformity;

(C) When available, the health IT developer's explanation of the deficiency or deficiencies;

(D) The dates surveillance was initiated and completed;

(E) The results of randomized surveillance, including pass rate for each criterion in instances where the Health IT Module is evaluated at more than one location;

(F) The number of sites that were used in randomized surveillance;

(G) The date of the ONC–ACB's determination of non-conformity;

(H) The date on which the ONC–ACB approved a corrective action plan;

(I) The date corrective action began (effective date of approved corrective action plan);

(J) The date by which corrective action must be completed (as specified by the approved corrective action plan);

(K) The date corrective action was completed; and

(L) A description of the resolution of the non-conformity or non-conformities.

(2) [Reserved]

(g) *Records retention*. (1) Retain all records related to the certification of Health IT Modules to the ONC Certification Criteria for Health IT beginning with the codification of those certification criteria in the Code of Federal Regulations through a minimum of 3 years after the end of calendar year that included the effective date of the removal of those certification criteria from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (g)(1) of this section;

(h) *Certification decision*. Only certify Health IT Modules that have been:

(1) Tested, using test tools and test procedures approved by the National Coordinator, by an:

(i) ONC–ATL;

(ii) ONC–ATL, National Voluntary Laboratory Accreditation Program-accredited testing laboratory under the ONC Health IT Certification Program, and/or an ONC–ATCB for the purposes of performing gap certification; or

(2) Evaluated by it for compliance with a conformance method approved by the National Coordinator.

(i) *Surveillance*. Conduct surveillance of certified health IT in accordance with its accreditation, §170.556, and the following requirements:

(1) Submit an annual surveillance plan to the National Coordinator.

(2) Report, at a minimum, on a quarterly basis to the National Coordinator the results of its surveillance, including surveillance results that identify:

(i) The names of health IT developers;

(ii) Names of products and versions;

(iii) Certification criteria and ONC Health IT Certification Program requirements surveilled;

(iv) The type of surveillance (*i.e.*, reactive or randomized);

(v) The dates surveillance was initiated and completed; and

(vi) As applicable, the number of sites that were used in randomized surveillance.

(3) Annually submit a summative report of surveillance results to the National Coordinator.

(j) *Refunds.* Promptly refund any and all fees received for:

(1) Requests for certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Certifications that will not be completed as a result of its conduct; and

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or Health IT Module(s);

(k) *Disclosures.* Ensure adherence to the following requirements when issuing any certification and during surveillance of Health IT Modules the ONC–ACB has certified.

(1) *Mandatory Disclosures.* A health IT developer must conspicuously include the following on its website and in all marketing materials, communications statements, and other assertions related to the Health IT Module's certification:

(i) The disclaimer ''This Health IT Module is compliant with the ONC Certification Criteria for Health IT and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services.''

(ii) For a Health IT Module certified to the ONC Certification Criteria for Health IT, the information specified by paragraphs (f)(1)(i), (vi) through (viii), (xv), and (xvi) of this section as applicable for the specific Health IT Module.

(iii) In plain language, a detailed description of all known material information concerning additional types of costs or fees that a user may be required to pay to implement or use the Health IT Module's capabilities, whether to meet provisions of HHS programs requiring the use of certified health IT or to achieve any other use within the scope of the health IT's certification. The additional types of costs or fees required to be disclosed include but are not limited to costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(iv) The types of information required to be disclosed under paragraph (k)(iii) of this section include but are not limited to:

(A) Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a health IT developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.

(B)–(C) [Reserved]

(v) Health IT self-developers are excluded from the requirements of paragraph (k)(1)(iii) of this section.

(2)–(3) [Reserved]

(4) A certification issued to a Health IT Module based solely on the applicable certification criteria adopted by the ONC Health IT Certification Program must be separate and distinct from any other certification(s) based on other criteria or requirements.

(l) *Certification and Design Mark.* Display the ONC Certified health IT Certification and Design Mark on all certifications issued under the ONC Health IT Certification Program in a manner that complies with the Criteria and Terms of Use for the ONC Certified

health IT Certification and Design Mark, and ensure that use of the mark by health IT developers whose products are certified under the ONC Health IT Certification Program is compliant with the Criteria and Terms of Use for the ONC Certified health IT Certification and Design Mark.

(m) *Adaptations and updates.* On a quarterly basis each calendar year, obtain a record of:

(1) All adaptations of certified Health IT Modules;

(2) All updates made to certified Health IT Modules affecting the capabilities in certification criteria to which the ''safety-enhanced design'' criteria apply;

(3) All uses cases for §170.315(d)(13);

(4) All updates made to certified Health IT Modules in compliance with §170.405(b)(3); and

(5) All updates to certified Health IT Modules and all certifications of Health IT Modules issued including voluntary use of newer standards versions per §170.405(b)(8) or (9). Record of these updates may be obtained by aggregation of ONC–ACB documentation of certification activity.

(n) *Complaints reporting.* Submit a list of complaints received to the National Coordinator on a quarterly basis each calendar year that includes the number of complaints received, the nature/substance of each complaint, and the type of complainant for each complaint.

(o) *Scope reduction.* Be prohibited from reducing the scope of a Health IT Module's certification when it is under surveillance or under a corrective action plan.

(p) *Real world testing.* (1) Review and confirm that applicable health IT developers submit real world testing plans in accordance with §170.405(b)(1).

(2) Review and confirm that applicable health IT developers submit real world testing results in accordance with §170.405(b)(2).

(3) Submit real world testing plans by December 15 of each calendar year and results by March 15 of each calendar year to ONC for public availability.

(q) *Attestations.* Review and submit health IT developer Conditions and Maintenance of Certification requirements attestations made in accordance with §170.406 to ONC for public availability.

(r) *Test results from ONC–ATLs.* Accept test results from any ONC–ATL that is:

(1) In good standing under the ONC Health IT Certification Program, and

(2) Compliant with its ISO/IEC 17025 accreditation requirements as required by 170.524(a).

(s) *Information for direct review.* Report to ONC, no later than a week after becoming aware of, any information that could inform whether ONC should exercise direct review under §170.580(a).

(t) *Health IT Module voluntary standards and implementation specifications updates notices.* Ensure health IT developers opting to take advantage of the flexibility for voluntary updates of standards and implementation specifications in certified Health IT Modules per §170.405(b)(8) provide timely advance written notice to the ONC–ACB and all affected customers.

(1) Maintain a record of the date of issuance and the content of developers' §170.405(b)(8) notices; and

(2) Timely post content or make publicly accessible via the CHPL each §170.405(b)(8) notice received, publicly on the CHPL attributed to the certified Health IT Module(s) to which it applies.

(u) *Insights.* Confirm that developers of certified health IT submit responses for Insights Conditions and Maintenance of Certification requirements in accordance with §170.407.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011; 77 FR 54291, Sept. 4, 2012; 79 FR 54479, Sept. 11, 2014; 80 FR 62755, Oct. 16, 2015; 80 FR 76872, Dec. 11, 2015; 81 FR 72465, Oct. 19, 2016; 85 FR 25950, May 1, 2020; 85 FR 70084, Nov. 4, 2020; 89 FR 1435, Jan. 9, 2024]

§170.524 Principles of proper conduct for ONC–ATLs.

An ONC–ATL shall:

(a) *Accreditation.* Maintain its NVLAP accreditation for the ONC Health IT Certification Program, including accreditation to ISO/IEC 17025 (incorporated by reference, *see* §170.599);

(b) *Mandatory training.* Attend all mandatory ONC training and program update sessions;

(c) *Training program.* Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test health IT;

(d) *Reporting.* Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key testing personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to test health IT.

(e) *Onsite observation.* Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any testing performed pursuant to the ONC Health IT Certification Program;

(f) *Records retention.* (1) Retain all records related to the testing of Health IT Modules to the ONC Certification Criteria for Health IT beginning with the codification of those certification criteria in the Code of Federal Regulations through a minimum of three years after the end of calendar year that included the effective date of the removal of those certification criteria from the Code of Federal Regulations; and

(2) Make the records available to HHS upon request during the retention period described in paragraph (f)(1) of this section;

(g) *Approved testing methods.* Only test health IT using test tools and test procedures approved by the National Coordinator; and

(h) *Refunds.* Promptly refund any and all fees received for:

(1) Requests for testing that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing that will not be completed as a result of its conduct; and

(3) Previous testing that it performed if its conduct necessitates the retesting of Health IT Modules.

[81 FR 72465, Oct. 19, 2016, as amended at 85 FR 25951, May 1, 2020; 89 FR 1435, Jan. 9, 2024]

§ 170.525 Application submission.

(a) An applicant for ONC–ACB or ONC–ATL status must submit its application either electronically via email (or Web site submission if available), or by regular or express mail.

(b) An application for ONC–ACB or ONC–ATL status may be submitted to the National Coordinator at any time.

[81 FR 72465, Oct. 19, 2016]

§ 170.530 Review of application.

(a) *Method of review and review timeframe.* (1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.* (1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.* (1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC–ACB or ONC–ATL status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National

Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot reapply for ONC–ACB or ONC–ATL status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with §170.535.

(d) *Satisfactory application.* (1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ACB or ONC–ATL status.

(3) Once notified by the National Coordinator of its successful achievement of ONC–ACB or ONC–ATL status, the applicant may represent itself as an ONC–ACB or ONC–ATL (as applicable) and begin certifying or testing (as applicable) health information technology consistent with its authorization.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72465, Oct. 19, 2016]

§ 170.535 ONC–ACB and ONC–ATL application reconsideration.

(a) *Basis for reconsideration request.* An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC–ACB or ONC–ATL status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.* (1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC–ACB or ONC–ATL status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

[76 FR 1325, Dec. 7, 2011, as amended at 81 FR 72466, Oct. 19, 2016]

§ 170.540 ONC–ACB and ONC–ATL status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC–ACBs and ONC–ATLs, including the date each was authorized and the type(s) of certification or scope of testing, respectively, each has been authorized to perform.

(b) *Representation.* Each ONC–ACB or ONC–ATL must prominently and unambiguously identify the scope of its authorization on its Web site and in all

marketing and communications statements (written and oral) pertaining to its activities under the ONC Health IT Certification Program.

(c) *Renewal.* An ONC–ACB or ONC–ATL is required to renew its status every three years. An ONC–ACB or ONC–ATL is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC–ACB's or ONC–ATL's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

[81 FR 72466, Oct. 19, 2016]

§ 170.545 [Reserved]

§ 170.550 Health IT Module certification.

(a) *Certification scope.* When certifying Health IT Module(s), an ONC–ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) *Health IT product scope options.* An ONC–ACB must provide the option for an Health IT Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC–ACB may provide the option for and perform gap certification of previously certified Health IT Module(s).

(d) *Upgrades and enhancements.* An ONC–ACB may provide an updated certification to a previously certified Health IT Module(s).

(e) *Standards updates.* ONC–ACBs must provide an option for certification of Health IT Modules consistent with § 171.405(b)(7) or (8) to any one or more of the criteria referenced in § 170.405(a) based on newer versions of standards included in the criteria which have been approved by the National Coordinator for use in certification.

(f) [Reserved]

(g) *Health IT Module dependent criteria.* When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC–ACB must certify the Health IT Module in accordance with the certification criteria at:

(1) Section 170.315(g)(3) if the Health IT Module is presented for certification to one or more listed certification criteria in § 170.315(g)(3);

(2) Section 170.315(g)(4);

(3) Section 170.315(g)(5); and

(4) Section 170.315(g)(6) if the Health IT Module is presented for certification with C–CDA creation capabilities within its scope. If the scope of certification sought includes multiple certification criteria that require C–CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each. If the scope of certification sought includes multiple certification criteria that require C–CDA creation, § 170.315(g)(6) need only be tested in association with one of those certification criteria and would not be expected or required to be tested for each so long as all applicable C–CDA document templates have been evaluated as part of § 170.315(g)(6) for the scope of the certification sought.

(5) Section 170.315(b)(10) when a health IT developer presents a Health IT Module for certification that can store electronic health information at the time of certification by the product, of which the Health IT Module is a part.

(h) *Privacy and security certification framework*—(1) *General rule.* When certifying a Health IT Module to the ONC Certification Criteria for Health IT, an ONC–ACB can only issue a certification to a Health IT Module if the privacy and security certification criteria in paragraphs (h)(3)(i) through (ix) of this section have also been met (and are included within the scope of the certification).

(2) *Testing.* In order to be issued a certification, a Health IT Module would only need to be tested once to each applicable privacy and security criterion in paragraphs (h)(3)(i) through (ix) of this section so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification, except for the following:

(i) A Health IT Module presented for certification to §170.315(e)(1) must be separately tested to §170.315(d)(9); and

(ii) A Health IT Module presented for certification to §170.315(e)(2) must be separately tested to §170.315(d)(9).

(3) *Applicability.* (i) Section 170.315(a)(1) through (3), (5), (12), (14), and (15) are also certified to the certification criteria specified in §170.315(d)(1) through (7), (d)(12), and (13).

(ii) Section 170.315(a)(4), (9), (10), and (13) are also certified to the certification criteria specified in §170.315(d)(1) through (3), and (d)(5) through (7), (d)(12), and (13).

(iii) Section 170.315(b)(1) through (3) and (6) through (9) are also certified to the certification criteria specified in §170.315(d)(1) through (3) and (d)(5) through (8), (12), and (13);

(iv) Section 170.315(c) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A), (B), (d)(2)(ii) through (v), (d)(3), (5), (12), and (13);

(v) Section 170.315(e)(1) is also certified to the certification criteria specified in §170.315(d)(1) through (3), (5), (7), (9), (12), and (13);

(vi) Section 170.315(e)(2) and (3) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), (d)(3), (5), (9), (12), and (13);

(vii) Section 170.315(f) is also certified to the certification criteria specified in §170.315(d)(1) through (3), (7), (12), and (13);

(viii) Section 170.315(g)(7) through (10) is also certified to the certification criteria specified in §170.315(d)(1), (9), (12), and (13); and (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), or (d)(10);

(ix) Section 170.315(h) is also certified to the certification criteria specified in §170.315(d)(1), (d)(2)(i)(A) and (B), (d)(2)(ii) through (v), (d)(3), (12), and (13); and

(i) [Reserved]

(j) *Direct Project transport method.* An ONC–ACB can only issue a certification to a Health IT Module for §170.315(h)(1) if the Health IT Module's certification also includes §170.315(b)(1).

(k) *Inherited certified status.* An ONC–ACB must accept requests for a newer version of a previously certified Health IT Module(s) to inherit the certified status of the previously certified Health IT Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Health IT Module(s), an ONC–ACB must review an attestation submitted by the developer(s) of the Health IT Module(s) to determine whether any change in the newer version has adversely affected the Health IT Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC–ACB may grant certified status to a newer version of a previously certified Health IT Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(l) *Conditions of certification attestations.* Ensure that the health IT developer of the Health IT Module has met its responsibilities under subpart D of this part.

(m) *Time-limited certification and certification status for certain ONC Certification Criteria for Health IT.* An ONC–ACB may only issue a certification to a Health IT Module and permit continued certified status for:

(1) Section 170.315(a)(10) and (13) and §170.315(e)(2) for the period before January 1, 2022.

(2) Section 170.315(b)(6) for the period before December 31, 2023.

(3) Section 170.315(g)(8) for the period before December 31, 2022.

[76 FR 1325, Dec. 7, 2011, as amended at 77 FR 54291, Sept. 4, 2012; 79 FR 54480, Sept. 11, 2014; 80 FR 62757, Oct. 16, 2015; 85 FR 25952, May 1, 2020; 85 FR 70085, Nov. 4, 2020; 89 FR 1435, Jan. 9, 2024; 89 FR 8549, Feb. 8, 2024]

§170.553 [Reserved]

§170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Health IT Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) *Applicability of a newer version of a minimum standard.* (1) ONC–ACBs are not required to certify Health IT Module(s) according to newer versions of

standards adopted and named in subpart B of this part, unless:

(i) The National Coordinator approves a newer version for use in certification and a health IT developer voluntarily elects to seek certification of its health IT in accordance with §170.405(b)(9) or update its certified health IT to the newer version in accordance with §170.405(b)(8); or

(ii) The new version is incorporated by reference in §170.299.

(2) A certified Complete EHR or certified Health IT Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

[77 FR 54291, Sept. 4, 2012, as amended at 85 FR 25952, May 1, 2020]

§ 170.556 In-the-field surveillance and maintenance of certification for Health IT.

(a) *In-the-field surveillance.* Consistent with its accreditation under 170.523(a) to ISO/IEC 17065 and the requirements of this subpart, an ONC–ACB must initiate surveillance ''in the field'' as necessary to assess whether a certified Health IT Module continues to conform to the requirements in subparts A, B, C and E of this part once the certified Health IT Module has been implemented and is in use in a production environment.

(1) *Production environment.* An ONC–ACB's assessment of a certified capability in the field must be based on the use of the capability in a production environment, which means a live environment in which the capability has been implemented and is in use.

(2) *Production data.* An ONC–ACB's assessment of a certified capability in the field must be based on the use of the capability with production data unless the use of test data is specifically approved by the National Coordinator.

(b) *Reactive surveillance.* An ONC–ACB must initiate surveillance (including, as necessary, in-the-field surveillance required by paragraph (a) of this section) whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified Health IT Module's continued conformity to the requirements of its certification.

(1) *Review of required disclosures.* When an ONC–ACB performs reactive surveillance under this paragraph, it must verify that the requirements of §170.523(k)(1) have been followed as applicable to the issued certification.

(2) [Reserved]

(c) *Randomized surveillance.* During each calendar year surveillance period, an ONC–ACB may conduct in-the-field surveillance for certain randomly selected Health IT Modules to which it has issued a certification.

(1) *Scope.* When an ONC–ACB selects a certified Health IT Module for randomized surveillance under this paragraph, its evaluation of the certified Health IT Module must include all certification criteria prioritized by the National Coordinator that are part of the scope of the certification issued to the Health IT Module.

(2) [Reserved]

(3) *Selection method.* An ONC–ACB must randomly select (subject to appropriate weighting and sampling considerations) and certified Health IT Modules for surveillance under this paragraph.

(4) *Number and types of locations for in-the-field surveillance.* For each certified Health IT Module selected for randomized surveillance under this paragraph, an ONC–ACB must:

(i) Evaluate the certified Health IT Module's capabilities at one or more locations where the certified Health IT Module is implemented and in use in the field.

(ii) Ensure that the locations are selected at random (subject to appropriate weighting and sampling considerations) from among all locations where the certified Health IT Module is implemented and in use in the field.

(d) *Corrective action plan and procedures.* (1) When an ONC–ACB determines, through surveillance under this section or otherwise, that a Health IT Module does not conform to the requirements of its certification, the ONC–ACB must notify the developer of its findings and require the developer to submit a proposed corrective action plan for the applicable certification

criterion, certification criteria, or certification requirement.

(2) The ONC–ACB shall provide direction to the developer as to the required elements of the corrective action plan.

(3) The ONC–ACB shall verify the required elements of the corrective action plan, consistent with its accreditation and any elements specified by the National Coordinator. At a minimum, any corrective action plan submitted by a developer to an ONC–ACB must include:

(i) A description of the identified non-conformities or deficiencies;

(ii) An assessment of how widespread or isolated the identified non-conformities or deficiencies may be across all of the developer's customers and users of the certified Health IT Module;

(iii) How the developer will address the identified non-conformities or deficiencies, both at the locations under which surveillance occurred and for all other potentially affected customers and users;

(iv) How the developer will ensure that all affected and potentially affected customers and users are alerted to the identified non-conformities or deficiencies, including a detailed description of how the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved.

(v) The timeframe under which corrective action will be completed.

(vi) An attestation by the developer that it has completed all elements of the approved corrective action plan.

(4) When the ONC–ACB receives a proposed corrective action plan (or a revised proposed corrective action plan), the ONC–ACB shall either approve the corrective action plan or, if the plan does not adequately address the elements described by paragraph (d)(3) of this section and other elements required by the ONC–ACB, instruct the developer to submit a revised proposed corrective action plan.

(5) *Suspension.* Consistent with its accreditation to ISO/IEC 17065 and procedures for suspending a certification, an ONC–ACB shall initiate suspension procedures for a Health IT Module:

(i) 30 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the developer has not submitted a proposed corrective action plan;

(ii) 90 days after notifying the developer of a non-conformity pursuant to paragraph (d)(1) of this section, if the ONC–ACB cannot approve a corrective action plan because the developer has not submitted a revised proposed corrective action plan in accordance with paragraph (d)(4) of this section; and

(iii) Immediately, if the developer has not completed the corrective actions specified by an approved corrective action plan within the time specified therein.

(6) *Withdrawal.* If a or certified Health IT Module's certification has been suspended, an ONC–ACB is permitted to initiate certification withdrawal procedures for the Health IT Module (consistent with its accreditation to ISO/IEC 17065 and procedures for withdrawing a certification) when the health IT developer has not completed the actions necessary to reinstate the suspended certification.

(e) *Reporting of surveillance results requirements*—(1) *Rolling submission of in-the-field surveillance results.* The results of in-the-field surveillance under this section must be submitted to the National Coordinator, at a minimum, on a quarterly basis in accordance with §170.523(i)(2).

(2) *Confidentiality of locations evaluated.* The contents of an ONC–ACB's surveillance results submitted to the National Coordinator must not include any information that would identify any user or location that participated in or was subject to surveillance.

(3) *Reporting of corrective action plans.* When a corrective action plan is initiated for a Health IT Module, an ONC–ACB must report the Health IT Module and associated product and corrective action information to the National Coordinator in accordance with

§ 170.523(f)(1)(xxii) or (f)(2)(xi), as applicable.

(f) *Relationship to other surveillance requirements.* Nothing in this section shall be construed to limit or constrain an ONC–ACB's duty or ability to perform surveillance, including in-the-field surveillance, or to suspend or terminate the certification, of any certified Health IT Module as required or permitted by this subpart and the ONC–ACB's accreditation to ISO/IEC 17065.

[80 FR 62758, Oct. 16, 2015, as amended at 80 FR 76872, Dec. 11, 2015; 81 FR 72466, Oct. 19, 2016; 85 FR 25952, May 1, 2020]

§ 170.557 Authorized testing and certification methods.

(a) *ONC–ATL applicability.* An ONC–ATL must provide remote testing for both development and deployment sites.

(b) *ONC–ACB applicability.* An ONC–ACB must provide remote certification for both development and deployment sites.

[81 FR 72466, Oct. 19, 2016]

§ 170.560 Good standing as an ONC–ACB or ONC–ATL.

(a) *ONC–ACB good standing.* An ONC–ACB must maintain good standing by:

(1) Adhering to the Principles of Proper Conduct for ONC–ACBs;

(2) Refraining from engaging in other types of inappropriate behavior, including an ONC–ACB misrepresenting the scope of its authorization, as well as an ONC–ACB certifying Health IT Module(s) for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

(b) *ONC–ATL good standing.* An ONC–ATL must maintain good standing by:

(1) Adhering to the Principles of Proper Conduct for ONC–ATLs;

(2) Refraining from engaging in other types of inappropriate behavior, including an ONC–ATL misrepresenting the scope of its authorization, as well as an ONC–ATL testing health IT for which it does not have authorization; and

(3) Following all other applicable federal and state laws.

[81 FR 72466, Oct. 19, 2016; 85 FR 25953, May 1, 2020]

§ 170.565 Revocation of ONC–ACB or ONC–ATL status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC–ATL or ONC–ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or ONC Health IT Certification Program policies that threaten or significantly undermine the integrity of the ONC Health IT Certification Program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the ONC Health IT Certification Program, a program administered by HHS or any program administered by the federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC–ATL or ONC–ACB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC–ATL or ONC–ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–ATL or ONC–ACB requesting that the ONC–ATL or ONC–ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC–ATL or ONC–ACB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–ATL or ONC–ACB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–ATL or ONC–ACB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–ATL or ONC–ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC–ATL or ONC–ACB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the non-compliance notification, then the National Coordinator may propose to revoke the ONC–ATL or ONC–ACB's status.

(c) *Proposed revocation.* (1) The National Coordinator may propose to revoke an ONC–ATL or ONC–ACB's status if the National Coordinator has reliable evidence that the ONC–ATL or ONC–ACB has committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC–ATL or ONC–ACB's status if, after the ONC–ATL or ONC–ACB has been notified of a Type-2 violation, the ONC–ATL or ONC–ACB fails to:

(i) Rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the non-compliance notification within the specified timeframe under paragraph (b)(2) of this section.

(d) *Suspension of an ONC–ATL or ONC–ACB's operations.* (1) The National Coordinator may suspend the operations of an ONC–ATL or ONC–ACB under the ONC Health IT Certification Program based on reliable evidence indicating that:

(i) *Applicable to both ONC–ACBs and ONC–ATLs.* The ONC–ATL or ONC–ACB committed a Type-1 or Type-2 violation;

(ii) *Applicable to ONC–ACBs.* The continued certification of Health IT Modules by the ONC–ACB could have an adverse impact on the health or safety of patients.

(iii) *Applicable to ONC–ATLs.* The continued testing of Health IT Modules by the ONC–ATL could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) of this section have been met, an ONC–ATL or ONC–ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC–ATL or ONC–ACB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC–ATL or ONC–ACB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC–ATL or ONC–ACB's written response or if the ONC–ATL or ONC–ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC–ATL or ONC–ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with paragraph (c) of this section and suspend the ONC–ATL or ONC–ACB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC–ATL or ONC–ACB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.* (1) An ONC–ATL or ONC–ACB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC–ATL or ONC–ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC–ACB or ONC–ATL and reach a decision.

(f) *Good standing determination.* If the National Coordinator determines that an ONC–ATL or ONC–ACB's status should not be revoked, the National Coordinator will notify the ONC–ATL or ONC–ACB's authorized representative in writing of this determination.

(g) *Revocation.* (1) The National Coordinator may revoke an ONC–ATL or ONC–ACB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC–ATL or ONC–ACB in response to the proposed revocation notice; or

(ii) The ONC–ATL or ONC–ACB does not respond to a proposed revocation notice within the specified timeframe in paragraph (e)(1) of this section.

(2) A decision to revoke an ONC–ATL or ONC–ACB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation*—(1) *Effectuation.* The revocation of an ONC–ATL or ONC–ACB is effective as soon as the ONC–ATL or ONC–ACB receives the revocation notice.

(2) *ONC–ACB provisions.* (i) A certification body that has had its ONC–ACB status revoked is prohibited from accepting new requests for certification and must cease its current certification operations under the ONC Health IT Certification Program.

(ii) A certification body that has had its ONC–ACB status revoked for a Type-1 violation is not permitted to reapply for ONC–ACB status under the ONC Health IT Certification Program for a period of 1 year.

(iii) The failure of a certification body that has had its ONC–ACB status revoked to promptly refund any and all fees for certifications of Health IT Module(s) not completed will be considered a violation of the Principles of Proper Conduct for ONC–ACBs and will be taken into account by the National Coordinator if the certification body reapplies for ONC–ACB status under the ONC Health IT Certification Program.

(3) *ONC–ATL provisions.* (i) A testing lab that has had its ONC–ATL status revoked is prohibited from accepting new requests for testing and must cease its current testing operations under the ONC Health IT Certification Program.

(ii) A testing lab that has had its ONC–ATL status revoked for a Type-1 violation is not permitted to reapply for ONC–ATL status under the ONC Health IT Certification Program for a period of 1 year.

(iii) The failure of a testing lab that has had its ONC–ATL status revoked to promptly refund any and all fees for testing of health IT not completed will be considered a violation of the Principles of Proper Conduct for ONC–ATLs and will be taken into account by the National Coordinator if the testing lab reapplies for ONC–ATL status under the ONC Health IT Certification Program.

[81 FR 72466, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).

(a) The certified status of Health IT Module(s) certified by an ONC–ACB or tested by an ONC–ATL that had its status revoked will remain intact unless a Type-1 violation was committed by the ONC–ACB and/or ONC–ATL that calls into question the legitimacy of the certifications issued.

(b) If the National Coordinator determines that a Type-1 violation was committed by an ONC–ACB and/or ONC–ATL that called into question the legitimacy of certifications issued to health IT, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC–ACB's or ONC–ATL's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that the Health IT Module(s) certifications were based on unreliable testing and/or certification.

(c) If the National Coordinator determines that Health IT Module(s) certifications were based on unreliable testing and/or certification, the certification status of affected Health IT Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice.

(1) The certification status of affected Health IT Module(s) can only be maintained after the 120-day timeframe by being re-tested by an ONC–ATL in good standing, as necessary, and re-certified by an ONC–ACB in good standing.

(2) The National Coordinator may extend the time that the certification

status of affected Health IT Module(s) remains intact as necessary for the proper retesting and recertification of the affected health IT.

[81 FR 72467, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

§ 170.575 [Reserved]

§ 170.580 ONC review of certified health IT.

(a) *Direct review*—(1) *Purpose.* ONC may directly review certified health IT or a health IT developer's actions or practices to determine whether either conform to the requirements of the ONC Health IT Certification Program.

(2) *Circumstances that may trigger review*—(i) *Certified health IT causing or contributing to unsafe conditions.* ONC may initiate direct review under this section if it has a reasonable belief that certified health IT may not conform to the requirements of the Program because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety, taking into consideration—

(A) The potential nature, severity, and extent of the suspected conditions;

(B) The need for an immediate or coordinated governmental response; and

(C) If applicable, information that calls into question the validity of the health IT's certification or maintenance thereof under the Program.

(ii) *Impediments to ONC–ACB oversight of certified health IT.* ONC may initiate direct review under this section if it has a reasonable belief that certified health IT may not conform to requirements of the Program and the suspected non-conformity presents issues that—

(A) May require access to confidential or other information that is not available to an ONC–ACB;

(B) May require concurrent or overlapping review by two or more ONC–ACBs; or

(C) May exceed an ONC–ACB's resources or expertise.

(iii) *Noncompliance with a Condition and Maintenance of Certification requirement.* ONC may initiate direct review under this section if it has a reasonable belief that a health IT developer has not complied with a Condition or Maintenance of Certification requirement under subpart D of this part.

(3) *Relationship to ONC–ACBs and ONC–ATLs.* (i) ONC's review of certified health IT or a health IT developer's actions or practices is independent of, and may be in addition to, any surveillance of certified health IT conducted by an ONC–ACB.

(ii) ONC may assert exclusive review of certified health IT as to any matters under review by ONC and any similar matters under surveillance by an ONC–ACB.

(iii) ONC's determination on matters under its review is controlling and supersedes any determination by an ONC–ACB on the same matters.

(iv) An ONC–ACB and ONC–ATL shall provide ONC with any available information that ONC deems relevant to its review of certified health IT or a health IT developer's actions or practices.

(v) ONC may end all or any part of its review of certified health IT or a health IT developer's actions or practices under this section at any time and refer the applicable part of the review to the relevant ONC–ACB(s) if ONC determines that doing so would serve the effective administration or oversight of the ONC Health IT Certification Program.

(4) *Coordination with the Office of Inspector General.* (i) ONC may coordinate its review of a claim of information blocking with the Office of Inspector General or defer to the Office of Inspector General to lead a review of a claim of information blocking.

(ii) ONC may rely on Office of Inspector General findings to form the basis of a direct review action.

(b) *Notice*—(1) *Notice of potential non-conformity*—(i) *Circumstances that may trigger notice of potential non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of potential non-conformity if it has a reasonable belief that certified health IT or a health IT developer's actions or practices may not conform to the requirements of the ONC Health IT Certification Program.

(ii) *Health IT developer response.* (A) The health IT developer must respond

to the notice of potential non-conformity by:

(*1*) Cooperating with ONC and/or a third party acting on behalf of ONC;

(*2*) Providing ONC and/or a third party acting on behalf of ONC access, including in accordance with paragraph (b)(3) of this section, to the certified health IT under review;

(*3*) Providing ONC with a written explanation and all supporting documentation addressing the potential non-conformity within 30 days, or within the adjusted timeframe set in accordance with paragraph (b)(1)(ii)(B) of this section.

(B) ONC may adjust the 30-day timeframe specified in paragraph (b)(1)(ii)(A)(*3*) of this section to be shorter or longer based on factors including, but not limited to:

(*1*) The type of certified health IT and certification in question;

(*2*) The type of potential non-conformity to be corrected;

(*3*) The time required to correct the potential non-conformity; and

(*4*) Issues of public health or safety.

(iii) *ONC determination.* After receiving the health IT developer's written explanation and supporting documentation as required by paragraph (b)(1)(ii)(A)(*3*) of this section, ONC shall do one of the following:

(A) Issue a written determination ending its review.

(B) Request additional information and continue its review in accordance with a new timeframe ONC establishes under (b)(1)(ii)(A)(*3*) and (b)(1)(ii)(B) of this section.

(C) Substantiate a non-conformity and issue a notice of non-conformity.

(D) Issue a notice of proposed termination if the health IT is under review in accordance with paragraph (a)(2)(i) or (ii) of this section.

(2) *Notice of non-conformity*—(i) *Circumstances that may trigger notice of non-conformity.* At any time during its review of certified health IT or a health IT developer's actions or practices under paragraph (a) of this section, ONC may send a notice of non-conformity to the health IT developer if it determines that certified health IT or a health IT developer's actions or practices does not conform to the requirements of the ONC Health IT Certification Program.

(ii) *Health IT developer response.* (A) The health IT developer must respond to the notice of non-conformity by:

(*1*) Cooperating with ONC and/or a third party acting on behalf of ONC;

(*2*) Providing ONC and/or a third party acting on behalf of ONC access, including in accordance with paragraph (b)(3) of this section, to the certified health IT under review;

(*3*) Providing ONC with a written explanation and all supporting documentation addressing the non-conformity within 30 days, or within the adjusted timeframe set in accordance with paragraph (b)(1)(ii)(B) of this section; and

(*4*) Providing a proposed corrective action plan consistent with paragraph (c) of this section.

(B) ONC may adjust the 30-day timeframe specified in paragraph (b)(2)(ii)(A)(*3*) of this section to be shorter or longer based on factors including, but not limited to:

(*1*) The type of certified health IT and certification in question;

(*2*) The type of non-conformity to be corrected;

(*3*) The time required to correct the non-conformity; and

(*4*) Issues of public health or safety.

(iii) *ONC determination.* After receiving the health IT developer's response provided in accordance with paragraph (b)(2)(ii) of this section, ONC shall either issue a written determination ending its review or continue with its review under the provisions of this section.

(3) *Records access.* In response to a notice of potential non-conformity or notice of non-conformity, a health IT developer shall make available to ONC and for sharing within HHS, with other federal departments, agencies, and offices, and with appropriate entities including, but not limited to, third-parties acting on behalf of ONC:

(i) All records related to the development, testing, certification, implementation, maintenance and use of its certified health IT;

(ii) Any complaint records related to the certified health IT;

(iii) All records related to the Condition(s) and Maintenance of Certification requirements, including marketing and distribution records, communications, and contracts; and

(iv) Any other relevant information.

(c) *Corrective action plan and procedures*—(1) *Applicability.* If ONC determines that certified health IT or a health IT developer's action or practice does not conform to requirements of the ONC Health IT Certification Program, ONC shall notify the health IT developer of its determination and require the health IT developer to submit a proposed corrective action plan.

(2) ONC shall provide direction to the health IT developer as to the required elements of the corrective action plan, which shall include such required elements as ONC determines necessary to comprehensively and expeditiously resolve the identified non-conformity(ies). The corrective action plan shall, in all cases, at a minimum include the following required elements:

(i) An assessment and description of the nature, severity, and extent of the non-conformity;

(ii) Identification of all potentially affected customers;

(iii) A detailed description of how the health IT developer will promptly ensure that all potentially affected customers are notified of the non-conformity and plan for resolution;

(iv) A detailed description of how and when the health IT developer will resolve the identified non-conformity and all issues, both at the locations where the non-conformity was identified and for all affected customers;

(v) A detailed description of how the health IT developer will ensure that the identified non-conformity and all issues are resolved;

(vi) A detailed description of the supporting documentation that will be provided to demonstrate that the identified non-conformity and all issues are resolved; and

(vii) The timeframe under which all elements of the corrective action plan will be completed.

(viii) An explanation of, and agreement to execute, the steps that will be prevent the non-conformity from re-occurring.

(3) When ONC receives a proposed corrective action plan (or a revised proposed corrective action plan), it shall either approve the proposed corrective action plan or, if the plan does not adequately address all required elements, instruct the health IT developer to submit a revised proposed corrective action plan within a specified period of time.

(4) The health IT developer is responsible for ensuring that a proposed corrective action plan submitted in accordance with paragraph (b)(2)(ii)(A)(*4*) of this section or a revised corrective action plan submitted in accordance with paragraph (c)(3) of this section adequately addresses all required elements as determined by ONC no later than 90 days after the health IT developer's receipt of a notice of non-conformity.

(5) Health IT developers may request extensions for the submittal and/or completion of corrective action plans. In order to make these requests, health IT developers must submit a written statement to ONC that explains and justifies the extension request. ONC will evaluate each request individually and will make decisions on a case-by-case basis.

(6) Upon fulfilling all of its obligations under the corrective action plan, the health IT developer must submit an attestation to ONC, which serve as a binding official statement by the health IT developer that it has fulfilled all of its obligations under the corrective action plan.

(7) ONC may reinstitute a corrective action plan if it later determines that a health IT developer has not fulfilled all of its obligations under the corrective action plan as attested in accordance with paragraph (c)(6) of this section.

(d) *Suspension.* (1) ONC may suspend the certification of a Health IT Module at any time if ONC has a reasonable belief that the certified health IT may present a serious risk to public health or safety.

(2) When ONC decides to suspend a certification, ONC will notify the health IT developer of its determination through a notice of suspension.

(i) The notice of suspension will include, but may not be limited to:

(A) An explanation for the suspension;

(B) Information supporting the determination;

(C) The consequences of suspension for the health IT developer and the Health IT Module under the ONC Health IT Certification Program; and

(D) Instructions for appealing the suspension.

(ii) A suspension of a certification will become effective upon the date specified in the notice of suspension.

(3) The health IT developer must notify all potentially affected customers of the identified non-conformity(ies) and suspension of certification in a timely manner.

(4) When a certification is suspended, the health IT developer must cease and desist from any marketing, licensing, and sale of the suspended Health IT Module as ''certified'' under the ONC Health IT Certification Program from that point forward until such time ONC cancels the suspension in accordance with paragraph (d)(6) of this section.

(5) The certification of any health IT produced by a health IT developer that has the certification of one of its Health IT Modules suspended under the Program is prohibited, unless ONC cancels a suspension in accordance with paragraph (d)(6) of this section.

(6) ONC may cancel a suspension at any time if ONC no longer has a reasonable belief that the certified health IT presents a serious risk to public health or safety.

(e) *Proposed termination*—(1) *Applicability*. Excluding situations of non-compliance with a Condition or Maintenance of Certification requirement under subpart D of this part, ONC may propose to terminate a certification issued to a Health IT Module if:

(i) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(A) Fact-finding;

(B) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii)(A)(*3*) of this section;

(C) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(2)(ii)(A)(*3*) of this section; or

(D) A notice of suspension.

(ii) The information or access provided by the health IT developer in response to any ONC communication, including, but not limited to: Fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(iii) The health IT developer fails to cooperate with ONC and/or a third party acting on behalf of ONC;

(iv) The health IT developer fails to timely submit in writing a proposed corrective action plan;

(v) The health IT developer fails to timely submit a corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(vi) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or

(vii) ONC concludes that a certified health IT's non-conformity(ies) cannot be cured.

(2) When ONC decides to propose to terminate a certification, ONC will notify the health IT developer of the proposed termination through a notice of proposed termination.

(i) The notice of proposed termination will include, but may not be limited to:

(A) An explanation for the proposed termination;

(B) Information supporting the proposed termination; and

(C) Instructions for responding to the proposed termination.

(3) The health IT developer may respond to a notice of proposed termination, but must do so within 10 days of receiving the notice of proposed termination and must include appropriate documentation explaining in writing why its certification should not be terminated.

(4) Upon receipt of the health IT developer's written response to a notice of proposed termination, ONC has up to 30 days to review the information submitted by the health IT developer and make a determination. ONC may extend this timeframe if the complexity of the case requires additional time for ONC review. ONC will, as applicable:

(i) Notify the health IT developer in writing that it has ceased all or part of its review of the health IT developer's certified health IT.

(ii) Notify the health IT developer in writing of its intent to continue all or part of its review of the certified health IT under the provisions of this section.

(iii) Proceed to terminate the certification of the health IT under review consistent with paragraph (f) of this section.

(f) *Termination*—(1) *Applicability*. The National Coordinator may terminate a certification if:

(i) A determination is made that termination is appropriate after considering the information provided by the health IT developer in response to the proposed termination notice;

(ii) The health IT developer does not respond in writing to a proposed termination notice within the timeframe specified in paragraph (e)(3) of this section; or

(iii) A determination is made that the health IT developer is noncompliant with a Condition or Maintenance of Certification requirement under subpart D of this part or for the following circumstances when ONC exercises direct review under paragraph (a)(2)(iii) of this section:

(A) The health IT developer fails to timely respond to any communication from ONC, including, but not limited to:

(*1*) Fact-finding;

(*2*) A notice of potential non-conformity within the timeframe established in accordance with paragraph (b)(1)(ii)(A)(*3*) of this section; or

(*3*) A notice of non-conformity within the timeframe established in accordance with paragraph (b)(2)(ii)(A)(*3*) of this section.

(B) The information or access provided by the health IT developer in response to any ONC communication, including, but not limited to: Fact-finding, a notice of potential non-conformity, or a notice of non-conformity is insufficient or incomplete;

(C) The health IT developer fails to cooperate with ONC and/or a third party acting on behalf of ONC;

(D) The health IT developer fails to timely submit in writing a proposed corrective action plan;

(E) The health IT developer fails to timely submit a corrective action plan that adequately addresses the elements required by ONC as described in paragraph (c) of this section;

(F) The health IT developer does not fulfill its obligations under the corrective action plan developed in accordance with paragraph (c) of this section; or

(G) ONC concludes that the non-conformity(ies) cannot be cured.

(2) When ONC decides to terminate a certification, ONC will notify the health IT developer of its determination through a notice of termination.

(i) The notice of termination will include, but may not be limited to:

(A) An explanation for the termination;

(B) Information supporting the determination;

(C) The consequences of termination for the health IT developer and the Health IT Module under the ONC Health IT Certification Program; and

(D) Instructions for appealing the termination.

(ii) A termination of a certification will become effective after the following applicable occurrence:

(A) The expiration of the 10-day period for filing a statement of intent to appeal in paragraph (g)(3)(i) of this section if the health IT developer does not file a statement of intent to appeal.

(B) The expiration of the 30-day period for filing an appeal in paragraph (g)(3)(ii) of this section if the health IT developer files a statement of intent to appeal, but does not file a timely appeal.

(C) A final determination to terminate the certification per paragraph (g)(7) of this section if a health IT developer files an appeal.

(3) The health IT developer must notify all potentially affected customers of the identified non-conformity(ies) and termination of certification in a timely manner.

(4) ONC may rescind a termination determination before the termination becomes effective if ONC determines that termination is no longer appropriate.

(g) *Appeal*—(1) *Basis for appeal.* A health IT developer may appeal an ONC determination to suspend or terminate a certification issued to a Health IT Module and/or an ONC determination to issue a certification ban under § 170.581(a)(2) if the health IT developer asserts:

(i) ONC incorrectly applied ONC Health IT Certification Program requirements for a:

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2).

(ii) ONC's determination was not sufficiently supported by the information provided by ONC with its determination.

(2) *Method and place for filing an appeal.* A statement of intent to appeal followed by a request for appeal must be submitted to ONC in writing by an authorized representative of the health IT developer subject to the determination being appealed. The statement of intent to appeal and request for appeal must be filed in accordance with the requirements specified in the notice of:

(i) Termination;

(ii) Suspension; or

(iii) Certification ban under § 170.581(a)(2).

(3) *Time for filing a request for appeal.* (i) A statement of intent to appeal must be filed within 10 days of a health IT developer's receipt of the notice of:

(A) Suspension;

(B) Termination; or

(C) Certification ban under § 170.581(a)(2).

(ii) An appeal, including all supporting documentation, must be filed within 30 days of the filing of the intent to appeal.

(4) *Effect of appeal.* (i) A request for appeal stays the termination of a certification issued to a Health IT Module, but the Health IT Module is prohibited from being marketed, licensed, or sold as ''certified'' during the stay.

(ii) A request for appeal does not stay the suspension of a Health IT Module.

(iii) A request for appeal stays a certification ban issued under § 170.581(a)(2).

(5) *Appointment of a hearing officer.* The National Coordinator will assign the case to a hearing officer to adjudicate the appeal on his or her behalf.

(i) The hearing officer may not review an appeal in which he or she participated in the initial suspension, termination, or certification ban determination or has a conflict of interest in the pending matter.

(ii) The hearing officer must be trained in a nationally recognized ethics code that articulates nationally recognized standards of conduct for hearing officers/officials.

(6) *Adjudication.* (i) The hearing officer may make a determination based on:

(A) The written record, which includes the:

(1) ONC determination and supporting information;

(2) Information provided by the health IT developer with the appeal filed in accordance with paragraphs (g)(1) through (3) of this section; and

(3) Information ONC provides in accordance with paragraph (g)(6)(v) of this section; or

(B) All the information provided in accordance with paragraph (g)(6)(i)(A) and any additional information from a hearing conducted in-person, via telephone, or otherwise.

(ii) The hearing officer will have the discretion to conduct a hearing if he/she:

(A) Requires clarification by either party regarding the written record under paragraph (g)(6)(i)(A) of this section;

(B) Requires either party to answer questions regarding the written record under paragraph (g)(6)(i)(A) of this section; or

(C) Otherwise determines a hearing is necessary.

(iii) The hearing officer will neither receive witness testimony nor accept any new information beyond what was provided in accordance with paragraph (g)(6)(i) of this section.

(iv) The default process will be a determination in accordance with paragraph (g)(6)(i)(A) of this section.

(v) ONC will have an opportunity to provide the hearing officer with a written statement and supporting documentation on its behalf that clarifies,

as necessary, its determination to suspend or terminate the certification or issue a certification ban.

(7) *Determination by the hearing officer.* (i) The hearing officer will issue a written determination to the health IT developer within 30 days of receipt of the appeal or within a timeframe agreed to by the health IT developer and ONC and approved by the hearing officer, unless ONC cancels the suspension or rescinds the termination determination.

(ii) The National Coordinator's determination on appeal, as issued by the hearing officer, is final and not subject to further review.

[81 FR 72468, Oct. 19, 2016, as amended at 85 FR 25953, May 1, 2020]

§ 170.581 Certification ban.

(a) *Circumstances that may trigger a certification ban.* The certification of any of a health IT developer's health IT is prohibited when:

(1) The certification of one or more of the health IT developer's Health IT Modules is:

(i) Terminated by ONC under the ONC Health IT Certification Program;

(ii) Withdrawn from the ONC Health IT Certification Program by an ONC–ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer's health IT was the subject of a potential non-conformity or non-conformity as determined by ONC;

(iii) Withdrawn by an ONC–ACB because of a non-conformity with any of the certification criteria adopted by the Secretary under subpart C of this part;

(iv) Withdrawn by an ONC–ACB because the health IT developer requested it to be withdrawn (for reasons other than to comply with Program requirements) when the health IT developer's health IT was the subject of surveillance for a certification criterion or criteria adopted by the Secretary under subpart C of this part, including notice of pending surveillance; or

(2) ONC determines a certification ban is appropriate per its review under §170.580(a)(2)(iii).

(b) *Notice of certification ban.* When ONC decides to issue a certification ban to a health IT developer, ONC will notify the health IT developer of the certification ban through a notice of certification ban. The notice of certification ban will include, but may not be limited to:

(1) An explanation of the certification ban;

(2) Information supporting the certification ban;

(3) Instructions for appealing the certification ban if banned in accordance with paragraph (a)(2) of this section; and

(4) Instructions for requesting reinstatement into the ONC Health IT Certification Program, which would lift the certification ban.

(c) *Effective date of certification ban.* (1) A certification ban will be effective immediately if banned under paragraph (a)(1) of this section.

(2) For certification bans issued under paragraph (a)(2) of this section, the ban will be effective immediately after the following applicable occurrence:

(i) The expiration of the 10-day period for filing a statement of intent to appeal in §170.580(g)(3)(i) if the health IT developer does not file a statement of intent to appeal.

(ii) The expiration of the 30-day period for filing an appeal in §170.580(g)(3)(ii) if the health IT developer files a statement of intent to appeal, but does not file a timely appeal.

(iii) A final determination to issue a certification ban per §170.580(g)(7) if a health IT developer files an appeal timely.

(d) *Reinstatement.* The certification of a health IT developer's health IT subject to the prohibition in paragraph (a) of this section may commence once the following conditions are met.

(1) A health IT developer must request ONC's permission in writing to participate in the ONC Health IT Certification Program.

(2) The request must demonstrate that the customers affected by the certificate termination, certificate withdrawal, or noncompliance with a Condition or Maintenance of Certification requirement have been provided appropriate remediation.

(3) For noncompliance with a Condition or Maintenance of Certification

requirement, the noncompliance must be resolved.

(4) ONC is satisfied with the health IT developer's demonstration under paragraph (d)(2) of this section that all affected customers have been provided with appropriate remediation and grants reinstatement into the ONC Health IT Certification Program.

[85 FR 25954, May 1, 2020]

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish a document in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below. It is also available for inspection 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*.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41–22–749–01–11, *http://www.iso.org*.

(1) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, ''ISO/IEC Guide 65,'' IBR approved for § 170.503.

(2) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, ''ISO/IEC 17011,'' IBR approved for § 170.503.

(3) ISO/IEC 17025:2005(E)—General requirements for the competence of testing and calibration laboratories (Second Edition), 2005–05–15, ''ISO/IEC 17025,'' IBR approved for §§ 170.520(b) and 170.524(a).

(4) ISO/IEC 17025:2017(E)—General requirements for the competence of testing and calibration laboratories (Third Edition), 2017–11, ''ISO/IEC 17025,'' IBR approved for §§ 170.520(b), and 170.524(a).

(5) ISO/IEC 17065:2012(E)—Conformity assessment—Requirements for bodies certifying products, processes and services (First Edition), 2012, ''ISO/IEC 17065,'' IBR approved for §§ 170.503 and 170.523(a).

[81 FR 72471, Oct. 19, 2016, as amended at 85 FR 25955, May 1, 2020]

PART 171—INFORMATION BLOCKING

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AUTHORITY: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

SOURCE: 85 FR 25955, May 1, 2020, unless otherwise noted.

Subpart A—General Provisions

§ 171.100 Statutory basis and purpose.

(a) *Basis.* This part implements section 3022 of the Public Health Service Act, 42 U.S.C. 300jj–52.

(b) *Purpose.* The purpose of this part is to establish exceptions for reasonable and necessary activities that do not constitute information blocking as defined by section 3022(a)(1) of the Public Health Service Act, 42 U.S.C. 300jj–52.

§ 171.101 Applicability.

(a) This part applies to health care providers, health IT developers of certified health IT, health information exchanges, and health information networks, as those terms are defined in § 171.102.

(b) Health care providers, health IT developers of certified health IT, health information exchanges, and health information networks are subject to this part on and after April 5, 2021.

[85 FR 25955, May 1, 2020, as amended at 85 FR 70085, Nov. 4, 2020]

§ 171.102 Definitions.

For purposes of this part:

Access means the ability or means necessary to make electronic health information available for exchange or use.

Actor means a health care provider, health IT developer of certified health IT, health information network or health information exchange.

API Information Source is defined as it is in § 170.404(c).

API User is defined as it is in § 170.404(c).

Appropriate agency means a government agency that has established disincentives for health care providers that the Office of Inspector General (OIG) determines have committed information blocking.

Business associate is defined as it is in 45 CFR 160.103.

Certified API Developer is defined as it is in § 170.404(c).

Certified API technology is defined as it is in § 170.404(c).

Disincentive means a condition specified in § 171.1001(a) that is imposed by

an appropriate agency on a health care provider that OIG determines has committed information blocking for the purpose of deterring information blocking practices.

Electronic health information (EHI) means electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

(1) Psychotherapy notes as defined in 45 CFR 164.501; or

(2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Exchange means the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks.

Fee means any present or future obligation to pay money or provide any other thing of value.

Health care provider has the same meaning as ''health care provider'' in 42 U.S.C. 300jj.

Health information network or *health information exchange* means an individual or entity that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or services for access, exchange, or use of electronic health information:

(1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and

(2) That is for a treatment, payment, or health care operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164.

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT that is not offered to others, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)), and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj–11(c)(5) (ONC Health IT Certification Program).

Information blocking is defined as it is in § 171.103.

Interfere with or *interference* means to prevent, materially discourage, or otherwise inhibit.

Interoperability element means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that:

(1) May be necessary to access, exchange, or use electronic health information; and

(2) Is/Are controlled by the actor, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of electronic health information.

Offer health information technology or *offer health IT* means to hold out for sale, resale, license, or relicense or to sell, resell, license, relicense, or otherwise provide or supply health information technology (as that term is defined in 42 U.S.C. 300jj(5) and where such health information technology includes one or more Health IT Modules certified under the ONC Health IT Certification Program) for deployment by or for other individual(s) or entity(ies) under any arrangement except an arrangement consistent with subparagraph (3)(iii), below. Activities and arrangements described in subparagraphs (1) through (3) are considered to be excluded from what it means to offer health IT.

(1) Donation and subsidized supply arrangements are not considered offerings when an individual or entity donates, gives, or otherwise makes available funding to subsidize or fully cover the costs of a health care provider's acquisition, augmentation, or upkeep of health IT, provided such individual or entity offers and makes such subsidy

without condition(s) limiting the interoperability or use of the technology to access, exchange or use electronic health information for any lawful purpose.

(2) Implementation and use activities conducted by an individual or entity as follows:

(i) Issuing user accounts or login credentials to the individual's or entity's employees in the course of their employment or contractors within the scope of their contract in order for such employees or contractors to: use, operate, implement, configure, test, maintain, update or upgrade, or to give or receive training on, the individual's or entity's health IT system(s) or specific application(s) within such system(s).

(ii) Implementing, operating, or otherwise making available production instances of application programming interface (API) technology that supports access, exchange, and use of electronic health information that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a health information network or health information exchange.

(iii) Implementing, operating, and making available production instances of online portals for patients, clinicians or other health care providers, or public health entities to access, exchange, and use electronic health information that the individual or entity has in its possession, custody, control, or ability to query or transmit from or across a health information network or health information exchange.

(iv) Issuing login credentials or user accounts for the individual's or entity's production, development, or testing environments to public health authorities, or such authorities' employees or contractors, as a means of accomplishing or facilitating access, exchange, and use of electronic health information for public health purposes including but not limited to syndromic surveillance.

(v) Issuing login credentials or user accounts for independent healthcare professionals who furnish services in a healthcare facility to use the facility's electronic health record or other health IT system(s) in: furnishing, documenting, and accurately billing for care furnished in the facility; participating in clinical education or improvement activities conducted by or in the healthcare facility; or receiving training in use of the healthcare facility's health IT system(s).

(3) Consulting and legal services arrangements as follows:

(i) Legal services furnished by outside counsel—when furnishing legal services to a client in any matter or matters pertaining to the client's seeking, assessing, selecting, or resolving disputes over contracts or other arrangements by which the client obtains use of certified health IT. Outside counsel also does not offer health IT when facilitating limited access or use of a client's health IT by independent expert witnesses engaged by the outside counsel, opposing parties' counsel and experts, and special masters and court personnel, as appropriate to legal discovery.

(ii) Health IT consultant assistance with selection, implementation, and use of health IT —furnished to a health IT customer or user to help the customer do (or to do on behalf of a customer) any or all of the following with respect to any health IT product that the consultant does not sell or resell, license or relicense, or otherwise supply to the customer under any arrangement on a commercial basis or otherwise:

(A) Define the business needs of the customer or user or evaluate health IT product(s) against such business needs, or both;

(B) Negotiate for the purchase, lease, license, or other arrangement under which the health IT product(s) will be used; or

(C) Oversee or carry out configuration, implementation, or operation of health IT product(s).

(iii) Comprehensive and predominantly non-health IT administrative or operations management services—when an individual or entity furnishes a health care provider with administrative or operational management consultant services and the consultant acts as the agent of the provider or otherwise acts on behalf of the provider in dealings with one or more health IT developer(s) or vendor(s), or managing

the day-to-day operations and administrative duties for the health IT, or both. To be consistent with this subparagraph, such services must be furnished as part of a comprehensive array of predominantly non-health IT administrative and operational functions that would otherwise be executed by the health care provider.

Permissible purpose means a purpose for which a person is authorized, permitted, or required to access, exchange, or use electronic health information under applicable law.

Person is defined as it is in 45 CFR 160.103.

Practice means an act or omission by an actor.

Use means the ability for electronic health information, once accessed or exchanged, to be understood and acted upon.

[85 FR 25955, May 1, 2020, as amended at 89 FR 1435, Jan. 9, 2024; 89 FR 54717, July 1, 2024]

§ 171.103 Information blocking.

(a) Information blocking means a practice that except as required by law or covered by an exception set forth in subparts B, C, or D of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(b) If conducted by:

(1) A health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or

(2) A health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

[89 FR 1436, Jan. 9, 2024]

Subpart B—Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use Electronic Health Information

§ 171.200 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in this subpart B by meeting all applicable requirements and conditions of the exception at all relevant times.

§ 171.201 Preventing harm exception—when will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm will not be considered information blocking when the practice meets the conditions in paragraphs (a) and (b) of this section, satisfies at least one condition from each of paragraphs (c), (d), and (f) of this section, and also meets the condition in paragraph (e) of this section when applicable.

(a) *Reasonable belief.* The actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice. For purposes of this section, ''patient'' means a natural person who is the subject of the electronic health information affected by the practice.

(b) *Practice breadth.* The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.

(c) *Type of risk.* The risk of harm must:

(1) Be determined on an individualized basis in the exercise of professional judgment by a licensed health care professional who has a current or prior clinician-patient relationship with the patient whose electronic health information is affected by the determination; *or*

(2) Arise from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

(d) *Type of harm.* The type of harm must be one that could serve as grounds for a covered entity (as defined

in §160.103 of this title) to deny access (as the term ''access'' is used in part 164 of this title) to an individual's protected health information under:

(1) Section 164.524(a)(3)(iii) of this title where the practice is likely to, or in fact does, interfere with access, exchange, or use (as these terms are defined in §171.102) of the patient's electronic health information by their legal representative (including but not limited to personal representatives recognized pursuant to 45 CFR 164.502) and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;

(2) Section 164.524(a)(3)(ii) of this title where the practice is likely to, or in fact does, interfere with the patient's or their legal representative's access to, use or exchange (as these terms are defined in §171.102) of information that references another natural person and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;

(3) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with the patient's access, exchange, or use (as these terms are defined in §171.102) of their own electronic health information, regardless of whether the risk of harm that the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section; or

(4) Section 164.524(a)(3)(i) of this title where the practice is likely to, or in fact does, interfere with a legally permissible access, exchange, or use (as these terms are defined in §171.102) of electronic health information not described in paragraph (d)(1), (2), or (3) of this section, and regardless of whether the risk of harm the practice is implemented to substantially reduce is consistent with paragraph (c)(1) or (2) of this section.

(e) *Patient right to request review of individualized determination of risk of harm.* Where the risk of harm is consistent with paragraph (c)(1) of this section, the actor must implement the practice in a manner consistent with any rights the individual patient whose electronic health information is affected may have under §164.524(a)(4) of this title, or any Federal, State, or tribal law, to have the determination reviewed and potentially reversed.

(f) *Practice implemented based on an organizational policy or a determination specific to the facts and circumstances.* The practice must be consistent with an organizational policy that meets paragraph (f)(1) of this section or, in the absence of an organizational policy applicable to the practice or to its use in particular circumstances, the practice must be based on a determination that meets paragraph (f)(2) of this section.

(1) An organizational policy must:

(i) Be in writing;

(ii) Be based on relevant clinical, technical, and other appropriate expertise;

(iii) Be implemented in a consistent and non-discriminatory manner; and

(iv) Conform each practice to the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use.

(2) A determination must:

(i) Be based on facts and circumstances known or reasonably believed by the actor at the time the determination was made and while the practice remains in use; and

(ii) Be based on expertise relevant to implementing the practice consistent with the conditions in paragraphs (a) and (b) of this section, as well as the conditions in paragraphs (c) through (e) of this section that are applicable to the practice and its use in particular circumstances.

§171.202 Privacy exception—When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy not be considered information blocking?

An actor's practice of not fulfilling a request to access, exchange, or use electronic health information in order to protect an individual's privacy will not be considered information blocking when the practice meets all of the requirements of at least one of the subexceptions in paragraphs (b) through (e) of this section.

(a) *Definitions in this section.* (1) The term *HIPAA Privacy Rule* as used in this section means 45 CFR parts 160 and 164.

(2) The term *individual* as used in this section means one or more of the following—

(i) An individual as defined by 45 CFR 160.103.

(ii) Any other natural person who is the subject of the electronic health information being accessed, exchanged, or used.

(iii) A person who legally acts on behalf of a person described in paragraph (a)(1) or (2) of this section in making decisions related to health care as a personal representative, in accordance with 45 CFR 164.502(g).

(iv) A person who is a legal representative of and can make health care decisions on behalf of any person described in paragraph (a)(1) or (2) of this section.

(v) An executor, administrator, or other person having authority to act on behalf of a deceased person described in paragraph (a)(1) or (2) of this section or the individual's estate under State or other law.

(b) *Sub-exception—precondition not satisfied.* To qualify for the exception on the basis that State or Federal law requires one or more preconditions for providing access, exchange, or use of electronic health information that have not been satisfied, the following requirements must be met—

(1) The actor's practice is tailored to the applicable precondition not satisfied, is implemented in a consistent and non-discriminatory manner, and either:

(i) Conforms to the actor's organizational policies and procedures that:

(A) Are in writing;

(B) Specify the criteria to be used by the actor to determine when the precondition would be satisfied and, as applicable, the steps that the actor will take to satisfy the precondition; and

(C) Are implemented by the actor, including by providing training on the policies and procedures; or

(ii) Are documented by the actor, on a case-by-case basis, identifying the criteria used by the actor to determine when the precondition would be satisfied, any criteria that were not met, and the reason why the criteria were not met.

(2) If the precondition relies on the provision of a consent or authorization from an individual and the actor has received a version of such a consent or authorization that does not satisfy all elements of the precondition required under applicable law, the actor must:

(i) Use reasonable efforts within its control to provide the individual with a consent or authorization form that satisfies all required elements of the precondition or provide other reasonable assistance to the individual to satisfy all required elements of the precondition; and

(ii) Not improperly encourage or induce the individual to withhold the consent or authorization.

(3) For purposes of determining whether the actor's privacy policies and procedures and actions satisfy the requirements of paragraphs (b)(1)(i) and (b)(2) above when the actor's operations are subject to multiple laws which have inconsistent preconditions, they shall be deemed to satisfy the requirements of the paragraphs if the actor has adopted uniform privacy policies and procedures to address the more restrictive preconditions.

(c) *Sub-exception—health IT developer of certified health IT not covered by HIPAA.* If the actor is a health IT developer of certified health IT that is not required to comply with the HIPAA Privacy Rule, when engaging in a practice that promotes the privacy interests of an individual, the actor's organizational privacy policies must have been disclosed to the individuals and entities that use the actor's product or service before they agreed to use them, and must implement the practice according to a process described in the organizational privacy policies. The actor's organizational privacy policies must:

(1) Comply with State and Federal laws, as applicable;

(2) Be tailored to the specific privacy risk or interest being addressed; and

(3) Be implemented in a consistent and non-discriminatory manner.

(d) *Sub-exception—denial of an individual's request for their electronic health information consistent with 45 CFR*

164.524(a)(1) and (2). If an individual requests electronic health information under the right of access provision under 45 CFR 164.524(a)(1) from an actor that must comply with 45 CFR 164.524(a)(1), the actor's practice must be consistent with 45 CFR 164.524(a)(2).

(e) *Sub-exception—respecting an individual's request not to share information*. Unless otherwise required by law, an actor may elect not to provide access, exchange, or use of an individual's electronic health information if the following requirements are met—

(1) The individual requests that the actor not provide such access, exchange, or use of electronic health information without any improper encouragement or inducement of the request by the actor;

(2) The actor documents the request within a reasonable time period;

(3) The actor's practice is implemented in a consistent and non-discriminatory manner; and

(4) An actor may terminate an individual's request for a restriction to not provide such access, exchange, or use of the individual's electronic health information only if:

(i) The individual agrees to the termination in writing or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented by the actor; or

(iii) The actor informs the individual that it is terminating its agreement to not provide such access, exchange, or use of the individual's electronic health information except that such termination is:

(A) Not effective to the extent prohibited by applicable Federal or State law; and

(B) Only applicable to electronic health information created or received after the actor has so informed the individual of the termination.

§ 171.203 Security exception—When will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to protect the security of electronic health information not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to protect the security of electronic health information will not be considered information blocking when the practice meets the conditions in paragraphs (a), (b), and (c) of this section, and in addition meets either the condition in paragraph (d) of this section or the condition in paragraph (e) of this section.

(a) The practice must be directly related to safeguarding the confidentiality, integrity, and availability of electronic health information.

(b) The practice must be tailored to the specific security risk being addressed.

(c) The practice must be implemented in a consistent and non-discriminatory manner.

(d) If the practice implements an organizational security policy, the policy must—

(1) Be in writing;

(2) Have been prepared on the basis of, and be directly responsive to, security risks identified and assessed by or on behalf of the actor;

(3) Align with one or more applicable consensus-based standards or best practice guidance; and

(4) Provide objective timeframes and other parameters for identifying, responding to, and addressing security incidents.

(e) If the practice does not implement an organizational security policy, the actor must have made a determination in each case, based on the particularized facts and circumstances, that:

(1) The practice is necessary to mitigate the security risk to electronic health information; and

(2) There are no reasonable and appropriate alternatives to the practice that address the security risk that are less likely to interfere with access, exchange or use of electronic health information.

[85 FR 25955, May 1, 2020, as amended at 85 FR 70085, Nov. 4, 2020]

§ 171.204 Infeasibility exception—When will an actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request not be considered information blocking?

An actor's practice of not fulfilling a request to access, exchange, or use electronic health information due to the infeasibility of the request will not be considered information blocking when the practice meets one of the conditions in paragraph (a) of this section and meets the requirements in paragraph (b) of this section.

(a) *Conditions*—(1) *Uncontrollable events.* The actor cannot fulfill the request for access, exchange, or use of electronic health information because of a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority that in fact negatively impacts the actor's ability to fulfill the request.

(2) *Segmentation.* The actor cannot fulfill the request for access, exchange, or use of electronic health information because the actor cannot unambiguously segment the requested electronic health information from electronic health information that:

(i) Cannot be made available due to an individual's preference or because the electronic health information cannot be made available by law; or

(ii) May be withheld in accordance with § 171.201.

(3) *Third party seeking modification use.* The request is to enable use of EHI in order to modify EHI provided that the request for such use is not from a health care provider requesting such use from an actor that is its business associate.

(4) *Manner exception exhausted.* The actor is unable to fulfill a request for access, exchange, or use of electronic health information because paragraphs (a)(4)(i), (ii), and (iii) of this section are all true; and the actor complied with paragraph (a)(4)(iv) of this section.

(i) The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested.

(ii) The actor offered at least two alternative manners in accordance with § 171.301(b), one of which must use either technology certified to standard(s) adopted in part 170 (§ 171.301(b)(1)(i)) or published content and transport standards consistent with § 171.301(b)(1)(ii).

(iii) The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

(iv) In determining whether a requestor is similarly situated under paragraph (a)(4)(iii), an actor shall not discriminate based on:

(A) Whether the requestor is an individual as defined in § 171.202(a)(2)

(B) The health care provider type and size; and

(C) Whether the requestor is a competitor of the actor or whether providing such access, exchange, or use, would facilitate competition with the actor.

(5) *Infeasible under the circumstances.* (i) The actor demonstrates, prior to responding to the request pursuant to paragraph (b) of this section, through a contemporaneous written record or other documentation, its consistent and non-discriminatory consideration of the following factors that led to its determination that complying with the request would be infeasible under the circumstances:

(A) The type of electronic health information and the purposes for which it may be needed;

(B) The cost to the actor of complying with the request in the manner requested;

(C) The financial and technical resources available to the actor;

(D) Whether the actor's practice is non-discriminatory and the actor provides the same access, exchange, or use of electronic health information to its companies or to its customers, suppliers, partners, and other persons with whom it has a business relationship;

(E) Whether the actor owns or has control over a predominant technology, platform, health information

exchange, or health information network through which electronic health information is accessed or exchanged; and

(F) Why the actor was unable to provide access, exchange, or use of electronic health information consistent with the exception in § 171.301.

(ii) In determining whether the circumstances were infeasible under paragraph (a)(3)(i) of this section, it shall not be considered whether the manner requested would have:

(A) Facilitated competition with the actor; or

(B) Prevented the actor from charging a fee or resulted in a reduced fee.

(b) *Responding to requests.* If an actor does not fulfill a request for access, exchange, or use of electronic health information for any of the reasons provided in paragraph (a) of this section, the actor must, within ten business days of receipt of the request, provide to the requestor in writing the reason(s) why the request is infeasible.

[85 FR 25955, May 1, 2020, as amended at 89 FR 1436, Jan. 9, 2024]

§ 171.205 Health IT performance exception—When will an actor's practice that is implemented to maintain or improve health IT performance and that is likely to interfere with the access, exchange, or use of electronic health information not be considered information blocking?

An actor's practice that is implemented to maintain or improve health IT performance and that is likely to interfere with the access, exchange, or use of electronic health information will not be considered information blocking when the practice meets a condition in paragraph (a), (b), (c), or (d) of this section, as applicable to the particular practice and the reason for its implementation.

(a) *Maintenance and improvements to health IT.* When an actor implements a practice that makes health IT under that actor's control temporarily unavailable, or temporarily degrades the performance of health IT, in order to perform maintenance or improvements to the health IT, the actor's practice must be—

(1) Implemented for a period of time no longer than necessary to complete the maintenance or improvements for which the health IT was made unavailable or the health IT's performance degraded;

(2) Implemented in a consistent and non-discriminatory manner; and

(3) If the unavailability or degradation is initiated by a health IT developer of certified health IT, health information exchange, or health information network:

(i) *Planned.* Consistent with existing service level agreements between the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network supplied the health IT; or

(ii) *Unplanned.* Consistent with existing service level agreements between the individual or entity; or agreed to by the individual or entity to whom the health IT developer of certified health IT, health information exchange, or health information network supplied the health IT.

(b) *Assured level of performance.* An actor may take action against a third-party application that is negatively impacting the health IT's performance, provided that the practice is—

(1) For a period of time no longer than necessary to resolve any negative impacts;

(2) Implemented in a consistent and non-discriminatory manner; and

(3) Consistent with existing service level agreements, where applicable.

(c) *Practices that prevent harm.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a risk of harm to a patient or another person, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.201 at all relevant times to qualify for an exception.

(d) *Security-related practices.* If the unavailability of health IT for maintenance or improvements is initiated by an actor in response to a security risk to electronic health information, the actor does not need to satisfy the requirements of this section, but must comply with all requirements of § 171.203 at all relevant times to qualify for an exception.

Subpart C—Exceptions That Involve Procedures for Fulfilling Requests to Access, Exchange, or Use Electronic Health Information

§ 171.300 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in this subpart C by meeting all applicable requirements and conditions of the exception at all relevant times.

§ 171.301 Manner exception—When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested.* (1) An actor must fulfill a request for electronic health information in any manner requested, unless the actor is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested.

(2) If an actor fulfills a request for electronic health information in any manner requested:

(i) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(ii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(b) *Alternative manner.* If an actor does not fulfill a request for electronic health information in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request in the manner requested, the actor must fulfill the request in an alternative manner, as follows:

(1) The actor must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph (b)(1)(i) of this section and only proceeding to the next consecutive paragraph if the actor is technically unable to fulfill the request in the manner identified in a paragraph.

(i) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.

(ii) Using content and transport standards specified by the requestor and published by:

(A) The Federal Government; or

(B) A standards developing organization accredited by the American National Standards Institute.

(iii) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor.

(2) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302.

(3) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

[89 FR 1437, Jan. 9, 2024]

§ 171.302 Fees exception—When will an actor's practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking?

An actor's practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using electronic health information will not be considered information blocking when the practice meets the conditions in paragraph (a) of this section, does not include any of the excluded fees in paragraph (b) of this section, and, as applicable, meets the condition in paragraph (c) of this section.

(a) *Basis for fees condition.* (1) The fees an actor charges must be—

(i) Based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;

(ii) Reasonably related to the actor's costs of providing the type of access, exchange, or use of electronic health information to, or at the request of, the person or entity to whom the fee is charged;

(iii) Reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and

(iv) Based on costs not otherwise recovered for the same instance of service to a provider and third party.

(2) The fees an actor charges must not be based on—

(i) Whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor;

(ii) Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the electronic health information;

(iii) Costs the actor incurred due to the health IT being designed or implemented in a non-standard way, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information;

(iv) Costs associated with intangible assets other than the actual development or acquisition costs of such assets;

(v) Opportunity costs unrelated to the access, exchange, or use of electronic health information; or

(vi) Any costs that led to the creation of intellectual property, if the actor charged a royalty for that intellectual property pursuant to §171.303 and that royalty included the development costs for the creation of the intellectual property.

(b) *Excluded fees condition.* This exception does not apply to—

(1) A fee prohibited by 45 CFR 164.524(c)(4);

(2) A fee based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual;

(3) A fee to perform an export of electronic health information via the capability of health IT certified to §170.315(b)(10) of this subchapter for the purposes of switching health IT or to provide patients their electronic health information; and

(4) A fee to export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.

(c) *Compliance with the Conditions of Certification condition.* Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the Conditions of Certification in §170.402(a)(4), §170.404, or both of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

(d) *Definition of Electronic access.* The following definition applies to this section:

Electronic access means an internet-based method that makes electronic health information available at the time the electronic health information is requested and where no manual effort is required to fulfill the request.

§171.303 Licensing exception—When will an actor's practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking?

An actor's practice to license interoperability elements for electronic health information to be accessed, exchanged, or used will not be considered information blocking when the practice meets all of the following conditions.

(a) *Negotiating a license conditions.* Upon receiving a request to license an interoperability element for the access, exchange, or use of electronic health information, the actor must—

(1) Begin license negotiations with the requestor within 10 business days from receipt of the request; and

(2) Negotiate a license with the requestor, subject to the licensing conditions in paragraph (b) of this section, within 30 business days from receipt of the request.

(b) *Licensing conditions.* The license provided for the interoperability element(s) needed to access, exchange, or use electronic health information must meet the following conditions:

(1) *Scope of rights.* The license must provide all rights necessary to:

(i) Enable the access, exchange, or use of electronic health information; and

(ii) Achieve the intended access, exchange, or use of electronic health information via the interoperability element(s).

(2) *Reasonable royalty.* If the actor charges a royalty for the use of the interoperability elements described in paragraph (a) of this section, the royalty must be reasonable and comply with the following requirements:

(i) The royalty must be nondiscriminatory, consistent with paragraph (b)(3) of this section.

(ii) The royalty must be based solely on the independent value of the actor's technology to the licensee's products, not on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using electronic health information.

(iii) If the actor has licensed the interoperability element through a standards developing organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on terms consistent with those in this exception, the actor may charge a royalty that is consistent with such policies.

(iv) An actor may not charge a royalty for intellectual property if the actor recovered any development costs pursuant to § 171.302 that led to the creation of the intellectual property.

(3) *Non-discriminatory terms.* The terms (including royalty terms) on which the actor licenses and otherwise provides the interoperability elements must be non-discriminatory and comply with the following requirements:

(i) The terms must be based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons and requests.

(ii) The terms must not be based in any part on—

(A) Whether the requestor or other person is a competitor, potential competitor, or will be using electronic health information obtained via the interoperability elements in a way that facilitates competition with the actor; or

(B) The revenue or other value the requestor may derive from access, exchange, or use of electronic health information obtained via the interoperability elements.

(4) *Collateral terms.* The actor must not require the licensee or its agents or contractors to do, or to agree to do, any of the following—

(i) Not compete with the actor in any product, service, or market.

(ii) Deal exclusively with the actor in any product, service, or market.

(iii) Obtain additional licenses, products, or services that are not related to or can be unbundled from the requested interoperability elements.

(iv) License, grant, assign, or transfer to the actor any intellectual property of the licensee.

(v) Pay a fee of any kind whatsoever, except as described in paragraph (b)(2) of this section, unless the practice meets the requirements of the exception in § 171.302.

(5) *Non-disclosure agreement.* The actor may require a reasonable non-disclosure agreement that is no broader than necessary to prevent unauthorized disclosure of the actor's trade secrets, provided—

(i) The agreement states with particularity all information the actor claims as trade secrets; and

(ii) Such information meets the definition of a trade secret under applicable law.

(c) *Additional conditions relating to the provision of interoperability elements.* The actor must not engage in any practice that has any of the following purposes or effects.

(1) Impeding the efficient use of the interoperability elements to access, exchange, or use electronic health information for any permissible purpose.

(2) Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand.

(3) Degrading the performance or interoperability of the licensee's products or services, unless necessary to improve the actor's technology and

after affording the licensee a reasonable opportunity to update its technology to maintain interoperability.

[85 FR 25955, May 1, 2020, as amended at 85 FR 70085, Nov. 4, 2020]

Subpart D—Exceptions That Involve Practices Related to Actors' Participation in The Trusted Exchange Framework and Common Agreement (TEFCA℠)

SOURCE: 89 FR 1437, Jan. 9, 2024, unless otherwise noted.

§ 171.400 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in this subpart D by meeting all applicable requirements and conditions of the exception at all relevant times.

§§ 171.401—171.402 [Reserved]

§ 171.403 TEFCA manner exception—When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information to only via TEFCA not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request for access, exchange, or use of electronic health information to only via TEFCA will not be considered information blocking when the practice follows the conditions specified in paragraphs (a) through (d) of this section.

(a) *Mutually part of TEFCA.* The actor and requestor are both part of TEFCA.

(b) *Requestor capability.* The requestor is capable of such access, exchange, or use of the requested electronic health information from the actor via TEFCA.

(c) *Limitation.* The request for access, exchange, or use of EHI is not via the standards adopted in 45 CFR 170.215, including version(s) of those standards approved pursuant to 45 CFR 170.405(b)(8).

(d) *Fees and licensing.* (1) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302; and

(2) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

Subparts E–I [RESERVED]

Subpart J—Disincentives for Information Blocking by Health Care Providers

SOURCE: 89 FR 54717, July 1, 2024, unless otherwise noted.

§ 171.1000 Scope.

This subpart sets forth disincentives that an appropriate agency may impose on a health care provider that OIG determines has committed information blocking, and certain procedures related to those disincentives.

§ 171.1001 Disincentives.

(a) Centers for Medicare & Medicaid Services may apply the following disincentives:

(1) An eligible hospital or critical access hospital (CAH) as defined in 42 CFR 495.4 is not a meaningful electronic health record (EHR) user as also defined in 42 CFR 495.4.

(2) A Merit-based Incentive Payment System (MIPS) eligible clinician as defined in 42 CFR 414.1305, who is also a health care provider as defined in § 171.102, is not a meaningful EHR user for MIPS as defined in 42 CFR 414.1305.

(3) Accountable care organizations (ACOs) who are health care providers as defined in § 171.102, ACO participants, and ACO providers/suppliers will be removed from, or denied approval to participate, in the Medicare Shared Savings Program as defined in 42 CFR part 425 for at least 1 year.

(b) [Reserved]

§ 171.1002 Notice of disincentive.

Following referral of a determination of information blocking by OIG, an appropriate agency that imposes a disincentive or disincentives specified in § 171.1001 shall send a notice to the health care provider subject to the disincentive or disincentives, via usual methods of communication for the program or payment system under which

the disincentive is applied, that includes:

(a) A description of the practice or practices that formed the basis for the determination of information blocking referred by OIG;

(b) The basis for the application of the disincentive or disincentives being imposed;

(c) The effect of each disincentive; and

(d) Any other information necessary for a health care provider to understand how each disincentive will be implemented.

Subpart K—Transparency for Information Blocking Determinations, Disincentives, and Penalties

AUTHORITY: 42 U.S.C. 300jj–11(c)(4).

SOURCE: 89 FR 54718, July 1, 2024, unless otherwise noted.

§ 171.1100 Scope.

This subpart sets forth the information that will be posted on the Office of the National Coordinator for Health Information Technology's (ONC) public website about actors that have been determined by the HHS Office of Inspector General to have committed information blocking.

§ 171.1101 Posting of information for actors found to have committed information blocking.

(a) *Health care providers.* (1) ONC will post on its public website the following information about health care providers that have been subject to a disincentive in §171.1001(a) for information blocking:

(i) Health care provider name;

(ii) Business address;

(iii) The practice, as the term is defined in §171.102 and referenced in §171.103, found to have been information blocking, including when the practice occurred;

(iv) Disincentive(s) applied; and

(v) Where to find any additional information about the determination of information blocking that is publicly available via HHS or, where applicable, another part of the U.S. Government.

(2) The information specified in paragraph (a)(1) of this section will not be posted prior to a disincentive being imposed or the completion of any administrative appeals process pursued by the health care provider, and will not include information about a disincentive that has not been applied.

(3) Posting of the information specified in paragraph (a)(1) of this section will be conducted in accordance with existing rights to review information that may be associated with a disincentive specified in §171.1001.

(b) *Health IT developers of certified health IT and health information networks or health information exchanges.* (1) ONC will post on its public website the following information, to the extent applicable, about health information networks/health information exchanges and health IT developers of certified health IT (actors) that have been determined by the HHS Office of Inspector General to have committed information blocking:

(i) Type of actor;

(ii) Actor's legal name, including any alternative or additional trade name(s) under which the actor operates;

(iii) The practice, as the term is defined in §171.102 and referenced in §171.103, found to have been information blocking or alleged to be information blocking in the situation specified in paragraph (b)(2)(i) of this section, and including when the practice occurred; and

(iv) Where to find any additional information about the determination (or resolution of information blocking as specified in paragraph (b)(2)(i) of this section) of information blocking that is publicly available via HHS or, where applicable, another part of the U.S. Government.

(2) The information specified in paragraph (b)(1) of this section will not be posted until one of the following occurs:

(i) OIG enters into a resolution of civil money penalty (CMP) liability; or

(ii) A CMP imposed under subpart N of 42 CFR part 1003 has become final consistent with the procedures in subpart O of 42 CFR part 1003.

PARTS 172–179 [RESERVED]

SUBCHAPTER E—PRICE TRANSPARENCY

PART 180—HOSPITAL PRICE TRANSPARENCY

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AUTHORITY: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

SOURCE: 84 FR 65602, Nov. 27, 2019, unless otherwise noted.

Subpart A—General Provisions

§ 180.10 Basis and scope.

This part implements section 2718(e) of the Public Health Service (PHS) Act, which requires each hospital operating within the United States, for each year, to establish, update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. This part also implements section 2718(b)(3) of the PHS Act, to the extent that section authorizes CMS to promulgate regulations for enforcing section 2718(e). This part also implements section 1102(a) of the Social Security Act, which authorizes the Secretary to make and publish rules and regulations, not inconsistent with that Act, as may be necessary to the efficient administration of the functions for which the Secretary is charged under that Act.

§ 180.20 Definitions.

The following definitions apply to this part, unless specified otherwise:

Ancillary service means an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service.

Chargemaster (Charge Description Master or CDM) means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.

CMS template means a CSV format or JSON schema that CMS makes available for purposes of compliance with § 180.40(a).

De-identified maximum negotiated charge means the highest charge that a hospital has negotiated with all third party payers for an item or service.

De-identified minimum negotiated charge means the lowest charge that a hospital has negotiated with all third party payers for an item or service.

Discounted cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.

Encode means to convert hospital standard charge information into a machine-readable format that complies with § 180.50(c)(2).

Estimated allowed amount means the average dollar amount that the hospital has historically received from a third party payer for an item or service.

Gross charge means the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.

Hospital means an institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. For purposes of this definition, a State includes each of the

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

Items and services means all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples include, but are not limited to, the following:

(1) Supplies and procedures.

(2) Room and board.

(3) Use of the facility and other items (generally described as facility fees).

(4) Services of employed physicians and non-physician practitioners (generally reflected as professional charges).

(5) Any other items or services for which a hospital has established a standard charge.

Machine-readable file means a single digital file that is in a machine-readable format.

Machine-readable format means a digital representation of data or information in a file that can be imported or read into a computer system for further processing.

Payer-specific negotiated charge means the charge that a hospital has negotiated with a third party payer for an item or service.

Service package means an aggregation of individual items and services into a single service with a single charge.

Shoppable service means a service that can be scheduled by a healthcare consumer in advance.

Standard charge means the regular rate established by the hospital for an item or service provided to a specific group of paying patients. This includes all of the following as defined under this section:

(1) Gross charge.

(2) Payer-specific negotiated charge.

(3) De-identified minimum negotiated charge.

(4) De-identified maximum negotiated charge.

(5) Discounted cash price.

State forensic hospital means a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.

Third party payer means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021; 88 FR 82184, Nov. 22, 2023]

§ 180.30 Applicability.

(a) *General applicability*. Except as provided in paragraph (b) of this section, the requirements of this part apply to hospitals as defined at § 180.20.

(b) *Exception*. Federal and State hospitals are deemed by CMS to be in compliance with the requirements of this part including but not limited to:

(1) Federally owned hospital facilities, including facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities operated by the U.S. Department of Defense.

(2) Hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act.

(3) State forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities.

(c) *Online availability*. Unless otherwise stated, hospital charge information must be made public electronically via the internet.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021]

Subpart B—Public Disclosure Requirements

§ 180.40 General requirements.

A hospital must make public the following:

(a) A machine-readable file containing a list of all standard charges for all items and services as provided in § 180.50.

(b) A consumer-friendly list of standard charges for a limited set of shoppable services as provided in § 180.60.

§ 180.50 Requirements for making public hospital standard charges for all items and services.

(a) *General rules.* (1) A hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in this section.

(2) Each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location.

(3) Each hospital must:

(i) Beginning January 1, 2024, make a good faith effort to ensure that the standard charge information encoded in the machine-readable file is true, accurate, and complete as of the date indicated in the machine-readable file; and

(ii) Beginning July 1, 2024, affirm in its machine-readable file that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in accordance with the requirements of this section, and that the information encoded is true, accurate, and complete as of the date indicated in the machine-readable file.

(b) *Required data elements.* (1) Prior to July 1, 2024, a hospital must include all of the following corresponding data elements in its list of standard charges, as applicable:

(i) Description of each item or service provided by the hospital.

(ii) Gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(iii) Payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

(iv) De-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(v) De-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(vi) Discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(vii) Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier.

(2) Unless otherwise specified in this paragraph (b)(2), beginning July 1, 2024, each hospital must encode in its machine-readable file all standard charge information, as applicable, for each of the following required data elements:

(i) General data elements, including:

(A) Hospital name, license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges applies. Location name(s) and address(es) must include, at minimum, all inpatient facilities and stand-alone emergency departments; and

(B) The version number of the CMS template and the date of most recent update to the standard charge information in the machine-readable file.

(ii) Each type of standard charge as defined at §180.20 (gross charge, discounted cash price, payer-specific negotiated charge, de-identified minimum negotiated charge, and de-identified maximum negotiated charge) and, for payer-specific negotiated charges, the following additional data elements:

(A) Payer and plan names; plan(s) may be indicated as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category;

(B) Method used to establish the standard charge; and

(C) Whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard

charge is based on a percentage or algorithm. If the standard charge is based on a percentage or algorithm, the machine-readable file (MRF) must also describe the percentage or algorithm that determines the dollar amount for the item or service, and, beginning January 1, 2025, calculate and encode an estimated allowed amount in dollars for that item or service.

(iii) A description of the item or service that corresponds to the standard charge established by the hospital, including:

(A) A general description of the item or service;

(B) Whether the item or service is provided in connection with an inpatient admission or an outpatient department visit; and

(C) Beginning January 1, 2025, for drugs, the drug unit and type of measurement.

(iv) Coding information, including:

(A) Any code(s) used by the hospital for purposes of accounting or billing for the item or service;

(B) Corresponding code type(s). Such code types may include, but are not limited to, the CPT code, the HCPCS code, the DRG, the NDC, Revenue Center Codes (RCC), or other common payer identifier; and

(C) Beginning January 1, 2025, any modifier(s) that may change the standard charge that corresponds to a hospital item or service, including a description of the modifier and how it changes the standard charge.

(c) *Format.* (1) Prior to July 1, 2024, the information described in paragraph (b)(1) of this section must be published in a single digital file that is in a machine-readable format.

(2) Beginning July 1, 2024, the hospital's machine-readable file must conform to a CMS template layout, data specifications, and data dictionary for purposes of making public the standard charge information required under paragraph (b)(2) of this section.

(d) *Location and accessibility.* (1) A hospital must select a publicly available website for purposes of making public the standard charge information required under paragraph (b) of this section.

(2) The standard charge information must be displayed in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated.

(3) The hospital must ensure that the standard charge information is easily accessible, without barriers, including but not limited to ensuring the information is accessible:

(i) Free of charge;

(ii) Without having to establish a user account or password;

(iii) Without having to submit personal identifying information (PII); and

(iv) To automated searches and direct file downloads through a link posted on a publicly available website.

(4) The machine-readable file and standard charge information contained in that machine-readable file must be digitally searchable.

(5) The machine-readable file must use the following naming convention specified by CMS, specifically: <ein>_<hospital-name>_standardcharges. [json|csv].

(6) Beginning January 1, 2024, the hospital must ensure that the public website it selects to host its machine-readable file establishes and maintains, in the form and manner specified by CMS:

(i) A .txt file in the root folder that includes:

(A) The hospital location name that corresponds to the machine-readable file;

(B) The source page URL that hosts the machine-readable file;

(C) A direct link to the machine-readable file (the machine-readable file URL); and

(D) Hospital point of contact information.

(ii) A link in the footer on its website, including but not limited to the homepage, that is labeled ''Price Transparency'' and links directly to the publicly available web page that hosts the link to the machine-readable file.

(e) *Frequency of updates.* The hospital must update the standard charge information described in paragraph (b) of this section at least once annually.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021; 88 FR 82184, Nov. 22, 2023]

§ 180.60 Requirements for displaying shoppable services in a consumer-friendly manner.

(a) *General rules.* (1) A hospital must make public the standard charges identified in paragraphs (b)(3) through (6) of this section, for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

(i) In selecting a shoppable service for purposes of this section, a hospital must consider the rate at which it provides and bills for that shoppable service.

(ii) If a hospital does not provide 300 shoppable services, the hospital must make public the information specified in paragraph (b) of this section for as many shoppable services as it provides.

(2) A hospital is deemed by CMS to meet the requirements of this section if the hospital maintains an internet-based price estimator tool which meets the following requirements.

(i) Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

(ii) Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

(iii) Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.

(b) *Required data elements.* A hospital must include, as applicable, all of the following corresponding data elements when displaying its standard charges (identified in paragraphs (b)(3) through (6) of this section) for its list of shoppable services selected under paragraph (a)(1) of this section:

(1) A plain-language description of each shoppable service.

(2) An indicator when one or more of the CMS-specified shoppable services are not offered by the hospital.

(3) The payer-specific negotiated charge that applies to each shoppable service (and to each ancillary service, as applicable). Each list of payer-specific negotiated charges must be clearly associated with the name of the third party payer and plan.

(4) The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its undiscounted gross charge for the shoppable service (and corresponding ancillary services, as applicable).

(5) The de-identified minimum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).

(6) The de-identified maximum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).

(7) The location at which the shoppable service is provided, including whether the standard charges identified in paragraphs (b)(3) through (6) of this section for the shoppable service apply at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both.

(8) Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, as applicable, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), or other common service billing code.

(c) *Format.* A hospital has discretion to choose a format for making public the information described in paragraph (b) of this section online.

(d) *Location and accessibility of online data.* (1) A hospital must select an appropriate publicly available internet location for purposes of making public the information described in paragraph (b) of this section.

(2) The information must be displayed in a prominent manner that identifies the hospital location with which the information is associated.

(3) The shoppable services information must be easily accessible, without barriers, including but not limited to ensuring the information is:

(i) Free of charge.

(ii) Accessible without having to register or establish a user account or password.

(iii) Accessible without having to submit personal identifying information (PII).

(iv) Searchable by service description, billing code, and payer.

(e) *Frequency.* The hospital must update the standard charge information described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the information was most recently updated.

Subpart C—Monitoring and Penalties for Noncompliance

§ 180.70 Monitoring and enforcement.

(a) *Monitoring and assessment.* (1) CMS evaluates whether a hospital has complied with the requirements under §§ 180.40, 180.50, and 180.60.

(2) CMS may use methods to monitor and assess hospital compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

(i) CMS' evaluation of complaints made by individuals or entities to CMS.

(ii) CMS review of individuals' or entities' analysis of noncompliance.

(iii) CMS audit and comprehensive review.

(iv) Requiring submission of certification by an authorized hospital official as to the accuracy and completeness of the standard charge information in the machine-readable file.

(v) Requiring submission of additional documentation as may be necessary to make a determination of hospital compliance.

(b) *Actions to address hospital noncompliance.* If CMS concludes that the hospital is noncompliant with one or more of the requirements of § 180.40, § 180.50, or § 180.60, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

(1) Provide a written warning notice to the hospital of the specific violation(s). CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital.

(2) Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, according to § 180.80.

(3) Impose a civil monetary penalty on the hospital and publicize the penalty on a CMS website according to § 180.90 if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

(c) *Actions to address noncompliance of hospitals in health systems.* In the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b) of this section) and the hospital is determined by CMS to be part of a health system, CMS may notify health system leadership of the action and may work with health system leadership to address similar deficiencies for hospitals across the health system.

(d) *Publicizing assessments, compliance actions, and outcomes.* CMS may publicize on its website information related to the following:

(1) CMS' assessment of a hospital's compliance.

(2) Any compliance action taken against a hospital, the status of such compliance action, or the outcome of such compliance action.

(3) Notifications sent to health system leadership.

[84 FR 65602, Nov. 27, 2019, as amended at 88 FR 82185, Nov. 22, 2023]

§ 180.80 Corrective action plans.

(a) *Material violations requiring a corrective action plan.* CMS determines if a hospital's noncompliance with the requirements of this part constitutes material violation(s) requiring a corrective action plan. A material violation may include, but is not limited to, the following:

(1) A hospital's failure to make public its standard charges required by §180.40.

(2) A hospital's failure to make public its standard charges in the form and manner required under §§180.50 and 180.60.

(b) *Notice of violation.* CMS may request that a hospital submit a corrective action plan, specified in a notice of violation issued by CMS to a hospital.

(c) *Compliance with corrective action plan requests and corrective actions.* (1) A hospital required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the corrective action plan.

(2) A hospital's corrective action plan must specify elements including, but not limited to:

(i) The corrective actions or processes the hospital will take to address the deficiency or deficiencies identified by CMS.

(ii) The timeframe by which the hospital will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS' review and approval of a hospital's corrective action plan, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

(d) *Noncompliance with corrective action plan requests and requirements.* (1) A hospital's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital.

(2) A hospital's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 180.90 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a hospital identified as noncompliant according to §180.70, and that fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan as described in §180.80(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS provides a written notice of imposition of a civil monetary penalty to the hospital via certified mail or another form of traceable carrier.

(2) This notice to the hospital may include, but is not limited to, the following:

(i) The basis for the hospital's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the hospital has violated.

(B) The hospital's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in §180.80(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the hospital is required to meet the requirements of this part.

(B) If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.

(C) A date determined by CMS, such as one resulting from monitoring and assessment activities specified in §180.70, or development of a corrective action plan as specified in §180.80.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) Intent to publicize the hospital's noncompliance and CMS' determination to impose a civil monetary penalty on the hospital for noncompliance with the requirements of this part by posting the notice of imposition of a civil monetary penalty on a CMS website.

(vii) A statement of the hospital's right to a hearing according to subpart D of this part.

(viii) A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 180.110.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a hospital for a violation of each requirement of this part.

(2) CMS determines the daily dollar amount for a civil monetary penalty for which a hospital may be subject as follows:

(i) For each day during Calendar Year 2021 that a hospital is determined by CMS to be out of compliance, the maximum daily dollar amount for a civil monetary penalty to which the hospital may be subject is $300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is $300.

(ii) Beginning January 1, 2022, for each day a hospital is determined by CMS to be out of compliance:

(A) For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is $300, even if the hospital is in violation of multiple discrete requirements of this part.

(B) For a hospital with at least 31 and up to and including 550 beds, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times $10, even if the hospital is in violation of multiple discrete requirements of this part.

(C) For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is $5,500, even if the hospital is in violation of multiple discrete requirements of this part.

(D)(*1*) CMS will use the most recently available, finalized Medicare hospital cost report to determine the number of beds for a Medicare-enrolled hospital, for purposes of determining the maximum daily dollar civil monetary penalty amount under paragraph (c)(2) of this section.

(*2*) If the number of beds for the hospital cannot be determined according to paragraph (c)(2)(ii)(D)(*1*) of this section, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should the hospital fail to provide CMS with this documentation in the prescribed form and manner, and by the specified deadline, CMS will impose on the hospital the maximum daily dollar civil monetary penalty amount according to paragraph (c)(2)(ii)(C) of this section.

(3) The amount of the civil monetary penalty will be adjusted annually using the multiplier determined by OMB for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A hospital must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a hospital requests a hearing, pursuant to subpart D of this part, the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday,

then the timeframe is extended until the end of the next business day.

(e) *Posting of notice.* (1) CMS will post the notice of imposition of a civil monetary penalty described in paragraphs (b) and (f) of this section on a CMS website.

(2) In the event that a hospital elects to request a hearing, pursuant to subpart D of this part:

(i) CMS will indicate in its posting, under paragraph (e)(1) of this section, that the civil monetary penalty is under review.

(ii) If the civil monetary penalty is upheld, in whole, by a final and binding decision according to subpart D of this part, CMS will maintain the posting of the notice of imposition of a civil monetary penalty on a CMS website.

(iii) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty according to paragraph (b)(3) of this section, to conform to the adjudicated finding. CMS will make this modified notice public on a CMS website.

(iv) If the civil monetary penalty is overturned in full by a final and binding decision according to subpart D of this part, CMS will remove the notice of imposition of a civil monetary penalty from a CMS website.

(f) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021; 88 FR 82185, Nov. 22, 2023]

Subpart D—Appeals of Civil Monetary Penalties

§ 180.100 Appeal of penalty.

(a) A hospital upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) Civil money penalty means a civil monetary penalty according to §180.90.

(2) Respondent means a hospital that received a notice of imposition of a civil monetary penalty according to §180.90(b).

(3) References to a notice of assessment or proposed assessment, or notice of proposed determination of civil monetary penalties, are considered to be references to the notice of imposition of a civil monetary penalty specified in §180.90(b).

(4) Under §150.417(b) of this title, in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:

(i) The hospital's posting(s) of its standard charges, if available.

(ii) Material the hospital timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the hospital's compliance according to §180.70(a)(2).

(5) The ALJ's consideration of evidence of acts other than those at issue in the instant case under §150.445(g) of this title does not apply.

§ 180.110 Failure to request a hearing.

(a) If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in §180.90(b), CMS may impose the civil monetary penalty indicated in such notice and may impose additional penalties pursuant to continuing violations according to §180.90(f) without right of appeal in accordance with this part.

(1) If the 30th calendar day described in this paragraph (a) is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this title, unless the hospital can show good cause, as determined at §150.405(b) of this title,

for failing to timely exercise its right to a hearing.

PART 181 [RESERVED]

PART 182—PRICE TRANSPARENCY FOR COVID–19 DIAGNOSTIC TESTS

Subpart A—General Provisions

Sec.
182.10 Basis and scope.
182.20 Definitions.
182.30 Applicability.

Subpart B—Public Disclosure Requirements

182.40 Requirements for making public cash prices for a diagnostic test for COVID–19.

Subpart C—Monitoring and Penalties for Noncompliance

182.50 Monitoring and enforcement.
182.60 Corrective action plans.
182.70 Civil monetary penalties.

Subpart D—Appeals of Civil Monetary Penalties

182.80 Appeal of penalty.
182.90 Failure to request a hearing.

AUTHORITY: Section 3202(b), Pub. L. 116–136, 134 Stat. 281.

SOURCE: 85 FR 71203, Nov. 6, 2020, unless otherwise noted.

Subpart A—General Provisions

§ 182.10 Basis and scope.

This part implements section 3202(b)(1) of the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136, March 27, 2020) (CARES Act), which requires that during the emergency period declared under section 319 of the PHS Act (42 U.S.C. 247d), providers of diagnostic tests for COVID–19 make public the cash price for such tests on a public internet website of such provider. This part also implements section 3202(b)(2) of the CARES Act, which authorizes the Secretary to impose a civil monetary penalty (CMP) on any provider of a diagnostic test for COVID–19 that does not comply with section 3202(b)(1) of the CARES Act and that has not completed a corrective action plan to comply with that section, in an amount that does not exceed $300 per day that the violation is ongoing.

§ 182.20 Definitions.

The following definitions and abbreviated terms apply to this part:

Cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID–19 diagnostic test.

COVID–19 for purposes of this part is the abbreviated term for the virus called SARS-CoV–2 and the disease it causes, called coronavirus disease 2019.

Diagnostic test for COVID–19 (''COVID–19 diagnostic test'') means a COVID–19 *in vitro* diagnostic test described in section 6001 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020), as amended by section 3201 of the CARES Act (Pub. L. 116–136, March 27, 2020).

Provider of a diagnostic test for COVID–19 (''provider'') means any facility that performs one or more COVID–19 diagnostic tests.

§ 182.30 Applicability.

(a) *General applicability*. The requirements of this part apply to each provider of a diagnostic test for COVID–19 as defined at § 182.20.

(b) *Duration of requirements*. The requirements of this part are applicable during the public health emergency (PHE) determined to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the PHS Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

Subpart B—Public Disclosure Requirements

§ 182.40 Requirements for making public cash prices for a diagnostic test for COVID–19.

(a) *General rules*. (1) Except as provided under paragraph (b) of this section, a provider of a COVID–19 diagnostic test must make public the information described in paragraph (c) of this section electronically via the internet.

(2) The information described in paragraph (c) of this section, or a link to such information, must appear in a conspicuous location on a searchable homepage of the provider's website.

(3) The information described in paragraph (c) of this section must be displayed in a manner that is easily accessible, without barriers, and ensures that the information is accessible:

(i) Free of charge;

(ii) Without having to establish a user account or password; and

(iii) Without having to submit personal identifiable information (PII).

(4) The provider must include all of the following terms on its homepage:

(i) The provider's name;

(ii) The term ''price'';

(iii) The term ''cost'';

(iv) The term ''test'';

(v) The term ''COVID''; and

(vi) The term ''coronavirus''.

(b) *Exception.* A provider of a COVID–19 diagnostic test that does not have its own website must make public the information described in paragraph (c) of this section:

(1) In writing, within two business days upon request; and

(2) On a sign posted prominently at the location where the provider offers a COVID–19 diagnostic test, if such location is accessible to the public.

(c) *Required information.* For purposes of paragraphs (a) and (b) of this section, the provider must make public the following information:

(1) A plain-language description of each COVID–19 diagnostic test that is offered by the provider;

(2) The billing code used for each COVID–19 diagnostic test;

(3) The provider's cash price for each such COVID–19 diagnostic test; and

(4) Any additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID–19 diagnostic test.

Subpart C—Monitoring and Penalties for Noncompliance

§ 182.50 Monitoring and enforcement.

(a) *Monitoring.* (1) CMS may evaluate whether a provider has complied with the requirements under § 182.40.

(2) CMS may use methods to monitor and assess provider compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

(i) CMS' evaluation of complaints made to CMS.

(ii) CMS review of an individual's or entity's analysis of noncompliance as stated in the complaint.

(iii) CMS review of providers' websites.

(b) *Actions to address provider noncompliance.* If CMS concludes that the provider is noncompliant with one or more of the requirements of § 182.40, CMS may take any of the following actions:

(1) Provide a written warning notice to the provider of the specific violation(s).

(2) Request that the provider submit and comply with a corrective action plan under § 182.60.

(3) Impose a civil monetary penalty on the provider if the provider fails to respond to CMS' request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS.

§ 182.60 Corrective action plans.

(a) *Violations requiring a corrective action plan.* If CMS determines a provider's noncompliance with the requirements of this part continues after a warning notice, a corrective action plan may be required. A violation may include, but is not limited to, the following:

(1) A provider's failure to make public its cash price information required by § 182.40.

(2) A provider's failure to make public its cash price information in the form and manner required under § 182.40.

(b) *Notice of violation.* CMS may request that a provider submit and comply with a corrective action plan, specified in a notice of violation issued by CMS to a provider.

(c) *Compliance with corrective action plan requests and corrective actions.* (1) A provider required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the provider, and must comply with the requirements of the corrective action plan approved by CMS.

(2) A provider's corrective action plan must specify elements including, but not limited to:

(i) The corrective actions or processes the provider will take to address the deficiency or deficiencies identified by CMS.

(ii) The timeframe by which the provider will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS' review and approval of a provider's corrective action plan, CMS may monitor and evaluate the provider's compliance with the corrective actions specified in the corrective action plan.

(d) *Noncompliance with corrective action plan requests and requirements.* (1) A provider's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the provider.

(2) A provider's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 182.70 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a provider identified by CMS as noncompliant according to § 182.50, and that fails to respond to CMS' request to submit a corrective action plan or to comply with the requirements of a corrective action plan approved by CMS as described in § 182.60(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS will provide a written notice of imposition of a civil monetary penalty to the provider via certified mail or another form of traceable carrier.

(2) This notice to the provider may include, but is not limited to, the following:

(i) The basis for the provider's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the provider has violated.

(B) The provider's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 182.60(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the provider is required to meet the requirements of this part.

(B) A date determined by CMS, such as one resulting from monitoring activities specified in § 182.50, or development of a corrective action plan as specified in § 182.60.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) A statement of the provider's right to a hearing according to subpart D of this part.

(vii) A statement that the provider's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 182.90.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a provider for a violation of each requirement of this part.

(2) The maximum daily dollar amount for a civil monetary penalty to which a provider may be subject is $300. Even if the provider is in violation of multiple discrete requirements of this part, the maximum total sum that a single provider may be assessed per day is $300.

(3) The maximum daily amount of the civil monetary penalty will be adjusted annually using the multiplier determined by the Office of Management and Budget for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A provider must pay the

civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a provider requests a hearing, pursuant to subpart D of this part, the provider must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(4) In the event a civil money penalty is not paid in full within 60 days, CMS will follow the collections activities set forth in 45 CFR part 30.

(e) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

Subpart D—Appeals of Civil Monetary Penalties

§ 182.80 Appeal of penalty.

(a) A provider upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) ''Respondent'' means a provider, as defined in §182.20 that received a notice of imposition of a civil monetary penalty according to §182.70(b).

(2) In deciding whether the amount of a civil money penalty is reasonable, the administrative law judge (ALJ) may only consider evidence of record relating to the following:

(i) The provider's posting(s) of its cash price information, if available.

(ii) Material the provider timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the provider's compliance according to §182.70(a)(2).

(3) The ALJ's consideration of evidence of acts other than those at issue in the instant case under §150.445(g) of this title does not apply.

§ 182.90 Failure to request a hearing.

(a) If a provider does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in §182.70(b), CMS may impose the civil monetary penalty indicated in such notice without right of appeal in accordance with this part.

(1) If the 30th calendar day described paragraph (a) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(2) [Reserved]

(b) The provider has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with §150.405 of this title, unless the provider can show good cause, as determined at §150.405(b) of this title, for failing to timely exercise its right to a hearing.

PARTS 183 [RESERVED]

PART 184—PHARMACY BENEFIT MANAGER STANDARDS UNDER THE AFFORDABLE CARE ACT

Sec.

184.10 Basis and scope.
184.20 Definitions.
184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

AUTHORITY: 42 U.S.C. 1302, 1320b–23.

SOURCE: 86 FR 24295, May 5, 2021, unless otherwise noted.

§ 184.10 Basis and scope.

(a) *Basis.* (1) This part implements section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title XI of the Social Security Act.

(2) [Reserved]

(b) *Scope.* This part establishes standards for Pharmacy Benefit Managers that administer prescription drug benefits for health insurance issuers that

offer Qualified Health Plans with respect to the offering of such plans.

§ 184.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Health insurance issuer has the meaning given to the term in § 144.103 of this subtitle.

Plan year has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 156.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 156.20 of this subchapter.

§ 184.50 Prescription drug distribution and cost reporting by pharmacy benefit managers.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, any entity that provides pharmacy benefits management services on behalf of a qualified health plan (QHP) issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding *bona fide* service fees) that the pharmacy benefits manager (PBM) negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) *Bona fide* service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Limitations on disclosure.* Information disclosed by a PBM under this section shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A PBM that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of section 1927(b)(3)(C) of the Act.

PARTS 185–199 [RESERVED]

FINDING AIDS

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List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations (CFR) that were made by documents published in the FEDERAL REGISTER since January 1, 2019 are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters, parts and subparts as well as sections for revisions.

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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144 Authority citation revised 29014
144.103 Amended 29014
146.123 Added 29014
146.145 (b)(3)(i) revised; (b)(3)(viii) added 29024
146.152 (a) revised 17561
147 Authority citation revised 29025
147.106 (a) revised 17561
147.126 (c), (d), and (e) revised 29025
148 Authority citation revised 17561
148.122 (b)(1) revised 17561
153 Authority citation revised 17561
153.20 Amended 17561
153.320 (d) revised 17561
153.630 (b)(10) and (d)(2) revised; (g) added 17562
155 Authority citation revised 17562, 29027
155.20 Amended 17562
155.200 (c) revised 71710
155.205 (a) revised 17563
155.210 (b)(2) introductory text, (iii), (iv), and (e)(9) introductory text revised; (b)(2)(v) through (ix) removed 17563
155.215 (b)(2) revised 17563

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155.221 (a), (b), and (c) redesignated as (e), (f), and (g); heading, new (e), new (f) introductory text, new (2), new (3), new (4), new (6), new (7), and new (g) revised; new (a), new (b), new (c), (d), and (h) added 17566
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155.420 (a)(4)(iii) introductory text revised; (c)(3) redesignated as (c)(4); (b)(2)(vi), new (c)(3), and (d)(14) added; (d)(12) and (13) amended 29027
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155.1200 (d)(4) redesignated as (d)(5); new (d)(4) added; (b) introductory text, (1), (2), (c) introductory text, (d)(2), (3), and (5) revised 71710
156 Authority citation revised 17567, 71710
156.20 Amended 17567
156.130 (h) added 17567
156.280 (e)(2)(ii) redesignated as (e)(2)(iii); new (e)(2)(ii) added; heading and new (e)(2)(iii) revised 71710
156.1230 (a)(2) and (b)(2) removed; (b)(1) revised; (b)(3) redesignated as new (b)(2) 17568
160 Notification 18151
162 Authority citation revised 57629
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180.10—180.110 (Subchapter E) Added; eff. 1-1-21 65602

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146.145 (b)(3)(viii)(E) added 29259
147 Authority citation revised 71202
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147.140 (g)(3) and (4) redesignated as (g)(4) and (5); new (g)(3) added; (g)(1)(iii), (iv)(A), (B), (v), new (4)(i), and new (ii) revised; (g)(1) introductory text and new (5) amended 81120
147.210 Added 72305
147.211 Added 72305
147.212 Added 72305
149 Removed 29259
153 Policy statement 76979
155.120 (c)(1)(ii) revised 37247
155.220 (j)(2)(i) revised 37248
155.330 (e)(2)(i)(D) revised 29259
155.400 (e)(1)(i), (ii), and (iii) revised; (e)(1)(iv) removed 29260
155.420 (a)(4)(ii), (iii), (b)(1) introductory text, (3), and (d)(1)(ii) revised; (b)(5) removed 29260
155.430 (b)(1)(ii) and (d)(9) revised 29260
155.1318 Added; interim 71202
155.1320 (c)(1) heading and (2) added; interim 71203
155.1400 Revised 29261
155.1405 Revised 29261
156 Authority citation revised 29261
156.20 Amended 29261
156.111 Heading and (d) introductory text revised; (d)(2) and (f) added 29261
156.130 (h) revised 29261
156.200 (e) revised 37248
156.221 Added 25638
156.265 (f) and (g) revised 29261
156.270 (b) introductory text revised 29261
156.280 Correction: amended 2887
156.280 (e)(2)(ii) introductory text revised; interim 27629
156.1210 Revised 29262
156.1230 (b)(2) revised 37248
158 Authority citation revised 29262
158.110 (a) revised 29262
158.140 (b)(1)(i) revised 29262
158.150 (b)(2)(iv)(A)(*5*) revised 29262
158.160 (b)(2)(vii) added 29262
158.221 (b)(9) added 72310
160 Notification 19392, 22024, 29637
162.1102 (d) added; incorporation by reference 4242
162.1302 (d) added; incorporation by reference 4242
162.1802 (d) added; incorporation by reference 4242
164 Notification 19392, 22024, 29637

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170.101 Revised 25939
170.101 Revised; interim 70082
170.102 Amended 25939
170.102 Amended; interim 70082
170.200 Amended 25940
170.200 Revised; interim 70082
170.202 (a)(1) removed 25940
170.204 (b)(1), (2), and (c) removed 25940
170.205 (a)(1), (2), (d)(3), (e)(3), (h)(1), (i)(1), and (j) removed; (a)(5), (b)(1), (h)(3), and (k)(3) added 25940
170.205 (h)(3) and (k)(3) revised; interim 70082
170.207 (d)(2), (e)(2), (g)(1), (h), and (j) removed 25940
170.210 (a)(1) and (c)(1) removed; (e)(1)(i) and (h) amended 25940
170.210 (e)(1)(i), (2)(i), and (3) amended; (g) revised; interim 70082
170.213 Added 25941
170.213 Revised; interim 70082
170.215 Added 25941
170.215 (a)(2) revised; interim 70082
170.299 (c)(1) revised; (n) through (r) redesignated as (o) through (s); (c)(2), (3), (d)(2), (7), (8), (f)(3), (6), (7), (10), (11), (h)(1), (j)(1), (l)(3), new (r)(4), and new (5) removed; (e)(4), (5), (f)(30) through (34), (k)(3), (m)(5), and new (n) added 25941
170.299 (e)(4), (5), (f)(34), and (m)(5) revised; interim 70082
170.300 (a) and (c) amended 25941
170.300 (a), (c), and (d) revised; interim 70083
170.314 Removed 25941

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170.315 (a)(6), (7), (8), (11), (b)(4), (5), (e)(1)(ii)(B), (g)(7)(ii)(A)(*3*), (8)(ii)(A)(*3*), and (9)(ii)(A)(*3*) removed; (a)(9)(ii)(B)(*1*)(*iii*), (*2*), (b)(1)(ii)(A) introductory text, (*2*), (*3*), (B), (C) introductory text, (iii) introductory text, (e)(1)(i)(B)(*1*)(*ii*), and (*2*) introductory text amended; (b)(1)(iii)(A), (2), (3), (7), (8), (9), (c)(3), (e)(1)(i)(A)(*1*) through (*5*), (f)(5)(iii)(B)(*1*) through (*4*), (g)(1), (2), (3)(i), (6), and (9)(i)(A) revised; (b)(10), (d)(12), (13), (e)(1)(i)(A)(*6*), (*7*), (f)(5)(iii)(B)(*5*), and (g)(10) added 25941
170.315 Correction: amended 47099
170.315 (b)(1)(iii)(A)(*2*), (2)(i), (iii)(D) introductory text, (iv), (3)(ii)(B)(*2*), (7)(ii), (8)(i)(B), (9)(ii), (c)(3), (d)(13)(ii), (e)(1)(i)(A)(*2*), (f)(5)(iii)(B)(*1*), (*2*), (g)(6)(i)(B), (9)(i)(A)(*2*), (10)(v)(A)(*1*)(ii), and (10)(v)(A)(*2*)(ii) revised; (g)(10)(iv)(A)(*1*)(iii) added; interim 70083
170.315 Correction: (b)(1)(iii)(A)(*2*), (2)(i), (iii)(D) introductory text, (iv), (3)(ii)(B)(*2*), (7)(ii), (8)(i)(B), (9)(ii), (c)(3), (d)(13)(ii), (e)(1)(i)(A)(*2*), (f)(5)(iii)(B)(*1*), (*2*), (g)(6)(i)(B), (9)(i)(A)(*2*), (10)(v)(A)(*1*)(*ii*), and (*2*)(*ii*) revised; (g)(10)(v)(A)(*1*)(*iii*) added 78236
170.400—170.406 (Subpart D) Added 25945
170.401 (a) revised 70084
170.402 (a)(1), (4), and (b)(2) revised; interim in part 70084
170.403 Correction: amended 43711
170.403 (b)(1) revised; interim 70084
170.404 (b)(3) and (4) revised; interim 70084
170.405 Correction: amended 43711
170.405 (b)(1) introductory text, (2)(ii) introductory text, (3) introductory text, (4)(ii), (5)(ii), (6)(ii), and (7)(ii) revised; (b)(10) added; interim 70084

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170.405 Correction: (b)(1) introductory text, (2)(ii) introductory text, (3) introductory text, (ii), (4)(ii), (5)(ii), (6)(ii), and (7)(ii) revised; (b)(10) added 78236
170.501 (a) and (b) amended; (c) removed 25950
170.502 Amended 25950
170.503 Removed 25950
170.504 Removed 25950
170.505 Revised 25950
170.510 (a) removed; (b) and (c) redesignated as new (a) and (b) 25950
170.520 (a)(3) revised 25950
170.523 (a), (g), and (h), (k)(1)(ii), (iii), (4), (m) revised; (b) heading, (c) heading, (d) introductory text heading, (e) heading, (f) introductory text heading, (i) introductory text heading, (j) introductory text heading, (l) heading, and (p) through (t) added; (f)(2), (k)(1)(iv)(B), (C), (2), and (3) removed; (k) introductory text and (o) amended 25950
170.523 (f)(1)(xxi) removed; (k)(1) introductory text and (i) revised; interim 70084
170.524 (a) heading, (b) heading, (c) heading, (d) introductory text heading, (e) heading, (g) heading, and (h) introductory text heading added; (f) revised; (h)(3) amended 25951
170.545 Removed 25952
170.550 (a) heading, (b) heading, (d) heading, (e), (g) introductory text heading, (5), (l), and (m) added; (f) removed; (h) revised 25952
170.550 (m)(1), (2), and (3) revised; interim 70085
170.555 (a) amended; (b)(1) revised 25952
170.556 (c)(3) and section amended; (a) introductory text and (c) introductory text revised; (c)(2), (5), and (6) removed 25952
170.560 (a)(2) amended 25953
170.565 (d)(1)(ii), (iii), and (h)(2)(iii) amended 25953
170.570 (a), (b)(2), (c) introductory text, (1), and (2) amended 25953

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170.575 Removed 25953
170.580 (a)(1), (2)(i) heading, (ii) heading, (3)(i), (iv), (v), (b)(1)(i), (iii)(D), (2)(i), (3)(i), (ii), (c)(1), (e)(1) introductory text, (f)(1), (g)(1) introductory text, (i), (2), (3)(i), (4), (5)(i), (6)(v) revised; (a)(2)(iii), (4), (b)(3)(iii), and (iv) added; (d)(1), (2)(i)(C), (4), (5), and (f)(2)(i)(C) amended 25953
170.581 Revised 25954
170.599 (b)(4) redesignated as (b)(5); new (b)(4) added; new (b)(5) revised 25955
171 Added 25955
171.101 (b) revised 70085
171.103 (a)(2), (3), and (b) revised 70085
171.203 (e)(2) revised 70085
171.301 (a)(1), (2), and (b)(1)(ii)(A) revised 70085
171.303 (b)(2)(i) revised 70085
182 (Subchapter E-T) Heading and part added; interim 71203
182 (Subchapter E-T) Removed; interim 71205
182 Transferred to Subchapter E 71205

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144 Authority citation revised 36970
144.101 (d) and (e) redesignated as (e) and (f); new (d) added; interim 36970
144.102 Revised; interim 36970
144.103 Introductory text revised; interim 36970
147 Authority citation revised 36970
147.104 (b)(2)(ii) and (4)(ii) revised 24285
147.104 (b)(2)(i)(E) and (F) revised; (b)(2)(i)(G) added; eff. 11-26-21 53503
147.136 (a)(1), (c)(2)(i), (d)(1)(i)(A), (B), and (g) revised; (d)(1)(i)(C) and (ii) *Examples 3* through *7* added 56122
147.138 (c) revised; interim 36970
149 Added; interim 36970
149 Authority citation amended 56124
149.10 (b) revised 56124

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149.20 (a)(3) and (4) added; (b) introductory text revised 56124
149.20 (a)(1) and (b) introductory text revised; interim 66702
149.450 (a)(1) and (2)(i) revised 56124
149.510—149.520 (Subpart F) Added 56124
149.610—149.620 (Subpart G) Added 56134
149.710—149.740 (Subpart H) Added; interim 66702
150 Authority citation revised 24286
150.103 Amended 24286
150.205 (e)(2) amended 24286
150.213 (b) amended 24286
150.303 (a) introductory text amended 24286
150.305 (a)(1), (2), (b)(1), and (c)(1) amended 24286
150.311 (g) amended 24286
150.313 (b) amended 24286
150.401 Amended 24286
150.419 (a) amended 24286
150.427 (a) introductory text and (b) revised 24286
150.431 Revised 24286
150.441 (e) revised 24286
150.447 (a) amended 24286
153.320 (c) revised 24286
153.410 (d) revised 24286
153.620 (c) revised 24287
153.630 (d)(3) revised; (g)(4) and (5) added 24287
153.710 (e) through (g) redesignated as (f) through (h); new (e) added; new (h) introductory text amended 24288
155.20 Amended 24288
155.205 (c)(2)(i)(B), (iii)(B), (iv) introductory text, and (C) revised 24288
155.210 (e)(9) revised; eff. 11-26-21 53503
155.220 (c)(6) added 24288
155.221 (c) through (h) redesignated as (d) through (i); new (g) introductory text, (6), (7), and (h) amended; (j) added 6176
155.221 (b)(1), (3), and (4) revised; (c) through (h) redesignated as (d) through (i); new (c) added; new (g) introductory text, new (6), new (7), and new (h) amended 24289
155.221 Correction: Instruction revised 36071

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155.221 (j) removed; eff. 11-26-21 53503
155.320 (c)(3)(iii)(A) revised; (c)(3)(iii)(D) and (vi)(C)(2) removed 24289
155.410 (e)(3) and (f)(2) introductory text revised; (e)(4) and (f)(3) added; eff. 11-26-21 53503
155.420 (a)(4)(ii)(B), (iii) introductory text, (b)(2)(iv), (c)(2), and (e)(1) revised; (a)(4)(ii)(C), (b)(5), (c)(5), and (d)(15) added 24289
155.420 (a)(4)(ii)(B) amended; (a)(4)(ii)(C) and (iii) introductory text revised; (a)(4)(ii)(D), (b)(2)(vii), (d)(16), and (f) added; eff. 11-26-21 53503
155.1308 (f)(3)(i), (iv) introductory text, and (A) through (C) revised 6177
155.1308 (f)(3)(iv) introductory text and (A) through (C); eff. 11-26-21 53504
155.1318 Heading, (a), and (b)(3) revised; (b)(5) and (g) added; eff. 11-26-21 53504
155.1320 (a)(1) and (2) revised 6178
155.1320 (a), (c)(2) heading, and (i) revised; (c)(2)(ii)(F) and (iii) added; eff. 11-26-21 53505
155.1322 Added; eff. 11-26-21 53505
155.1328 (a) revised 6178
155.1328 (a) revised; eff. 11-26-21 53505
155.1330 Added; eff. 11-26-21 53505
155.1332 Added; eff. 11-26-21 53505
156 Authority citation revised 6178, 24290
156.50 (c) heading, (2), (d) heading, (1) introductory text, (2) introductory text, (i)(A), (B), (ii), (iii)(B), (3) introductory text, (4) through (6), and (7) introductory text revised; (c)(3) added 24290
156.115 (a)(3) revised; eff. 11-26-21 53506
156.130 (e) revised 24291
156.155 (a)(3) revised; (c) redesignated as (d); new (c) added; interim 36985
156.230 (f) added 6178
156.280 Heading and (e)(2)(ii) revised; eff. 11-26-21 53506

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156.295 Heading, (a) introductory text, (1), (2) introductory text, and (b) introductory text revised; (a)(3) removed 24292
156.420 (a)(1)(i), (2)(i), and (3)(i) revised 24292
156.480 Heading and (c) revised 24292
156.800—156.815 (Subpart I) Heading revised 24293
156.800 (a) introductory text and (b) revised 24293
156.805 (a) introductory text and (5)(i) revised; (f) added 24293
156.901—156.963 (Subpart J) Heading revised 24293
156.901 Amended 24293
156.903 (a) revised 24293
156.919 (a) revised 24293
156.927 (a) introductory text and (b) revised 24293
156.931 Revised 24293
156.941 (e) revised 24293
156.947 (a) revised 24293
156.1210 (a) revised; (b) redesignated as (d); new (b) and (c) added 24294
156.1215 (b) revised 24294
156.1220 (a)(1)(vii) and (3)(ii) revised; (a)(3)(iii) through (vi) redesignated as (a)(3)(iv) through (vii); new (a)(3)(iii) added 24294
156.1240 (a)(3) added 6178
158.103 Amended 24294
158.221 (b)(8) removed; (b)(9) redesignated as (b)(8) 24294
158.240 (g) added 24294
158.241 (a)(2) revised 24295
160 Notification 11139
164 Notification 11139
180.20 Amended 63998
180.30 (b) introductory text amended; (b)(3) added 63998
180.50 (d)(3)(ii) and (iii) amended; (d)(3)(iv) added 63998
180.90 (c)(2) revised 63998
184 Added 24295

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144.103 Amended 27386
147.104 (i) redesignated as (j); new (i) added 27386

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Subtitle A—Continued
149.140 (d)(1)(ii) through (iv) redesignated as (d)(1)(iii) through (v); (a)(18) and new (d)(1)(ii) added; (g) revised; eff. 10-25-22 52652
149.510 (a)(2)(viii) removed; (a)(2)(ix) through (xiii) redesignated as new (a)(2)(viii) through (xii); (c)(4)(ii)(A), (iii), (iv), (vi)(B), (f)(1)(v)(F), and (h) revised; eff. 10-25-22 52652
149.520 (b)(3) redesignated as (b)(4); new (b)(3) added; (b)(1), (2) introductory text, new (4)(iv)(F), and (c) revised; eff. 10-25-22 52654
153.320 (d) introductory text, (1)(iii), (4)(i)(A), and (B) revised; (d)(1)(iv) and (5) added 27387
153.710 (h)(1) introductory text, (iii), (iv), (2), and (3) revised; (h)(1)(v) added 27387
153.730 Revised 27387
155.206 (i) amended 27388
155.220 (c)(3)(i)(A), (L), and (j)(2)(ii) revised; (c)(3)(i)(M), (j)(2)(vi), and (viii) added; (j)(2)(iv) amended 27388
155.305 (f)(1)(i) and (5) revised 27388
155.320 (d)(4) introductory text, (i) introductory text, and (A) revised; (d)(4)(i)(D), (F), and (ii) removed; (d)(4)(i)(E) and (G) redesignated as new (d)(4)(i)(D) and new (E); new (d)(4)(i)(E) revised 27389
155.340 (i) added 27389
155.420 (g) added 27389
156 Authority citation revised 27389
156.50 (c)(3) removed; (d)(1) introductory text, (2)(i)(A), (B), (ii), (iii)(B), (3) introductory text, (4), (6), and (7) introductory text revised 27389
156.111 Heading, (d), and (e) introductory text revised; (f) removed 27390
156.115 (b)(2) revised 27390
156.125 (a) revised 27390
156.140 (c) revised 27390
156.200 (b)(3) revised 27391
156.201 Added 27391
156.230 (a) revised 27391
156.235 (a)(2)(i), (ii)(B), and (b)(2)(i) revised 27391

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156.330—156.350 (Subpart D) Heading revised 27392
156.340 (a), (b)(4), and (5) revised 27392
156.400 Amended 27392
156.430 (b)(1), (d) introductory text, (e) introductory text, and (1) revised 27392
158.140 (b)(2)(iii) revised 27393
158.150 (a) revised 27393
158.170 (b) introductory text revised 27393
180 Technical correction 2058

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Subtitle A
149.510 (d)(2)(ii) and (e)(2)(vii) revised; (e)(2)(viii) through (xi) redesignated as (e)(2)(ix) through (xii); (d)(3) and new (e)(2)(viii) added; (e)(2)(iii), (vi), new (ix), new (x), and new (xii) amended 88525
153.320 (d) introductory text, (1)(iv), and (4)(i)(B) revised 25916
153.630 (d)(2) revised; (d)(3) redesignated as (d)(4); new (d)(3) added 25916
153.710 (e) and (h)(1) introductory text revised 25916
155.106 (a)(3) and (c)(3) revised 25917
155.210 (c)(6) and (d)(7) amended; (d)(8) removed 25917
155.220 (g)(5)(i)(B), (h)(3), (j)(2)(ii) introductory text, and (iii) revised; (j)(2)(ii)(A) through (D) redesignated as (j)(2)(ii)(B) through (E); new (j)(2)(ii)(A) added 25917
155.225 (g)(4) amended; (g)(5) removed 25918
155.305 (f)(1)(ii)(B) and (f)(4) revised 25918
155.315 (f)(7) added 25918
155.320 (c)(5) added 25918
155.335 (j)(1) introductory text, (i), (ii), (iii)(A), (B), (iv), (2), and (3) introductory text revised; (j)(4) added 25918
155.420 (a)(4)(ii)(A), (B), (b)(2)(iv), (c)(2), and (d)(12) revised; (c)(6) added; (d)(6) heading removed 25919
155.430 (b)(3) added 25920

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155.505 (g) revised 25920
155.1500—155.1515 (Subpart P) Added 25920
156.201 Revised 25921
156.202 Added 25922
156.210 (d) added 25922
156.225 Heading revised; (a) and (b) amended; (c) added 25922
156.230 (a)(1) introductory text, (2)(i)(B), (e) introductory text revised; (a)(4) added; (f) removed 25922
156.235 (a)(1), (2)(i), (ii)(B), and (b)(2)(i) revised 25922
156.270 (f) revised 25923
156.1210 (c) revised 25923
156.1220 (a)(4)(ii) and (b)(1) revised 25923
160 Notification 22380
164 Notification 22380
180.20 Amended 82184
180.50 (a)(3) and (d)(6) added; (b) and (c) revised; (d)(4), (5), and (e) amended 82184
180.70 (a) heading, (2)(iii), and (b)(1) revised; (a)(2)(iv), (v), (c), and (d) added 82185
180.90 (b)(2)(ii)(C) amended 82185

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Subtitle A
144.103 Amended 23416
146.125 Revised 23418
146.136 (a) redesignated as (a)(2); new (a) heading, (1), (c)(3)(iii) introductory text, and (j) added; new (a)(2) introductory text, (c)(1)(ii), (2)(i), (ii)(A) introductory text, (C), (3)(i)(A), (C), (D), (iii)(A), (B), (iv), (4), (d)(3), (e)(4), and (i)(1) revised; new (a)(2) amended; eff. 11-22-24 77735
146.137 Added; eff. 11-22-24 77747
146.145 (b)(4)(ii)(D) and (iv) added 23418
146.180 (a)(3) through (7) redesignated as (a)(4) through (8); (a)(2), new (5), new (7)(i), and (f)(1) revised; new (a)(3) and (f)(4)(iii) added; eff. 11-22-24 77751

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147.104 (e) revised 37703
147.160 Revised; eff. 11-22-24 77751
148.102 (b) revised 23419
148.220 (b)(4) revised 23420
149 Correction: Amended 4548
149.510 Correction: Amended 4548
152.2 Amended; eff. 11-1-24 39436
153 Heading revised 26419
153.620 Heading and (c)(4) introductory text revised 26419
155.20 Amended; eff. 11-1-24 39436
155.30 Added; eff. 11-1-24 39436
155.105 (b)(2) and (3) amended; (b)(4) added 26419
155.106 (a)(2) revised 26419
155.120 (c)(1)(ii) revised 37703
155.170 (a)(2) revised 26419
155.205 (a), (b)(4), and (5) revised 26419
155.220 (c)(4)(iii) and (n) added; (h)(2) and (3) revised 26420
155.220 (j)(2)(i) revised 37703
155.221 (a) introductory text revised; (a)(1)(i), (ii), (b)(6), and (j) added 26420
155.302 (a)(1) revised 26421
155.305 (f)(4)(i) and (ii) added 26421
155.315 (e) revised 26421
155.320 (c)(1)(iii) added 26421
155.330 (d)(3) revised 26422
155.335 (j)(1)(ii) through (iv) and (2)(i) through (iii) revised; (j)(1)(v), (2)(iv), and (5) added 26422
155.400 (e)(2) revised 26423
155.410 (e)(4)(i) and (ii) revised; (e)(4)(iii) added 26423
155.420 (b)(1), (3)(i), and (d)(16) revised 26423
155.430 (b)(1)(iv) introductory text revised; (b)(1)(iv)(D) added 26423
155.1050 (a) revised 26423
155.1312 (c)(3) added 26424
155.1320 (c) introductory text revised 26424
156.111 (a), (b)(2), (e)(2), and (3) revised 26424
156.115 (d) revised 26425

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156.122 (a)(3)(i)(E) and (f) added 26425
156.200 (e) revised 37703
156.202 (d) and (e) added 26425
156.221 (b)(1)(ii) amended (b)(1)(iii), (c)(1), (4)(ii)(C), (e)(2), (f), and (i) revised; (b)(1)(iv), (v) amended 8986
156.222 Added 8986
156.223 Added 8988
156.520 (f) revised 26426
156.1215 (b) and (c) revised 26426
156.1230 (b)(2) revised 37703
160.103 Amended 33062
164.502 (a)(1)(vi) and (g)(5) revised; (a)(5)(iii) added 33063
164.509 Added 33063
164.512 Introductory text, (c), and (f)(1)(ii)(C) introductory text revised; (c)(3) added 33064
164.520 (a) and (b) revised; (d)(4) added 33064
164.535 Added 33066
170 Technical correction 72999
170.102 Amended 1426
170.205 (a)(5) revised; (a)(6) and (t) added 1426
170.205 (b)(1) and (2) revised; (c) and (u) added 51265
170.207 (a)(1), (c)(1), (d)(1), (4), (e)(1), (2), (f)(3), (m)(2), (n)(2), (3), (r)(2), and (s)(2) added; (a)(3) and (c)(2) removed; (n)(1), (o), and (p) revised 1426
170.210 (g) revised 1428
170.213 Revised 1428
170.215 Revised 1428
170.299 (j) removed; (f) through (i) redesignated as (g) through new (j); (a), (d) introductory text, (e) introductory text, new (g) introductory text, (m) introductory text, (o) introductory text, (p) introductory text, and (r) introductory text revised; (d)(17) through (19), (e)(6), new (f), (g)(35) through (40), (m)(6), (o)(2), (p)(5), (6), (r)(8), and (9) added 1428
170.299 (k) revised 51265

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170.315 Heading, introductory text, (a)(5) heading, (i) introductory text, (A)(*1*), (*2*), (C), (D), (E), (12), (b)(1)(iii)(A)(*1*), (*2*), (B)(*2*), (G) introductory text, (*3*), (2)(i), (ii), (iii)(D), (iv), (3), (6)(ii)(B)(*2*), (9)(ii), (c)(4)(iii)(C), (E), (G), (H), (I), (e)(1)(i)(A)(*1*), (*2*), (B)(*1*), (*2*), (f)(1)(i)(B), (C), (3)(ii), (4)(ii), (5), (g)(3) introductory text, (6)(i)(A), (B), (9)(i)(A)(*1*), (*2*), (10)(i)(A), (B), (ii)(A), (B), (iv)(A), (B), (v)(A)(*1*)(*i*), (*ii*), (B), (*2*)(*i*), (*ii*), (vi), and (vii) revised; (a)(5)(i)(F), (G), (H), (9)(vi), (b)(11), (e)(1)(iii) added 1429

170.315 Correction: (a)(12), (b)(1)(iii)(A)(*1*), (*2*); (B)(*2*), (G) introductory text, (*3*), (2)(i), (ii), (iii)(D) introductory text, (iv), (3)(ii)(A) introductory text, (6)(ii)(B)(*2*), and (9)(ii) revised 8548

170.315 Correction: Amended 8548

170.315 Correction: Instruction 9 amended 8548

170.315 Correction: (e)(1)(i)(A)(*1*), (*2*), (B)(*1*), and (*2*) introductory text revised; (e)(1)(iii) added 8548

170.315 Correction: (g)(3) introductory text, (6)(i)(A), (B), (9)(i)(A)(*1*), (*2*), (10)(i)(A), (B), (10)(ii)(A), (B), (10)(iv)(A), (B), (10)(v)(A)(*1*)(*i*), (*ii*), (g)(10)(v)(A)(*2*)(*i*), (*ii*), (B), (vi), and (vii) revised 8548

170.315 Correction: (g)(3)(i), (6)(i)(A), (B), (9)(i)(A)(*1*), (*2*), (10)(i)(A), (B), (ii)(A), (B), (iv)(A), (B), (v)(A)(*1*)(*i*), (*ii*), (*2*)(*i*), (*ii*), (B), (vi), and (vii) revised; (g)(3) amended; (g)(3)(i) added 16470

170.400—170.407 (Subpart D) Correction: Authority citation removed 16470

170.402 (a)(5), (b)(3), and (4) added 1433

170.404 (b)(2) revised 1433

170.405 (a) and (b)(2)(ii) revised; (b)(3) through (7) and (10) removed 1434

170.405 Correction: Instruction 12 amended 8548

170.405 Correction: Instruction 13 through 22 redesignated as Instruction 14 through 23 8549

170.405 Correction: Instruction 13 amended 8549

170.405 Technical correction 8548

170.406 Correction: (a)(5) and instruction 17 text amended 8549

170.407 Added 1434

170.407 Correction: (a)(3)(iv) through (vii) revised 16470

170.523 (f)(1) introductory text, (g)(1), (k)(1)(i), and (ii) revised; (f)(1)(xxi) and (u) added 1435

170.524 (f)(1) revised 1435

170.550 (g) introductory text and (m) introductory text revised 1435

170.550 (g) introductory text, (h)(1), and (m) introductory text revised 8549

170.580 CFR correction: (a)(3)(ii) reinstated 9784

171.102 Amended 1435, 54717

171.103 Revised 1436

171.204 (a)(1) and (3) revised; (a)(4) and (5) added 1436

171.301 Revised 1437

171.400—171.403 (Subpart D) Added 1437

171.1000—171.1002 (Subpart J) Added 54717

171.1100—171.1101 (Subpart K) Added 54717

180 Technical correction 9002