

SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

PARTS 140–143 [RESERVED]

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

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AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92.

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 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.

(e) 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]

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 148, 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 148 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 148. 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 148. 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 148.

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

[78 FR 13435, Feb. 27, 2013, as amended at 78 FR 65091, Oct. 30, 2013]

§ 144.103 Definitions.

For purposes of parts 146 (group market), 147 (group and individual market), 148 (individual market), 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 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.

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(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

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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(c); 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.

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 101 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 plan years beginning before January 1, 2016, a State may elect to define large employer by substituting "51 employees" for "101 employees."

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, unless otherwise provided under State law.

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

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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

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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 an issuer and 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 insur-

ance 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 a health insurance issuer offers using a particular product network type within a service area.

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 contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer’s consent) that is less than 12 months after the original effective date of the contract.

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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 100 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 plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.”

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.

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

[69 FR 78781, Dec. 30, 2004, as amended at 74 FR 51688, Oct. 7, 2009; 75 FR 27138, May 13, 2010; 75 FR 37235, June 28, 2010; 77 FR 16468, Mar. 21, 2012; 78 FR 65091, Oct. 30, 2013; 79 FR 10313, Feb. 24, 2014; 79 FR 13833, Mar. 11, 2014; 79 FR 14151, Mar. 12, 2014; 79 FR 30335, May 27, 2014; 80 FR 10861, Feb. 27, 2015]

Subpart B—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

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

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§ 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.

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§ 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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AUTHORITY: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (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 set forth in § 144.103 of this part.

(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 pros-

thesis 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

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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]

§ 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 cov-*

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erage 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 con-

ditions 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.

(i) *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

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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

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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.

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(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*—42V3(4839):

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 non-confinement, 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

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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

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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.

(i) *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

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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

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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 fac-

tor 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 ab-

sence 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

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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 bene-

ficiaries 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 non-financial 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)

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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 re-

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ward 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 re-

quirements 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 pro-

gram 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. ($\$6,000 \times 30\% = \$1,800$.)

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. ($\$6,000 \times 50\% = \$3,000$.)

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 ($\$5,000 \times 30\% = \$1,500$)), 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 non-federal 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.

(i) *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.)

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§ 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*.

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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 Non-discrimination 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 pre-existing 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 CYP₂D6 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 CYP₂D6 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]

§ 146.125 Applicability dates.

Section 144.103, §§146.111 through 146.119, 146.143, and 146.145 are applicable for plan years beginning on or after July 1, 2005. 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 and 146, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2004.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005]

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 determina-

tion, 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 of-

fering 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

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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 in-

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urance 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 sys-

tems, 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 non-quantitative 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

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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

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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 im-

poses 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%	25%	37.5%	12.5%	
		(200x/800x)	(200x/800x)	(300x/800x)	(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 sub-

stance 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 con-

sidered 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 para-

graph (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,

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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.

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(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]

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.

(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 are excepted benefits if they satisfy the requirements of paragraph (b)(3)(v) of this section. Furthermore, benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vi) 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—

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(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 gate-

keeper) 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 wrap-around 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 wrap-around 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 wrap-around 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 wrap-around coverage is first offered; or

(2) The date on which the last collective bargaining agreement relating to the plan terminates after the date limited wrap-around coverage is first offered (determined without regard to any extension agreed to after the date limited wrap-around coverage is first offered).

(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.

(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.

(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 primary coverage, such as coinsurance or deductibles. 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.

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(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.

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(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]

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

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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).

(Approved by the Office of Management and Budget under control number 0938-0702)

[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 (d) 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.

(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 ap-

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plies 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.

(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);

(ii) The product is offered as the same product network type (for exam-

ple, 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.

(Approved by the Office of Management and Budget under control number 0938-0702)

[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 79 FR 30335, May 27, 2014; 79 FR 53004, Sept. 5, 2014]

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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

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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.

(Approved by the Office of Management and Budget under control number 0938–0702)

[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.

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(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

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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]

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

Sec.

- 147.100 Basis and scope.
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- 147.131 Exemption and accommodations in connection with coverage of preventive health services.
- 147.136 Internal claims and appeals and external review processes.
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- 147.145 Student health insurance coverage.
- 147.150 Coverage of essential health benefits.
- 147.160 Parity in mental health and substance use disorder benefits.
- 147.200 Summary of benefits and coverage and uniform glossary.

AUTHORITY: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

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, rating area is determined in the small group market using the group policyholder's principal business address and in the individual market using the primary policyholder's address. For plans (other than qualified health plans offered through the Federally-facilitated Small Business Health Options Program) for which an issuer can demonstrate that it relied in good faith on guidance from an applicable State authority issued before August 28, 2013, that differs from this paragraph (a)(1)(ii), the preceding sentence will not apply until the first plan year beginning on or after January 1, 2015 with respect to coverage in the small group market.

(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 mar-

ket, 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 Federally-facilitated SHOP, as permitted by §156.285(a)(4) of this subchapter, 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.* A single age band for individuals age 0 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 will apply in that state which 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]

§ 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) 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 Small Business Health Options Program (SHOP) in a State, coverage must become effective consistent with the dates described in §155.725 of this subchapter, except as provided in paragraph (b)(1)(iii) of this section.

(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, except as provided in paragraph (b)(1)(iii) of this section.

(iii) *Exception in certain effective dates of coverage.* Only with respect to coverage offered outside of an Exchange or

SHOP, for a plan selection received by an issuer on or before December 15, 2013, the issuer must ensure a coverage effective date of January 1, 2014, and for a plan selection received by an issuer between the 16th and 31st of the month of December 2013, an issuer generally must ensure a coverage effective date of February 1, 2014. The preceding sentence does not prevent an issuer from aligning the plan selection and coverage effective dates with those required by the Exchange or SHOP, as applicable, in the applicable state, consistent with §155.410(c) of this subchapter.

(2) *Limited open enrollment periods.* A health insurance issuer in the individual market must provide a limited open enrollment period for the events described in §155.420(d) of this subchapter, excluding §155.420(d)(3) of this subchapter (concerning citizenship status), §155.420(d)(8) of this subchapter (concerning Indians), and §155.420(d)(9) of this subchapter (concerning exceptional circumstances).

(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, enrollees 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 applica-

ble 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, gender identity, sexual orientation, 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) *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]

§ 147.106 Guaranteed renewability of coverage.

(a) *General rule.* Subject to paragraphs (b) through (d) 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.

(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);

(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

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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 eligi-

bility would otherwise be prohibited under applicable Federal law.

(2) Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual’s health insurance coverage in the individual market.

(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]

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions—(1) 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).

(2) *Examples.* The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see §146.111(a)(1)(ii)):

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.

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.* In this *Example 2*, *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.

(b) *Applicability*—(1) *General applicability date.* Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014; in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) *Early applicability date for children.* The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) *Applicability to grandfathered health plans.* See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

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

Example 1. (i) *Facts.* Individual *F* commences employment and enrolls *F* and *F*'s 16-year-old child in the group health plan maintained by *F*'s employer, with a first day of coverage of October 15, 2010. *F*'s child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enroll-

ing in the plan. *F*'s child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan year beginning January 1, 2011, is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) *Facts.* Individual *G* applies for a policy of family coverage in the individual market for *G*, *G*'s spouse, and *G*'s 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because *G*'s 13-year-old child has autism.

(ii) *Conclusion.* In this *Example 2*, the issuer's denial of *G*'s application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011, denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to *G*'s 13-year-old child.

[75 FR 37235, June 28, 2010]

§ 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

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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,

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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

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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.

(i) *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*

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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.* 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 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, student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage of a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health plans. (Other requirements of Federal or State law, including section 609 of

ERISA or section 1908 of the Social Security Act, may mandate coverage of certain children.)

(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.

(f) *Transitional rules for individuals whose coverage ended by reason of reaching a dependent eligibility threshold—(1) In general.* The relief provided in the

transitional rules of this paragraph (f) applies with respect to any child—

(i) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group or individual health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010 by reason of the application of this section.

(2) *Opportunity to enroll required—(i)* If a group health plan, or group or individual health insurance coverage, in which a child described in paragraph (f)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the child's coverage ended (or did not begin) for the reasons described in paragraph (f)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(ii) The written notice must include a statement that children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage of children ended before attainment of age 26 are eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's child (in the individual market, to the primary subscriber on behalf of the primary subscriber's child). In addition, for a group health plan or group health insurance coverage, the notice may be included

with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (f)(2) is provided to an employee whose child is entitled to an enrollment opportunity under this paragraph (f), the obligation to provide the notice of enrollment opportunity under this paragraph (f)(2) with respect to that child is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (f)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* For purposes of this Part, any child enrolling in a group health plan pursuant to paragraph (f)(2) of this section must be treated as if the child were a special enrollee, as provided under the rules of 45 CFR 146.117(d). Accordingly, the child (and, if the child would not be a participant once enrolled in the plan, the participant through whom the child is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

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

Example 1. (i) *Facts.* Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual B, an employee of Y, and Individual C, B's child and a full-time student, were enrolled in Y's group health plan at the beginning of the 2010 plan year. On June 10, 2010,

C turns 23 years old and loses dependent coverage under Y's plan. On or before January 1, 2011, Y's group health plan gives B written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to C that lasts at least 30 days.

Example 2. (i) *Facts.* Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual D, an employee of Z, and Individual E, D's child, are enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E turns 22 years old and ceases to be eligible as a dependent under Z's plan and loses coverage. D drops coverage but remains an employee of Z.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that D did not drop coverage. Instead, D switched to a lower-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) *Facts.* Same facts as *Example 2*, except that E elected COBRA continuation coverage.

(ii) *Conclusion.* In this *Example 4*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) *Facts.* Employer X maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) *Conclusion.* In this *Example 5*, notwithstanding that the child was not previously covered under the plan, the plan must provide the child, not later than January 1, 2011,

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an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(g) *Special rule for grandfathered group health plans*—(1) For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act and that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the adult child is 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 group health plan of a parent.

(2) For plan years beginning on or after January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act must comply with the requirements of paragraphs (a) through (f) of this section.

(h) *Applicability date*. The provisions of this section apply for plan years (in the individual market, 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.

[75 FR 27138, May 13, 2010, as amended at 75 FR 34566, June 17, 2010]

§ 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 benefits for any individual.

(2) *Annual limits*—(i) *General rule*. Except as provided in paragraphs (a)(2)(ii), (b), and (d) 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 benefits for any individual.

(ii) *Exception for health flexible spending arrangements*. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue

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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.

(d) *Restricted annual limits permissible prior to 2014*—(1) *In general*. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year (in the individual market, policy year) beginning on or after September 23, 2010, but before September 23, 2011, \$750,000.

(ii) For a plan year (in the individual market, policy year) beginning on or after September 23, 2011, but before September 23, 2012, \$1,250,000.

(iii) For plan years (in the individual market, policy years) beginning on or

after September 23, 2012, but before January 1, 2014, \$2,000,000.

(2) *Only essential health benefits taken into account.* In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) *Waiver authority of the Secretary.* For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary may establish a program under which the requirements of paragraph (d)(1) of this section relating to annual limits may be waived (for such period as is specified by the Secretary) for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

(e) *Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit—(1) In general.* The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits under a group health plan or group or individual health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a lifetime limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, by reason of the application of this section.

(2) *Notice and enrollment opportunity requirements—(i)* If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan—or group

or individual health insurance coverage—described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(ii) The notices required under paragraph (e)(2)(i) of this section may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notices may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For either notice, with respect to a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an individual, the obligation to provide the notice with respect to that individual is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the

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rules of § 146.117(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

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

Example 1. (i) *Facts.* Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For plan years beginning before September 23, 2010, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2008 plan year. On June 10, 2008, B incurred a claim for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. B is still eligible for coverage under Y's group health plan. On or before January 1, 2011, Y's group health plan gives B written notice informing B that the lifetime limit on the dollar value of all benefits no longer applies, that individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to enroll in the plan, and that individuals can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (e) by providing a timely written notice and enrollment opportunity to B that lasts at least 30 days.

Example 2. (i) *Facts.* Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z and is still eli-

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gible for coverage under Z's group health plan.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that Z's plan had two benefit packages (a low-cost and a high-cost option). Instead of dropping coverage, D switched to the low-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible. The plan would have to provide D and E the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if D had not switched to the low-cost benefit package option.

Example 4. (i) *Facts.* Employer Q maintains a group health plan with a plan year beginning October 1 and ending September 30. For the plan year beginning on October 1, 2009, Q has an annual limit on the dollar value of all benefits of \$500,000.

(ii) *Conclusion.* In this *Example 4*, Q must raise the annual limit on the dollar value of essential health benefits to at least \$750,000 for the plan year beginning October 1, 2010. For the plan year beginning October 1, 2011, Q must raise the annual limit to at least \$1.25 million. For the plan year beginning October 1, 2012, Q must raise the annual limit to at least \$2 million. Q may also impose a restricted annual limit of \$2 million for the plan year beginning October 1, 2013. After the conclusion of that plan year, Q cannot impose an overall annual limit.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the annual limit for the plan year beginning on October 1, 2009, is \$1 million and Q lowers the annual limit for the plan year beginning October 1, 2010 to \$750,000.

(ii) *Conclusion.* In this *Example 5*, Q complies with the requirements of this paragraph (e). However, Q's choice to lower its annual limit means that under § 147.140(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

Example 6. (i) *Facts.* For a policy year that began on October 1, 2009, Individual T has individual health insurance coverage with a lifetime limit on the dollar value of all benefits of \$1 million. For the policy year beginning October 1, 2010, the issuer of T's health insurance coverage eliminates the lifetime limit and replaces it with an annual limit of

\$1 million dollars. In the policy year beginning October 1, 2011, the issuer of *T*'s health insurance coverage maintains the annual limit of \$1 million dollars.

(i) *Conclusion.* In this *Example 6*, the issuer's replacement of a lifetime limit with an equal dollar annual limit allows it to maintain status as a grandfathered health policy under § 147.140(g)(1)(vi)(B). Since grandfathered health plans that are individual health insurance coverage are not subject to the requirements of this section relating to annual limits, the issuer does not have to comply with this paragraph (e).

(f) *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 the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits, and the prohibition on lifetime limits apply to individual health insurance coverage that is a grandfathered health plan but the rules on annual limits do not apply to individual health insurance coverage that is a grandfathered health plan).

[75 FR 37236, June 28, 2010]

§ 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 unless the individual 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 writ-

ten 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; or

(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 towards the cost of coverage.

(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. 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

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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 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 the rules regarding rescissions and advance notice apply to all grandfathered health plans).

[75 FR 37238, June 28, 2010]

§ 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, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

(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

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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; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(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 para-

graph (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 paragraph (a)(3)(ii) 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. Moreover, nothing in this section 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.

(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

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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) *In general.* 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.

(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) 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 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) 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 plan or policy year.

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(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).

[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]

§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

(a) *Religious employers.* In issuing guidelines under §147.130(a)(1)(iv), the Health Resources and Services Administration may establish an exemption from such guidelines with respect to a group health plan established or maintained by a religious employer (and health insurance coverage provided in connection with a group health plan established or maintained by a religious employer) with respect to any requirement to cover contraceptive services under such guidelines. For purposes of this paragraph (a), a “religious employer” is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(b) *Eligible organizations.* An eligible organization is an organization that meets the criteria of paragraphs (b)(1) through (3) of this section.

(1) The organization opposes providing coverage for some or all of any contraceptive items or services required to be covered under §147.130(a)(1)(iv) on account of religious objections.

(2)(i) The organization is organized and operates as a nonprofit entity and

holds itself out as a religious organization; or

(ii) The organization is organized and operates as a closely held for-profit entity, as defined in paragraph (b)(4) of this section, and the organization's highest governing body (such as its board of directors, board of trustees, or owners, if managed directly by its owners) has adopted a resolution or similar action, under the organization's applicable rules of governance and consistent with state law, establishing that it objects to covering some or all of the contraceptive services on account of the owners' sincerely held religious beliefs.

(3) The organization must self-certify in the form and manner specified by the Secretary of Labor or provide notice to the Secretary of Health and Human Services as described in paragraph (c) of this section. 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 (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or 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) A closely held for-profit entity is an entity that—

- (i) Is not a nonprofit entity;
- (ii) 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); and
- (iii) Has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer individuals, or has an ownership structure that is substantially similar thereto, as of the date of the entity's self-certification or notice described in paragraph (b) or (c) of this section.

(iv) For the purpose of the calculation in paragraph (b)(4)(iii) of this section, the following rules apply:

(A) Ownership interests owned by a corporation, partnership, estate, or trust are considered owned proportionately by such entity's shareholders,

partners, or beneficiaries. Ownership interests owned by a nonprofit entity are considered owned by a single owner.

(B) An individual is considered to own the ownership interests owned, directly or indirectly, by or for his or her family. Family includes only brothers and sisters (including half-brothers and half-sisters), a spouse, ancestors, and lineal descendants.

(C) If a person holds an option to purchase ownership interests, he or she is considered to be the owner of those ownership interests.

(v) A for-profit entity that seeks further information regarding whether it qualifies for the accommodation described in this section may send a letter describing its ownership structure to the Department of Health and Human Services. An entity must submit the letter in the manner described by the Department of Health and Human Services. If the entity does not receive a response from the Department of Health and Human Services to a properly submitted letter describing the entity's current ownership structure within 60 calendar days, as long as the entity maintains that structure it will be considered to meet the requirement set forth in paragraph (b)(4)(iii) of this section.

(c) *Contraceptive coverage—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 complies for one or more plan years with any requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with §147.130. An issuer may not require any

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further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (*i.e.*, whether it is a student health insurance plan within the meaning of §147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. 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 Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) *Payments for contraceptive services*—(i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under §147.130(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under §147.130(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), or impose any 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.

(d) *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 accommodation in paragraph (c) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (c) 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 (d): “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].”

(e) *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 (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any 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 requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Application to student health insurance coverage*. The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education as defined in 20 U.S.C. 1002 in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In ap-

plying this section in the case of student health insurance coverage, a reference to “plan participants and beneficiaries” is a reference to student enrollees and their covered dependents.

[78 FR 39896, July 2, 2013, as amended at 79 FR 51101, Aug. 27, 2014; 80 FR 41346, July 14, 2015]

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope*. This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under §147.140 of this part. 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. Paragraph (g) of this section sets forth the applicability date for this section.

(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) or (b)(3)(ii)(F) of this section).

(vi) *Final external review decision. A final external review decision*, as used in paragraph (d) of this section, 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 of this part.)

(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

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.

(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 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 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 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 45 CFR 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.

(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)(2)(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.

(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.

(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) or (b)(3) 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, the State external review process may require a nominal filing fee from the claimant requesting an external review. 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 (in the individual market, policy 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 IRO 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 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 claimant and the issuer (or, if applicable, the plan) 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, 2011, 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, 2011, 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) 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, 2012, the Federal external review process will apply 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.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided after the first day of the first plan year (in the individual market, policy year) beginning on or after July 1, 2011, the Federal external review process will apply 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 as of the first day of the plan year (in the individual market, policy year).

(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).

(1) *Scope*—(i) *In general.* Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to

the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies, at a minimum, to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

(ii) *Suspension of general rule.* Unless or until this suspension is revoked in guidance by the Secretary, with respect to claims for which external review has not been initiated before September 20, 2011, the Federal external review process established pursuant to this paragraph (d) applies only to:

(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; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(iii) *Examples.* This rules of paragraph (d)(1)(ii) 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. Accord-

ingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) 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 during the suspension period under paragraph (d)(1)(ii) 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.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is

eligible for external review, minimum qualifications for IROs, a process for approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for IRO decision-making, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(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 under paragraph (b) of this section; 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 pursuant to paragraph (d)(3) of this section 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 service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent 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 any 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.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants, beneficiaries, and enrollees describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees.

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(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 include 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;

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(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 apply for plan years (in the individual market, 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 internal claims and appeals and external review processes do not apply to grandfathered health plans).

[75 FR 43350, July 23, 2010, as amended at 76 FR 37232, June 24, 2011; 76 FR 44492, July 26, 2011; 78 FR 68296, Nov. 13, 2013]

§ 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 partici-

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pant, 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) *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 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.

(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 ac-

cept 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 equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(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) *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 *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 apply for plan years (in the individual market, policy years)

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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 patient protections do not apply to grandfathered health plans).

[75 FR 37233, June 28, 2010]

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage*. *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 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.

(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

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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, in any plan materials provided to a participant or beneficiary (in the individual market, primary subscriber) describing the benefits provided under the plan or health insurance coverage, 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.

(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 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.healthreform.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 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.

(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.

(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.* Same facts as *Example 1*, except that the plan sponsor eliminates Option *F* because of its high cost and transfers employees covered under Option *F* to Option *G*. If instead of transferring employees from Option *F* to Option *G*, Option *F* was amended to match the terms of Option *G*, then Option *F* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan did not have a bona fide employment-based reason to transfer employees from Option *F* to Option *G*. Therefore, Option *G* ceases to be a grandfathered health plan with respect to all employees. (However, any other benefit package maintained by the plan sponsor is analyzed separately under the rules of this section.)

Example 3. (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 3*, 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 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 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 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 paragraph (g)(2) 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.

(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.

(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)(3)(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, 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)(3)(i) of this section (that is, \$5 times medical inflation, plus \$5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(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)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 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)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 146.121(d) of

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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.

(B) *Decrease in limit for a plan or coverage with only a lifetime limit*. A group health plan, or group or 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.

(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).

(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 con-

tract 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) *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 this purpose, 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 medical inflation (as defined in paragraph (g)(3)(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.

(4) *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 condi-

tion, 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 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. 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% ($40 - 30 = 10$; $10 \div 30 = 0.3333$; $0.3333 = 33.33\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 ($475 - 387.142 = 87.858$; $87.858 \div 387.142 = 0.2269$). 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*, except the grandfathered health plan subsequently increases the \$40 copayment requirement to \$45 for a later plan year. 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% ($45 - 30 = 15$; $15 \div 30 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 ($485 - 387.142 = 97.858$; $97.858 \div 387.142 = 0.2527$). 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 \times 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.* On March 23, 2010, a grandfathered 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. Within the 12-month period before the \$15 copayment takes effect, the greatest value of

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the overall medical care component of the CPI-U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% ($15 - 10 = 5$; $5 \div 10 = 0.5$; $0.5 = 50\%$). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is $0.0720 (415.0 - 387.142 = 27.858; 27.858 \div 387.142 = 0.0720)$. 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 22.20% ($0.0720 = 7.20\%$; $7.20\% + 15\% = 22.20\%$), or $\$5.36 (\$5 \times 0.0720 = \$0.36; \$0.36 + \$5 = \$5.36)$. The $\$5$ increase in copayment in this *Example 5* 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 6. (i) *Facts.* The same facts as *Example 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 $\$5$.

(ii) *Conclusion.* In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is $0.0720 (415.0 - 387.142 = 27.858; 27.858 \div 387.142 = 0.0720)$. 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 $\$5.36 (\$5 \times 0.0720 = \$0.36; \$0.36 + \$5 = \$5.36)$. The $\$5$ increase in copayment in this *Example 6* 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 7. (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 7*, 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 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $\$5000$ for self-only coverage and $\$12,000$ for family coverage. The required employee contribution for the coverage is $\$1000$ for self-only coverage and $\$4000$ for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ($(5000 - 1000)/5000$) for self-only coverage and 67% ($(12,000 - 4000)/12,000$) for family coverage. For a subse-

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quent plan year, the COBRA premium is $\$6000$ for self-only coverage and $\$15,000$ for family coverage. The employee contributions for that plan year are $\$1200$ for self-only coverage and $\$5000$ for family coverage. Thus, the contribution rate based on cost of coverage is 80% ($(6000 - 1200)/6000$) for self-only coverage and 67% ($(15,000 - 5000)/15,000$) for family coverage.

(ii) *Conclusion.* In this *Example 8*, 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 9. (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 9*, 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).

[75 FR 34566, June 17, 2010, as amended at 75 FR 70121, Nov. 15, 2010]

§ 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) *Annual limits.* (i) Notwithstanding the annual dollar limits requirements of §147.126, for policy years beginning before September 23, 2012, a health insurance issuer offering student health insurance coverage may not establish an annual dollar limit on essential health benefits that is lower than \$100,000.

(ii) Notwithstanding the annual dollar limits requirements of §147.126, for policy years beginning on or after September 23, 2012, but before January 1, 2014, a health insurance issuer offering student health insurance coverage may not establish an annual dollar limit on essential health benefits that is lower than \$500,000.

(iii) For policy years beginning on or after January 1, 2014, a health insurance issuer offering student health insurance coverage must comply with the annual dollar limits requirements in §147.126.

(3) *Single risk pool.* Student health insurance coverage is not subject to the requirements of section 1312(c) of the Affordable Care Act.

(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.

(d) *Notice—*(1) *Requirements.* (i) A health insurance issuer that provides student health insurance coverage, and does not meet the annual dollar limits requirements under section 2711 of the Public Health Service Act, must provide a notice informing students that the policy does not meet the minimum annual limits requirements under section 2711 of the Public Health Service Act. The notice must include the dollar amount of the annual limit along with a description of the plan benefits to which the limit applies for the student health insurance coverage.

(ii) The notice must state that the student may be eligible for coverage as a dependent in a group health plan of a parent's employer or under the parent's individual market coverage if the student is under the age of 26.

(iii) The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the insurance policy or certificate and in any other plan materials summarizing the terms of the coverage (such as a summary description document).

(iv) The notice must be provided for policy years beginning before January 1, 2014.

(2) *Model language.* The following model language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (d): “Your student health insurance coverage, offered by [name of health insurance issuer], may not meet the minimum standards required by the

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health care reform law for the restrictions on annual dollar limits. The annual dollar limits ensure that consumers have sufficient access to medical benefits throughout the annual term of the policy. Restrictions for annual dollar limits for group and individual health insurance coverage are \$1.25 million for policy years before September 23, 2012; and \$2 million for policy years beginning on or after September 23, 2012 but before January 1, 2014. Restrictions for annual dollar limits for student health insurance coverage are \$100,000 for policy years before September 23, 2012, and \$500,000 for policy years beginning on or after September 23, 2012, but before January 1, 2014. Your student health insurance coverage put an annual limit of: [Dollar amount] on [which covered benefits—notice should describe all annual limits that apply]. If you have any questions or concerns about this notice, contact [provide contact information for the health insurance issuer]. Be advised that you may be eligible for coverage under a group health plan of a parent's employer or under a parent's individual health insurance policy if you are under the age of 26. Contact the plan administrator of the parent's employer plan or the parent's individual health insurance issuer for more information."

(e) *Applicability.* The provisions of this section apply for policy years beginning on or after July 1, 2012.

[77 FR 16468, Mar. 21, 2012, as amended at 78 FR 13439, Feb. 27, 2013; 79 FR 13834, Mar. 11, 2014]

§ 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

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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 non-grandfathered and grandfathered health plans as defined in § 147.140.

[78 FR 68296, Nov. 13, 2013]

§ 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 re-enrollment*. 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 sec-

tion 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

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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 insur-

ance 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)

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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)(i) 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

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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 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 to individuals and covered dependents in the individual market, this section is applicable to health insurance issuers beginning with respect to SBCs issued for

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coverage that begins on or after January 1, 2016.

[80 FR 34310, June 16, 2015]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

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AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

SOURCE: 62 FR 16995, Apr. 8, 1997, unless otherwise noted.

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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, applicability, and effective dates.

(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 date.* Except as provided in §148.124 (certificate of creditable coverage), §148.170 (standards relating to benefits for mothers and newborns), and §148.180 (prohibition of health discrimination based on genetic information), 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.

[79 FR 30340, May 27, 2014]

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 paragraph (c) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

(2) Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market.

(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 mar-

ket 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

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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.

(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);

(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]

§ 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 moth-

er, 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 pro-

viding 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.

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(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 determina-

tion 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 pre-existing 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 connec-

tion 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 CYP₂D6 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 CYP₂D6 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*.

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(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.

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(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(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 non-coordination of benefits.

(4) Hospital indemnity or other fixed indemnity insurance only if—

(i) The benefits are provided only to individuals who attest, in their fixed indemnity insurance application, that they have other health coverage that is minimum essential coverage within the meaning of section 5000A(f) of the Internal Revenue Code, or that they are treated as having minimum essential coverage due to their status as a bona fide resident of any possession of the United States pursuant to Code section 5000A(f)(4)(B).

(ii) There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage.

(iii) 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.

(iv) A notice is displayed prominently in the application materials in at least 14 point type that has the following language: “THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE. LACK OF MAJOR MEDICAL COVERAGE (OR OTHER MINIMUM ESSENTIAL COVERAGE) MAY RESULT IN AN ADDITIONAL PAYMENT WITH YOUR TAXES.”

(v) The requirement of paragraph (b)(4)(iv) of this section applies to all hospital or other fixed indemnity insurance policy years beginning on or after January 1, 2015, and the requirement of paragraph (b)(4)(i) of this section applies to hospital or other fixed indemnity insurance policies issued on or after January 1, 2015, and to hospital or other fixed indemnity policies issued before that date, upon their first renewal occurring on or after October 1, 2016.

(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 non-discrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic non-discrimination 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.

[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]

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

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(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.

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(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.

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(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.

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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 fac-

simile (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

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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—REQUIREMENTS FOR THE EARLY RETIREE REINSURANCE PROGRAM

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149.700 Change of ownership requirements.

AUTHORITY: Section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24466, May 5, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 149.1 Purpose and basis.

This part implements the Early Retiree Reinsurance Program, as required by section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

§ 149.2 Definitions.

For purposes of this part, the following definitions apply:

Authorized representative means an individual with legal authority to sign and bind a sponsor to the terms of a contract or agreement.

Benefit option means a particular benefit design, category of benefits, or

cost-sharing arrangement offered within an employment-based plan.

Certified means that the sponsor and its employment-based plan or plans meet the requirements of this part and the sponsor's application to participate in the program has been approved by the Secretary.

Chronic and high-cost condition means a condition for which \$15,000 or more in health benefit claims are likely to be incurred during a plan year by one plan participant.

Claim or medical claim means documentation, in a form and manner to be specified by the Secretary, indicating the health benefit provided, the provider or supplier, the incurred date, the individual for whom the health benefit was provided, the date and amount of payment net any known negotiated price concessions, and the employment-based plan and benefit option under which the health benefit was provided. The terms *claim* or *medical claim* include medical, surgical, hospital, prescription drug and other such claims as determined by the Secretary.

Early retiree means a plan participant who is age 55 and older who is enrolled for health benefits in a certified employment-based plan, who is not eligible for coverage under title XVIII of the Act, and who is not an active employee of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan. In this part, the term *early retiree* also includes the enrolled spouse, surviving spouse, and dependents of such individuals. The determination of whether an individual is not an active employee is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed to be an active employee if, under the Medicare Secondary Payer rules in 42 CFR 411.104 and related guidance published by the Centers for Medicare & Medicaid Services, the person is considered to be receiving coverage by reason of current employment status. This presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor may also treat a person receiving coverage under its employ-

ment-based plan as a dependent in accordance with the rules of its plan, regardless of whether that individual is considered a dependent for Federal or state tax purposes. For purposes of this definition of early retiree, an employer maintaining, or currently contributing to, the employment-based plan or any employer that has made substantial contributions to fund such plan, means a plan sponsor (as defined in this section).

Employment-based plan means a group health plan as defined in this section of the regulation.

Good cause means:

(1) New and material evidence exists that was not readily available at the time the reimbursement determination was made;

(2) A clerical error in the computation of the reimbursement determination was made by the Secretary; or

(3) The evidence that was considered in making the reimbursement determination clearly shows on its face that an error was made.

Group health plan means group health plan as defined in 42 CFR 423.882 that provides health benefits to early retirees, but excludes Federal governmental plans.

Health benefits means medical, surgical, hospital, prescription drug, and other benefits that may be specified by the Secretary, whether self-funded or delivered through the purchase of health insurance or otherwise. Such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. Health benefits do not include benefits specified at 45 CFR 146.145(c)(2) through (4).

Incurred means the point in time when the sponsor, health insurance issuer (as defined in 45 CFR 160.103), employment-based plan, plan participant, or a combination of these or similar stakeholders, become responsible for payment of the claim.

Negotiated price concession means any direct or indirect remuneration (including discounts, direct or indirect subsidies, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or

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reduced-price services, grants, or other price concessions or similar benefits) offered to some or all purchasers, which may include a sponsor, a health insurance issuer, or an employment-based plan) that would serve to decrease the costs incurred under the employment-based plan.

Plan participant means anyone enrolled in an applicable plan including an early retiree, as defined in this section, a retiree, a retiree's spouse and dependent, an active employee and an active employee's spouse and dependent.

Plan year means the year that is designated as the plan year in the plan document of an employment-based plan, except that if the plan document does not designate a plan year, if the plan year is not a 12-month plan year, or if there is no plan document, the plan year is:

- (1) The deductible or limit year used under the plan;
- (2) The policy year, if the plan does not impose deductibles or limits on a 12-month basis;
- (3) The sponsor's taxable year, if the plan does not impose deductibles or limits on a 12-month basis, and either the plan is not insured or the insurance policy is not renewed on a 12-month basis, or;
- (4) The calendar year, in any other case.

Post point-of-sale negotiated price concession means any negotiated price concession that an employment-based plan or insurer receives with respect to a given health benefit, after making payment for that health benefit.

Program means the Early Retiree Reinsurance Program established in section 1102 of the Patient Protection and Affordable Care Act.

Secretary means the Secretary of the United States Department of Health & Human Services or the Secretary's designee.

Sponsor means a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the pri-

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mary source of financing, the term means the employer.

Sponsor agreement means an agreement between the sponsor and the United States Department of Health & Human Services, or its designee, which is made to comply with the provisions of this part.

Subpart B—Requirements for Eligible Employment-Based Plans

§ 149.30 General requirements.

A sponsor is eligible to participate in the program if it meets the requirements of section 1102 of the Patient Protection and Affordable Care Act, this part, and guidance developed by the Secretary.

§ 149.35 Requirements to participate.

(a) A sponsor's employment-based plan must—

- (1) Be certified by the Secretary.
- (2) Include programs and procedures that have generated or have the potential to generate cost-savings with respect to plan participants with chronic and high-cost conditions.

(b) A sponsor must—

(1) Make available information, data, documents, and records as specified in § 149.350.

(2) Have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as applicable) regarding disclosure of information, data, documents, and records, to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, the information, data, documents and records necessary for the sponsor to comply with the program, this part, and program guidance.

(3) Ensure that policies and procedures to protect against fraud, waste and abuse under this program are in place, and must comply timely with requests from the Secretary to produce the policies and procedures and any documents or data to substantiate the implementation of the policies and procedures and their effectiveness.

(4) Submit an application to the Secretary in the manner, and at the time,

required by the Secretary as specified in § 149.40.

§ 149.40 Application.

(a) The applicant must submit an application to participate in this program to the Secretary, which is signed by an authorized representative of the applicant who certifies that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief.

(b) Applications will be processed in the order in which they are received.

(c) An application that fails to meet all the requirements of this part will be denied and the applicant must submit another application if it wishes to participate in the program. The new application will be processed based on when the new submission is received.

(d) An applicant need not submit a separate application for each plan year but must identify in its application the plan year start and end date cycle (starting month and day, and ending month and day) for which it is applying.

(e) An applicant must submit an application for each plan for which it will submit a reimbursement request.

(f) In connection with each application the applicant must submit the following:

(1) Applicant's Tax Identification Number.

(2) Applicant's name and address.

(3) Contact name, telephone number and email address.

(4) Plan sponsor agreement signed by an authorized representative, which includes—

(i) An assurance that the sponsor has a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan, as applicable, regarding disclosure of information to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, information, data, documents, and records necessary for the sponsor to comply with the requirements of the program.

(ii) An acknowledgment that the information in the application is being provided to obtain Federal funds, and

that all subcontractors acknowledge that information provided in connection with a subcontract is used for purposes of obtaining Federal funds.

(iii) An attestation that policies and procedures are in place to detect and reduce fraud, waste, and abuse, and that the sponsor will produce the policies and procedures, and necessary information, records and data, upon request by the Secretary, to substantiate existence of the policies and procedures and their effectiveness.

(iv) Other terms and conditions required by the Secretary.

(5) A summary indicating how the applicant will use any reimbursement received under the program to meet the requirements of the program, including:

(i) How the reimbursement will be used to reduce premium contributions, co-payments, deductibles, coinsurance, or other out-of-pocket costs for plan participants, to reduce health benefit or health benefit premium costs for the sponsor, or to reduce any combination of these costs;

(ii) What procedures or programs the sponsor has in place that have generated or have the potential to generate cost savings with respect to plan participants with chronic and high-cost conditions; and

(iii) How the sponsor will use the reimbursement to maintain its level of contribution to the applicable plan.

(6) Projected amount of reimbursement to be received under the program for the first two plan year cycles with specific amounts for each of the two cycles.

(7) A list of all benefit options under the employment-based plan that any early retiree for whom the sponsor receives program reimbursement may be claimed.

(8) Any other information the Secretary requires.

(g) An application must be approved, and the plan and the sponsor certified, by the Secretary before a sponsor may request reimbursement under the program.

(h) The Secretary may reopen a determination under which an application had been approved or denied:

(1) Within 1 year of the determination for any reason;

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(2) Within 4 years of the determination if the evidence that was considered in making the determination shows on its face that an error was made; or

(3) At any time in instances of fraud or similar fault.

§ 149.41 Consequences of Non-Compliance, Fraud, or Similar Fault.

Upon failure to comply with the requirements of this part, or if fraud, waste, and abuse, or similar fault are found, the Secretary may recoup or withhold funds, terminate or deny a sponsor's application, or take a combination of these actions.

§ 149.45 Funding limitation.

(a) Based on the projected or actual availability of program funding, the Secretary may deny applications that otherwise meet the requirements of this part, and if an application is approved, may deny all or part of a sponsor's reimbursement request.

(b) The Secretary's decision to stop accepting applications or satisfying reimbursement requests based on the availability of funding is final and binding, and is not appealable.

Subpart C—Reinsurance Amounts

§ 149.100 Amount of reimbursement.

(a) For each early retiree enrolled in a certified plan in a plan year, the sponsor receives reimbursement in the amount of 80 percent of the costs for health benefits (net of negotiated price concessions for health benefits) for claims incurred during the plan year that are attributed to health benefits costs between the cost threshold and cost limit, and that are paid by the employment-based plan or by the insurer (if an insured plan), and by the early retiree.

(b) Costs are considered paid by an early retiree, if paid by that individual or another person on behalf of the early retiree, and the early retiree (or person paying on behalf of the early retiree) is not reimbursed through insurance or otherwise, or other third party payment arrangement.

(c) Reimbursement is calculated by first determining the costs for health benefits net of negotiated price conces-

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sions, within the applicable plan year for each early retiree, and then subtracting amounts below the cost threshold and above the cost limit within the applicable plan year for each such individual.

(d) For purposes of determining amounts below the cost threshold and above the cost limit for any given early retiree, all costs for health benefits paid by the employment-based plan (or by the insurer, if applicable), or by or on behalf of, an early retiree, for all benefit options the early retiree is enrolled in with respect to a given certified employment-based plan for a given plan year, will be combined. For each early retiree enrolled in an employment-based plan, there is only one cost threshold and one cost limit per plan year regardless of the number of benefit options the early retiree is enrolled in during that plan year.

§ 149.105 Transition provision.

For a certified plan that has a plan year that begins before June 1, 2010 and ends on any date thereafter, the reinsurance amount for the plan year must be determined as follows:

(a) With respect to claims incurred before June 1, 2010, the amount of such claims up to \$15,000 count toward the cost threshold and the cost limit. The amount of claims incurred before June 1, 2010 that exceed \$15,000 are not eligible for reimbursement and do not count toward the cost limit.

(b) The reinsurance amount to be paid is based only on claims incurred on and after June 1, 2010, that fall between the cost threshold and cost limit for the plan year.

§ 149.110 Negotiated price concessions.

(a) The amount of negotiated price concessions that will be taken into account in determining the reinsurance amount will reflect negotiated price concessions that have already been subtracted from the amount the employment-based plan or insurer paid for the cost of health benefits and the amount of post-point-of-sale negotiated price concessions received.

(b) At a time specified by the Secretary, sponsors are required to disclose the amount of post-point-of-sale price concessions that were received

but not accounted for in their submitted claims.

§ 149.115 Cost threshold and cost limit.

The following cost threshold and cost limits apply individually, to each early retiree as defined in §149.2:

(a) The cost threshold is equal to \$15,000 for plan years that start on any date before October 1, 2011.

(b) The cost limit is equal to \$90,000 for plan years that start on any date before October 1, 2011.

(c) The cost threshold and cost limit specified in paragraphs (a) and (b) of this section, for plan years that start on or after October 1, 2011, will be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of \$1,000) for the year involved.

Subpart D—Use of Reimbursements

§ 149.200 Use of reimbursements.

(a) A sponsor must use the proceeds under this program:

(1) To reduce the sponsor's health benefit premiums or health benefit costs,

(2) To reduce health benefit premium contributions, copayments, deductibles, coinsurance, or other out-of-pocket costs, or any combination of these costs, for plan participants, or

(3) To reduce any combination of the costs in (a)(1) and (a)(2) of this section.

(b) Proceeds under this program must not be used as general revenue for the sponsor.

Subpart E—Reimbursement Methods

§ 149.300 General reimbursement rules.

Reimbursement under this program is conditioned on provision of accurate information by the sponsor or its designee. The information must be submitted, in a form and manner and at the times provided in this subpart and other guidance specified by the Secretary. A sponsor must provide the information specified in section §149.335.

§ 149.310 Timing.

(a) An employment-based plan and a sponsor must be certified by the Secretary before claims can be submitted and a reimbursement request may be made. Reimbursement will be made with respect to submitted claims for health benefits at a time and in a manner to be specified by the Secretary, after the sponsor or its designee submits the claims to the Secretary. Claims must satisfy the requirements of this subpart in order to be eligible for reimbursement.

(b) Claims for health benefits may be submitted for a given plan year only upon the approval of an application that references that plan year cycle. Claims for an early retiree for a plan year cannot be submitted until the total paid costs for health benefits for that early retiree incurred for that plan year exceed the applicable cost threshold.

(c) For employment-based plans for which a provider in the normal course of business does not produce a claim, such as a staff-model health maintenance organization, the information required in a claim must be produced and provided to the Secretary, as set out in this regulation and applicable guidance.

§ 149.315 Reimbursement conditioned upon available funds.

Notwithstanding a sponsor's compliance with this part, reimbursement is conditioned upon the availability of program funds.

§ 149.320 Universe of claims that must be submitted.

(a) Claims submitted for an early retiree, as defined in §149.2, must include claims below the applicable cost threshold for the plan year.

(b) Claims must not be submitted until claims are submitted for amounts that exceed the applicable cost threshold for the plan year for the early retiree.

(c) Sponsors must not submit claims for health benefits for an early retiree to the extent the sponsor has already submitted claims for the early retiree that total more than the applicable cost limit for the applicable plan year.

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§ 149.325 Requirements for eligibility of claims.

A claim may be submitted only if it represents costs for health benefits for an early retiree, as defined in § 149.2, has been incurred during the applicable plan year, and has been paid.

§ 149.330 Content of claims.

Each claim on its face must include the information specified in, and meet, the definition of claim or medical claim found at § 149.2.

§ 149.335 Documentation of costs of actual claims involved.

(a) A submission of claims consists of a list of early retirees for whom claims are being submitted, and documentation of the actual costs of the items and services for claims being submitted, in a form and manner specified by the Secretary.

(b) In order for a sponsor to receive reimbursement for the portion of a claim that an early retiree paid, the sponsor must submit prima facie evidence that the early enrollee paid his or her portion of the claim.

§ 149.340 Rule for insured plans.

With respect to insured plans, the claims and data specified in the subpart may be submitted directly to the Secretary by the insurer.

§ 149.345 Use of information provided.

The Secretary may use data and information collected under this section only for the purpose of, and to the extent necessary in, carrying out this part including, but not limited to, determining reimbursement and reimbursement-related oversight and program integrity activities, or as otherwise allowed by law. Nothing in this section limits the Office of the Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 149.350 Maintenance of records.

(a) The sponsor of the certified plan (or a subcontractor, as applicable) must maintain and furnish to the Secretary, upon request the records enumerated in paragraph (b) of this sec-

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tion. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law.

(b) The records that must be retained are as follows—

(1) All documentation, data, and other information related to this part.

(2) Any other records specified by the Secretary.

(c) The Secretary may issue additional guidance addressing record-keeping requirements, including (but not limited to) the use of electronic media.

(d) The sponsor must require its health insurance issuer or employment-based plan, as applicable, to maintain and produce upon request records to satisfy subparagraph (a) of this regulation.

(e) The sponsor is responsible for ensuring that the records are maintained and provided according to this subpart.

Subpart F—Appeals

§ 149.500 Appeals.

(a) An adverse reimbursement determination is final and binding unless appealed pursuant to paragraph (e) of this section.

(b) Except as provided in paragraph (c) of this section, a sponsor may request an appeal of an adverse reimbursement determination.

(c) A sponsor may not appeal an adverse reimbursement determination if the denial is based on the unavailability of funds.

(d) An adverse reimbursement determination is a determination constituting a complete or partial denial of a reimbursement request.

(e) If a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 calendar days of receipt of the determination pursuant to guidance issued by the Secretary.

§ 149.510 Content of request for appeal.

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for

the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider.

§ 149.520 Review of appeals.

(a) In conducting review of the appeal, the Secretary reviews the appeal, the evidence and findings upon which the adverse reimbursement determination was made, and any other written evidence submitted by the sponsor or the Secretary's designee and will provide a ruling on the appeal request.

(b) In conducting the review, the Secretary reviews the determination at issue, the evidence and findings upon which it was based, any written documents submitted to the Secretary by the sponsor and the Secretary's designee, and determines whether to uphold, reverse or modify the Secretary's initial reimbursement determination.

(c) A decision by the Secretary under this provision is final and binding.

(d) Regardless of the Secretary's decision, additional reimbursement is contingent upon the availability of funds at the time of the Secretary's determination.

(e) The Secretary informs the sponsor and the applicable Secretary's designee of the decision. The Secretary sends a written decision to the sponsor or the applicable Secretary's designee upon request.

Subpart G—Disclosure of Data Inaccuracies

§ 149.600 Sponsor's duty to report data inaccuracies.

A sponsor is required to disclose any data inaccuracies upon which a reimbursement determination is made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance.

§ 149.610 Secretary's authority to reopen and revise a reimbursement determination.

(a) The Secretary may reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor:

(1) Within 1 year of the reimbursement determination for any reason.

(2) Within 4 years of a reimbursement determination for good cause.

(3) At any time, in instances of fraud or similar fault.

(b) For purposes of this section, the Secretary does not find good cause if the only reason for the revision is a change of legal interpretation or administrative ruling upon which the determination to reimburse was made.

(c) A decision by the Secretary not to revise a reimbursement determination is final and binding (unless fraud or similar fault is found) and cannot be appealed.

Subpart H—Change of Ownership Requirements

§ 149.700 Change of ownership requirements.

(a) *Change of ownership consists of:* (1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable state law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership; exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify the Secretary at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for health benefits, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a

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sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

(f) Failure to notify the Secretary at least 60 days before the anticipated effective date of the change may result in the Secretary recovering funds paid under this program.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

Subpart A—General Provisions

Sec.

- 150.101 Basis and scope.
- 150.103 Definitions.

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- 150.203 Circumstances requiring CMS enforcement.
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- 150.465 Collection and use of penalty funds.

AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92).

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 health 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 HIPAA 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]

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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

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§§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 HIPAA 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]

§ 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

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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 HIPAA 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]

§ 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:

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(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 HIPAA 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.

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(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]

§ 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 HIPAA requirement.

(2) *Individual health insurance policy.* To the extent an individual health insurance policy is subject to an applicable HIPAA 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 HIPAA 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 HIPAA 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 HIPAA 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]

§ 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.

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(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 HIPAA requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005; 78 FR 13440, Feb. 27, 2013]

§ 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

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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 HIPAA 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]

§ 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 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.

§ 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 non-compliance 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

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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

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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 post-marked by the U.S. Postal Service, de-

posited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone 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.

§ 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

§ 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:

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(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, or by telephone. 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.

§ 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 in triplicate, including one original of any signed documents, 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. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

§ 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

§ 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 letter to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

§ 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 with-

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holding 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 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.

§ 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

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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 or by telephone 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.

§ 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

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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.

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(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)).

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.

(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.

[75 FR 45029, July 30, 2010, as amended at 77 FR 52616, Aug. 30, 2012]

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

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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;

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(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 individual's 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.

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(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.

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(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, ei-

ther 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

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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—

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(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,

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to ensure that there are no lapses in health coverage for those individuals.

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

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- 153.310 Risk adjustment administration.
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- 153.400 Reinsurance contribution funds.
- 153.405 Calculation of reinsurance contributions.
- 153.410 Requests for reinsurance payment.
- 153.420 Data collection.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

- 153.500 Definitions.
- 153.510 Risk corridors establishment and payment methodology.
- 153.520 Attribution and allocation of revenue and expense items.
- 153.530 Risk corridors data requirements.
- 153.540 Compliance with risk corridors standards.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

- 153.600 [Reserved]
- 153.610 Risk adjustment issuer requirements.
- 153.620 Compliance with risk adjustment standards.
- 153.630 Data validation requirements when HHS operates risk adjustment.

Subpart H—Distributed Data Collection for HHS-Operated Programs

- 153.700 Distributed data environment.
- 153.710 Data requirements.
- 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: Secs. 1311, 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

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):

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(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.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

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(c) 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.

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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]

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 ben-

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efit 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

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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

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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

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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 rein-

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surance 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:

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(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,

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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

§ 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 the applicable annual HHS notice of benefit and payment parameters; 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) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(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 the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

[77 FR 17247, Mar. 23, 2012, as amended at 78 FR 15528, Mar. 11, 2013]

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§ 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 individ-

ually 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

§ 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

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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 Payer 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 govern-

ment 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

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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

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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

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its compliance with the requirements of this subpart.

[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]

§ 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.* HHS or its designee may audit an issuer of a reinsurance-eligible plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. 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 H,

the issuer must complete all of the following:

- (1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.
- (2) Implement that plan.
- (3) Provide to HHS written documentation of the corrective actions once taken.

[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]

§ 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 pre-

mium, 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.

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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, re-

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duced 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.

[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]

§ 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

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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 pursuant to subpart C of this part; and

(iii) Any cost-sharing reduction payments received by the issuer for the QHP issuer's QHPs in a market within a State to the extent not reimbursed to the provider furnishing the item or service.

(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]

§ 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

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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 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]

§ 153.620 Compliance with 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.* HHS or its designee may audit an issuer of a risk adjustment covered plan to assess its compliance with the requirements of this subpart and subpart H of this part. The issuer must ensure that its relevant contractors, subcontractors, or agents cooperate with any audit under this section. 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 H of this part, the issuer must complete all of the following:

(1) Within 30 calendar days of the issuance of the final audit report, provide a written corrective action plan to HHS for approval.

(2) Implement that plan.

(3) Provide to HHS written documentation of the corrective actions once taken.

[77 FR 17245, Mar. 23, 2012, as amended at 78 FR 65095, Oct. 30, 2013; 79 FR 13836, Mar. 11, 2014]

§ 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.

(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) Validating medical records according to industry standards for coding and reporting; and

(iv) 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 cer-

tified 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. However, for validation of risk adjustment data for the 2014 and 2015 benefit years, the initial validation auditor may meet an inter-rater reliability standard of 85 percent for review outcomes.

(9) Enforcement actions. 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 may impose civil money penalties in accordance with the procedures set forth in § 156.805 of this subchapter.

(10) Default data validation charge. 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 risk adjustment 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) *Data validation appeals.* An issuer may appeal the findings of a second validation audit or the application of a risk score error rate to its risk adjustment payments and charges.

(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.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13836, Mar. 11, 2014]

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) *Interim dedicated distributed data environment reports.* Within 30 calendar days of the date of an interim 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 interim 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 timeframe specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the interim dedicated distributed data environment report.

(e) *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

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the benefit year specified in the report; or

(2) Describe to HHS any discrepancy it identifies in the final dedicated distributed data environment report.

(f) *Unresolved discrepancies.* If a discrepancy first identified in an interim or final dedicated distributed data environment report in accordance with paragraphs (d)(2) or (e)(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) *Risk corridors and MLR reporting.* (1) Notwithstanding any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, 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; reinsurance payment; cost-sharing reconciliation 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 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 amount of the advance payments of cost-sharing reductions paid to the issuer by HHS for the benefit year; and

(iv) For medical loss ratio report only, the risk corridors payment to be made or charge assessed by HHS as reflected in the notification provided under §153.510(d).

(2) An issuer must report any adjustment made following any discrepancy report made under paragraph (d)(2) or (e)(2) of this section, or any request for reconsideration under §156.1220(a) of

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this subchapter with respect to any risk adjustment payment or charge, including an assessment of risk adjustment user fees; reinsurance payment; cost-sharing reconciliation payment or charge; or risk corridors payment or charge; or following any audit, where such adjustment has not be accounted for in a prior risk corridors or medical loss ratio report, in the next following risk corridors or medical loss ratio report.

[78 FR 15531, Mar. 11, 2013, as amended at 79 FR 13837, Mar. 11, 2014]

§ 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.

§ 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

- Sec.
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Subpart B—Disclosure and Review Provisions

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 154.225 Determination by CMS or a State of an unreasonable rate increase.
 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

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:

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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 that a health insurance issuer offers 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:

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(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]

§ 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 grandfathered health plan coverage as defined in 45 CFR §147.140, or to excepted benefits as described in section 2791(c) of the PHS Act.

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 10 percent or more applicable to a 12-month period that begins on January 1, as calculated under paragraph (c) 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 (c) 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 is available by August 1. States interested in proposing a State-specific threshold for approval are required to submit a proposal to the Secretary by August 1.

(b) The Secretary will publish a notice no later than September 1 of each year, to be effective on January 1 of the following year, concerning whether a threshold under paragraph (a)(1) or (a)(2) of this section applies to the state; except that, with respect to the 12-month period that begins on September 1, 2011, the threshold under paragraph (a)(1) of this section applies.

(c) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if—

(1) For rates filed for coverage beginning before January 1, 2017, the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold.

(2) For rates filed for coverage beginning on or after January 1, 2017, an increase in the plan-adjusted index rate (as described in §156.80 of this subchapter) for any plan within the product meets or exceeds the applicable threshold.

(d) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (c) 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.

[76 FR 29985, May 23, 2011, as amended at 78 FR 13440, Feb. 27, 2013; 80 FR 10863, Feb. 27, 2015]

§ 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)

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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) If any plan within a product is subject to a rate increase, a health insurance issuer must submit a Rate Filing Justification for all products in the single risk pool, including new or discontinuing products, on a form and in a manner prescribed by the Secretary.

(b) The Rate Filing Justification must consist of the following Parts:

(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) A health insurance issuer must complete and submit Parts I and III of the Rate Filing Justification described in paragraphs (b)(1) and (b)(3) of this section to CMS and, as long as the applicable state accepts such submissions, to the applicable state. If a rate increase is subject to review, then the health insurance issuer must also complete and submit to CMS and, if applicable, the state Part II of the Rate Filing Justification described in paragraph (b)(2) of this section.

(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.

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(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 Web site 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 5.65.

(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]

§ 154.220 Timing of providing the rate filing justification.

A health insurance issuer must submit a Rate Filing Justification for all rate increases that are filed in a State, or effective in a State that does not require the rate increase to be filed, 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 rate increases for coverage effective on or after January 1, 2016, the health insurance issuer must submit to CMS and the applicable State a Rate Filing Justification by the earlier of the following:

(1) The date by which the State requires that a proposed rate increase be filed with the State; or

(2) The date specified in guidance by the Secretary.

[80 FR 10864, Feb. 27, 2015]

§ 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

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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(i);

(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]

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

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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 30 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]

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

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- 155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.
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AUTHORITY: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1332, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (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 non-profit, 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

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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.

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) An employer, employee, or 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 ap-

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plicant, 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.

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.

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 101 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 plan years beginning before January 1, 2016, a State may elect to define large employer by substituting “51 employees” for “101 employees.” The number of employees shall be determined using the method set forth in section 4980H(c)(2) of the Code, effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which the method shall be used for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013.

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

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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 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

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employer who employed an average of at least 1 but not more than 100 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 plan years beginning before January 1, 2016, a State may elect to define small employer by substituting “50 employees” for “100 employees.” The number of employees shall be determined using the method set forth in section 4980H(c)(2) of the Code, effective for plan years beginning on or after January 1, 2016, except for operations of a Federally-facilitated SHOP for which the method shall be used for plan years beginning on or after January 1, 2014 and in connection with open enrollment activities beginning October 1, 2013.

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.

State means each of the 50 States and the District of Columbia.

[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]

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); and

(3) The entire geographic area of the State is in the service area of an Exchange, or multiple Exchanges consistent with §155.140(b).

(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]

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§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange after 2014.* A State electing to seek approval of its Exchange later than January 1, 2013 must:

(1) Comply with the State Exchange approval requirements and process set forth in § 155.105;

(2) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 6.5 months prior to the Exchange's first effective date of coverage; and

(3) Develop a plan jointly with HHS to facilitate the transition from a Federally-facilitated Exchange to a State Exchange.

(b) *Transition process for State Exchanges that cease operations.* A State that ceases operations of its Exchange after January 1, 2014 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.

[77 FR 18444, Mar. 27, 2012, as amended at 79 FR 13837, Mar. 11, 2014]

§ 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, sex, gender identity or sexual orientation.

(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]

§ 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

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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

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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 State-required benefit enacted on or before December 31, 2011 is not considered in addition to the essential health benefits.

(3) The Exchange shall identify which state-required benefits are in excess of 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 Exchange.

[78 FR 12865, Feb. 25, 2013]

Subpart C—General Functions of an Exchange

§ 155.200 Functions of an Exchange.

(a) *General requirements.* The Exchange must perform the minimum functions described in this subpart and in subparts 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 operated by the State must perform the minimum functions described in subpart H and all applicable provisions of other subparts referenced therein while the Exchange operated by HHS must perform the minimum functions described in this subpart and in subparts D, E, F, G, and K 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 related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act.

(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.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 39523, July 1, 2013; 78 FR 54134, Aug. 30, 2013]

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center.* 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.

(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, including at a minimum:

(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 eligibility determination to be made in accordance with subpart D of this part.

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(5) Allows a qualified individual to select a QHP in accordance with subpart E of this part.

(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.

(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 an agent or broker subject to § 155.220(c)(3)(i), beginning November 1, 2015, or when such entity 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, beginning no later than the first day of the individual market open enrollment period for the 2017 benefit year, 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, as determined in guidance published by the Secretary.

(B) For an agent or broker subject to § 155.220(c)(3)(i), 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, 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, as determined in guidance published by the Secretary.

(iv) For Exchanges, QHP issuers, and an agent or broker subject to § 155.220(c)(3)(i), Web site 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 an agent or broker subject to §155.220(c)(3)(i), 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 Web site that is maintained by the agent or broker 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.

(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.

(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]

§ 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 (1) 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, sub-grantees, 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 non-compliance.* 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 non-compliance 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 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(1), within six years from the date on which the violation occurred.

(1) *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

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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]

§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

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the terms of a Navigator grant, to ensure expertise in:

(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 as described in paragraph (c)(2)(i) of this section and an entity from at least one of the other 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 gifts, including gift cards or cash, unless they are of nominal value, or provide promotional items that market or promote the products or services of a third party, to any applicant or potential enrollee as an inducement for enrollment. Gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as, but not limited to, 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;

(8) Solicit any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact, unless the individual has a pre-existing relationship with the individual Navigator or Navigator entity and other applicable State and Federal laws are otherwise complied with. Outreach and education activities may be conducted by going door-to-door or through other unsolicited means of direct contact, including calling a consumer; or

(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

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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 of the functions and responsibilities of 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

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(7) Maintain a physical presence in the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. 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.

(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]

§ 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

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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 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 in the following subjects:

(i) QHPs (including the metal levels described at § 156.140(b) of this subchapter), and how they operate, including benefits covered, payment processes, rights and processes for appeals and grievances, and contacting individual plans;

(ii) The range of insurance affordability programs, including Medicaid, the Children's Health Insurance Program (CHIP), and other public programs;

(iii) The tax implications of enrollment decisions;

(iv) Eligibility requirements for premium tax credits and cost-sharing reductions, and the impacts of premium tax credits on the cost of premiums;

(v) Contact information for appropriate federal, state, and local agencies for consumers seeking additional information about specific coverage options not offered through the Exchange;

(vi) Basic concepts about health insurance and the Exchange; the benefits of having health insurance and enrolling through an Exchange; and the individual responsibility to have health insurance;

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(vii) Eligibility and enrollment rules and procedures, including how to appeal an eligibility determination;

(viii) Providing culturally and linguistically appropriate services;

(ix) Ensuring physical and other accessibility for people with a full range of disabilities;

(x) Understanding differences among health plans;

(xi) Privacy and security standards applicable under § 155.260 for handling and safeguarding consumers' personally identifiable information;

(xii) Working effectively with individuals with limited English proficiency, people with a full range of disabilities, and vulnerable, rural, and underserved populations;

(xiii) Customer service standards;

(xiv) Outreach and education methods and strategies; and

(xv) Applicable administrative rules, processes and systems related to Exchanges and QHPs.

(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 con-

sumer'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.

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(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 of the functions and responsibilities of 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.* All non-Navigator entities 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 entities funded through an Exchange Establishment Grant under section 1311(a) of the Affordable Care Act must maintain a physical presence in

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the Exchange service area, so that face-to-face assistance can be provided to applicants and enrollees. 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; 80 FR 10865, Feb. 27, 2015]

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents and 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 or broker if—

(1) The agent or broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange Web site as described in §155.405;

(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) When an Internet Web site of the agent or broker is used to complete the QHP selection, at a minimum the Internet Web site must:

(i) Disclose and display all QHP information provided by the Exchange or directly by QHP issuers consistent with the requirements of §155.205(b)(1) and §155.205(c), and to the extent that not all information required under §155.205(b)(1) is displayed on the agent or broker's Internet Web site for a QHP, prominently display a standardized disclaimer provided by HHS stating that information required under §155.205(b)(1) for the QHP is available on the Exchange Web site, and provide a Web link to the Exchange Web site;

(ii) Provide consumers the ability to view all QHPs offered through the Exchange;

(iii) Not provide financial incentives, such as rebates or giveaways;

(iv) Display all QHP data provided by the Exchange;

(v) Maintain audit trails and records in an electronic format for a minimum of ten years.

(vi) 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; and

(vii) For the Federally-facilitated Exchange, prominently display a standardized disclaimer provided by HHS,

and provide a Web link to the Exchange Web site.

(4) When an agent or broker, through a contract or other arrangement, uses the Internet Web site of another agent or broker to help an applicant or enrollee complete a QHP selection in the Federally-facilitated Exchange, and the agent or broker accessing the Web site pursuant to the arrangement is listed as the agent of record on the enrollment:

(i) The agent or broker who makes the Web site available must:

(A) Provide HHS with a list of agents and brokers who enter into such an arrangement to the Federally-facilitated Exchange, if requested 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 pursuant to §155.260(b), by the agent or broker accessing the Internet Web site, should it become aware of any such potential breach.

(ii) HHS retains the right to temporarily suspend the ability of the agent or broker making its Web site available to transact information with HHS, if HHS discovers a security and privacy incident or breach, for the period in

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which HHS begins to conduct an investigation and until the incident or breach is remedied to HHS' satisfaction.

(d) *Agreement.* An agent or 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 or broker and the Exchange under which the agent or 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; and

(3) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260.

(e) *Compliance with State law.* An agent or 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 and brokers, including applicable State law related to confidentiality and conflicts of interest.

(f) *Termination notice to HHS.* (1) An agent or 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 or broker's notice of termination.

(3) Prior to the date of termination, an agent or broker should—

(i) Notify applicants, qualified individuals, or enrollees that the agent or broker is assisting, of the agent's or 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 termination becomes effective under paragraph this paragraph (f) or paragraph (g) of this section, the agent or broker will not be able to assist any individual through the Federally-facilitated Exchange, and the agent's or broker's agreement with the Exchange pursuant to § 155.260(b) will also be terminated through the termination without cause process set forth in that agreement. The agent or broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchange.

(g) *Standards for termination for cause from the Federally-facilitated Exchange.*

(1) If, in HHS's determination, a specific finding of noncompliance or pattern of noncompliance is sufficiently severe, HHS may terminate an agent's or broker's agreement with the Federally-facilitated Exchange for cause.

(2) An agent or broker may be determined noncompliant if HHS finds that the agent or broker violated—

(i) Any standard specified under this section;

(ii) Any term or condition of its agreement with the Federally-facilitated Exchange required under paragraph (d) of this section, or if the agreement with the Federally-facilitated Exchange under § 155.260(b) is terminated;

(iii) Any State law applicable to agents or 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 or brokers.

(3) HHS will notify the agent or broker of the specific finding of noncompliance or pattern of noncompliance, 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.

(4) After the period in paragraph (g)(3) of this section has elapsed, the agent or broker will no longer be registered with the Federally-facilitated Exchange or able to transact information with HHS.

(h) *Request for reconsideration of termination for cause from the Federally-facilitated Exchange*—(1) *Request for reconsideration*. An agent or 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 or broker must submit a request for reconsideration to the HHS reconsideration entity within 30 calendar days of the date of the written notice from HHS.

(3) *Notice of reconsideration decision*. The HHS reconsideration entity will provide the agent or broker with a written notice of the reconsideration decision within 30 calendar days of the date it receives the request for reconsideration. This decision will constitute HHS's final determination.

(i) *Use of agents' and brokers' Internet Web sites 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 and brokers to use an Internet Web site to assist qualified employers and facilitate enrollment of enrollees in a QHP through the Exchange, under paragraph (c)(3) of this section.

[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; 80 FR 10865, Feb. 27, 2015]

EDITORIAL NOTE: At 78 FR 54134, Aug. 30, 2013, §155.222 was amended by revising (d)(3); however, the amendment could not be incorporated because there was no regulatory text provided in the amendment for (d)(3).

§ 155.222 Standards for HHS-approved vendors of Federally-facilitated Exchange training and information verification 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, in order to have its training and information verification program recognized for agents and brokers assist-

ing with or facilitating enrollment in individual market or SHOP coverage through the Exchanges consistent with §155.220.

(2) As part of the training program, the vendor must require agents and brokers to provide identifying information and proof of valid State licensure, and successfully complete the required curriculum and identity proofing.

(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 the following:

(i) Prior experience with successfully conducting online training, verification of valid State license, as well as providing technical support to a large customer base; and

(ii) The ability to conduct identity proofing.

(2) Adhere to HHS specifications for content, format, and delivery of training and information verification, which include offering continuing education units (CEUs) for at least five States in which a Federally-facilitated Exchange is operating.

(3) Collect, store, and share with HHS all data from agent and broker users of the vendor's training and information verification in a manner, format, and frequency specified by HHS, and protect the data in accordance with applicable privacy and security laws and regulations.

(4) Execute an agreement with HHS, in a form and manner to be determined by HHS, which requires the vendor to comply with HHS guidelines for interfacing with HHS data systems, the implementation of the training and information verification processes, 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 and information verification.

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(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 and information verification 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 and information verification 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]

§ 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—

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(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.

(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

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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 of the functions and responsibilities of 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 gifts, including gift cards or cash, unless they are of nominal value, or provide promotional items that market or promote the products or services of a third party, to any applicant or potential enrollee as an inducement for enrollment. Gifts, gift cards, or cash may exceed nominal value for the purpose of providing reimbursement for legitimate expenses incurred by a consumer in an effort to receive Exchange application assistance, such as, but not limited to, travel or postage expenses;

(5) Solicit any consumer for application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact, including calling a consumer to provide application or enrollment assistance without the consumer initiating the contact, unless the individual has a pre-existing relationship with the individual certified application counselor or designated organization and other applicable State and Federal laws are otherwise complied with. Outreach and education activities may be conducted by going door-to-door or through other unsolicited means of direct contact, including calling a consumer; or

(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]

§ 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.

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(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) The SHOP must provide required notices either through standard mail, or if an employer or employee elects, electronically, provided that the requirements for electronic notices in 42 CFR 435.918(b)(2) through (5) are met for the employer or employee.

[77 FR 11718, Feb. 27, 2012, as amended at 78 FR 42314, July 15, 2013]

§ 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

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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 §155.20; or determining eligibility for exemptions from the individual 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 stand-

ards 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

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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 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]

§ 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 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 pursuant 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]

§ 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 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 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 eli-

gibility 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 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;

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(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 com-

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promise 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]

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 or through contracting arrangements in accordance with §155.110(a), provided that any contracting arrangement for eligibility determinations for Medicaid and CHIP is subject to the standards in 42 CFR 431.10(c)(2); 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.

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(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]

§ 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

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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, as defined in 26 CFR 1.36B–1(e), of greater than or equal to 100 percent but not more than 400 percent of the FPL 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, with the exception of coverage in the individual market, in accordance with section 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 if HHS notifies the Exchange as part of the process described in §155.320(c)(3) that advance payments of the premium tax credit were made on behalf of the tax filer or either spouse if the tax filer is a married couple for a 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 his or her 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 implementing regulations and reconcile the advance payments of the premium tax credit for that period.

(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.

(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.

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(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

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(ii) Section 5000A(e)(5) of the Code (relating to individuals with hardships).

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 15533, Mar. 11, 2013; 78 FR 42315, July 15, 2013]

§ 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 eligibility for 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 or cost-sharing reductions upon determination that an employee is eligible for advance payments of the premium tax credit or cost-sharing reductions. Such notice must:

(1) Identify the employee;

(2) Indicate that the employee has been determined eligible for advance payments of the premium tax credit;

(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

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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]

§ 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

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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 appli-

cant's attestation that he or she meets the requirements of § 155.305(a)(2) by—

(1) 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 current, accurate, and offer less administrative complexity than paper verification; or

(2) Except as provided in paragraph (e)(3) of this section, if an approved data source is unavailable, accepting his or her attestation without further verification.

(3) To the extent that an applicant's attestation is not reasonably compatible with information from approved data sources described in paragraph (e)(1) of this section 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

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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.

(g) *Exception for special circumstances.* For an applicant who does not have

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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]

§ 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(1)(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

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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).

(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 increases 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).

(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(1)(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 and 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 greater than ten percent 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.

(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 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 available to the Exchange in accordance with paragraph (c)(1)(ii) of this section, in which case the Exchange must request additional documentation using the procedures specified in § 155.315(f).

(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 ten percent 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).

(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 paragraph (c)(3)(vi)(D) of this section, 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 paragraph (c)(3)(vi)(D) of this section, 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.

(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) Except as specified in paragraphs (d)(3)(ii) or (iii) of this section, the Exchange must accept an applicant's attestation regarding the verification specified in paragraph (d) of this section without further verification.

(ii) 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

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Exchange, the Exchange must follow the procedures specified in §155.315(f).

(iii) Except as specified in paragraph (d)(3)(iv) of this section, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section for an applicant, the Exchange must select a statistically significant random sample of such applicants and—

(A) Provide notice to the applicant indicating that the Exchange will be contacting any employer identified on the application for the applicant and the members of his or her household, 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) Make reasonable attempts to contact any employer identified on the application for the applicant and the members of his or her household, 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;

(E) 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

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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);

(F) If, after a period of 90 days from the date on which the notice described in paragraph (d)(3)(iii)(A) of this section is sent to the applicant, the Exchange is unable to obtain the necessary information from an employer, the Exchange must determine the applicant's eligibility based on his or her attestation(s) regarding coverage provided by that employer.

(G) To carry out the process described in paragraph (d)(3)(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.

(iv) For eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions that are effective before January 1, 2015, if the Exchange does not have any of the information specified in paragraphs (d)(2)(i) through (iii) of this section for an applicant, the Exchange may accept an applicant's attestation regarding enrollment in an eligible employer-sponsored plan and eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested without further verification, instead of following the procedure in paragraph (d)(3)(iii) of this section.

(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.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42316, July 15, 2013; 78 FR 54136, Aug. 30, 2013; 79 FR 30347, May 27, 2014]

§ 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) The Exchange must periodically examine available data sources described in §§155.315(b)(1) and (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 Medicare, Medicaid, CHIP, or the BHP, if a BHP 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.

(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) 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, 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 within the 30-day period specified in paragraph (e)(2)(i)(B), proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(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.

(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 recalculate the amount of advance payments of the premium tax credit in such a manner as to—

(i) 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; and

(ii) Ensure that the advance payment provided on the tax filer's behalf is greater than or equal to zero and is calculated in accordance with 26 CFR 1.36B-3(d).

(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]

§ 155.335 Annual eligibility redetermination.

(a) *General requirement.* (1) Except as specified in paragraphs (1) 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 So-

cial 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

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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).

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(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—

(1) And the product under which the QHP in which he or she is enrolled remains available through the Exchange for renewal, consistent with §147.106 of this subchapter, such enrollee will have his or her enrollment through the Exchange in a QHP under that product renewed, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(1) occurs under the same product in which the enrollee was enrolled, as follows:

(i) The enrollee's coverage will be renewed in the same plan as the enrollee's current QHP, unless the current QHP is not available.

(ii) If the enrollee's current QHP is not available, the enrollee's coverage will be renewed in a plan at the same metal level as the enrollee's current QHP.

(iii) If the enrollee's current QHP is not available and the enrollee's product no longer includes a plan at the same metal level as the enrollee's current QHP, the enrollee's coverage will be renewed in a plan that is one metal level higher or lower than the enrollee's current QHP; or

(iv) If the enrollee's current QHP is not available and the enrollee's product no longer includes a plan that is at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee's coverage will be renewed in any other plan offered under the product in which the enrollee's current QHP is offered in which the enrollee is eligible to enroll.

(2) And the product under which the QHP in which he or she is enrolled is not available through the Exchange for renewal, consistent with §147.106 of this subchapter, such enrollee may be enrolled in a plan under a different product offered by the same QHP issuer, to the extent permitted by applicable State law, unless he or she terminates coverage, including termination of coverage in connection with voluntarily selecting a different QHP, in accordance with §155.430. The Exchange will ensure that re-enrollment in coverage under this paragraph (j)(2) occurs as follows:

(i) The enrollee will be re-enrolled in a plan through the Exchange at the same metal 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;

(ii) If the issuer does not offer another plan through the Exchange at the same metal level as the enrollee's current QHP, the enrollee will be re-enrolled in a plan through the Exchange that is one metal level higher or lower than 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; or

(iii) If the issuer does not offer another plan through the Exchange at the same metal level as, or one metal level higher or lower than the enrollee's current QHP, the enrollee will be re-enrolled in any other plan offered through the Exchange by the same issuer in which the enrollee is eligible to enroll.

(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 sec-

tion 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.

(1) *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]

§ 155.340

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§ 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 termi-

nates 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 in-

dividuals 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

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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.

[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]

§ 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 notifi-

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cation 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

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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

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(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 Exchange will, require payment of the first month's premium to effectuate an enrollment. Exchanges may, and the Federally-facilitated Exchange will, establish a standard policy for setting premium payment deadlines:

(1) In a Federally-facilitated Exchange, for first month (or binder payment) premiums:

(i) For coverage being effectuated under regular coverage effective dates, as provided for in §§155.410(f) and 155.420(b)(1), premium payment deadlines must be no earlier than the coverage effective date, but no later than 30 calendar days from the coverage effective date; and

(ii) For coverage being effectuated under special effective dates, as provided in §155.420(b)(2), premium payment deadlines must be 30 calendar days from the date the issuer receives the enrollment transaction.

(2) [Reserved]

(f) *Processing enrollment transactions.* The Exchange may provide requirements to QHP issuers regarding the instructions for processing electronic enrollment-related transactions.

[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]

§ 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—

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(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 year beginning on January 1, 2016, the annual open enrollment period begins on November 1, 2015 and extends through January 31, 2016.

(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 year beginning on January 1, 2016, the Exchange must ensure that coverage is effective—

(i) January 1, 2016, for QHP selections received by the Exchange on or before December 15, 2015.

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(ii) February 1, 2016, for QHP selections received by the Exchange from December 16, 2015 through January 15, 2016.

(iii) March 1, 2016, for QHP selections received by the Exchange from January 16, 2016 through January 31, 2016.

(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]

§ 155.415 Allowing issuer application assisters to assist with eligibility applications.

(a) *Exchange option.* An Exchange, to the extent permitted by State law, may permit issuer 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 meet the requirements set forth in § 156.1230(a)(2) of this subchapter.

(b) [Reserved]

[78 FR 54136, Aug. 30, 2013]

§ 155.420 Special enrollment periods.

(a) *General requirements.* (1) 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) 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.

(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—

(i) Between the first and the fifteenth day of any month, the Exchange must ensure a coverage effective date of the first day of the following month; and

(ii) Between the sixteenth and the last day of any month, the Exchange must ensure a coverage effective date of the first day of the second following month.

(2) *Special effective dates.* (i) In the case of birth, adoption, placement for adoption, or placement in foster care 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, or placement in foster care, or it may permit the qualified individual or enrollee to elect a coverage effective date of the first of the month following the date of birth, adoption, placement for adoption, or placement in foster care, 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 birth, adoption, placement for adoption or placement in foster care 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 paragraphs (d)(4), (d)(5), (d)(9), or (d)(10) 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 consumer loses coverage as described in paragraph (d)(1) or (d)(6)(iii), or gains access to a new QHP as described in paragraph (d)(7) of this section, 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 on the first day of the month following the loss of coverage. If the plan selection is

made after the day 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.

(v) In the case of a 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 the court order is effective, or it may permit the qualified individual or enrollee to elect a coverage effective date in accordance with paragraph (b)(1) of this section. If the Exchange permits the qualified individual or enrollee 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 qualified individual or enrollee.

(vi) 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.

(3) *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 paragraph (b)(1) or (b)(2)(ii) 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 (b)(1) or (b)(2)(ii) of this section, the Exchange may provide a coverage effective date for a qualified individual earlier than specified in such paragraphs.

(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, the Exchange may provide a coverage effective date of the first of the following month.

(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).

(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 his or her dependent who is described in paragraph (d)(1) or (d)(6)(iii) or, beginning on January 1, 2017 or earlier at the option of the Exchange, paragraph (d)(7) of this section, has 60 days before and after the triggering event to select a QHP. Prior to January 1, 2017, a qualified individual or his or her dependent who is described in paragraph (d)(7) of this section may select a QHP in accordance with paragraph (c)(1) of this section.

(3) *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.

(d) 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 following 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 or individual health insurance coverage, even if the qualified individual or his or her dependent has the option to renew such coverage. The date of the loss of coverage is the last day of the plan or policy year;

(iii) Loses pregnancy-related coverage described under section 1902(a)(10)(A)(i)(IV) and (a)(10)(A)(ii)(IX) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(IV), (a)(10)(A)(ii)(IX)). The date of the loss of coverage is the last day the consumer would have pregnancy-related 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.

(ii) Effective January 1, 2017 or earlier 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, which was not previously a citizen, national, or lawfully present individual gains such status;

(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) *Newly eligible or ineligible for advance payments of the premium tax credit, or change in eligibility for cost-sharing reductions.* (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; or

(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 in a non-Medicaid expansion State who was previously ineligible for advance payments of the premium tax credit solely because of a household income below 100 percent of the FPL, who was ineligible for Medicaid during that same timeframe, and who has experienced a change in household income that makes the qualified individual newly eligible for advance payments of the premium tax credit.

(7) The qualified individual or enrollee, or his or her dependent, gains access to new QHPs as a result of a permanent move;

(8) The qualified individual who is 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;

(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.

(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 premiums prior to expiration of COBRA coverage, or

(2) Situations allowing for a rescission as specified in 45 CFR 147.128.

[77 FR 18444, Mar. 27, 2012, as amended at 78 FR 42321, July 15, 2013; 78 FR 65095, Oct. 30, 2013; 79 FR 30348, May 27, 2014; 79 FR 59138, Oct. 1, 2014; 80 FR 10866, Feb. 27, 2015; 80 FR 38653, July 7, 2015]

§ 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 a situation, the Exchange must initiate termination of his or her enrollment in

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the QHP upon completion of the re-termination process specified in § 155.330.

(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.

(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 3-month grace period required for individuals receiving advance payments of the premium tax credit has been exhausted as described in § 156.270(g); or,

(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 subtitle;

(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) Any other reason for termination of coverage described in § 147.106 of this subchapter.

(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) Fourteen days after the termination is requested by the enrollee, if the enrollee does not provide reasonable notice; or

(iii) On a date on or after the date on which the termination is requested by the enrollee, subject to the determination of the enrollee's QHP issuer, if the enrollee's QHP issuer agrees to effectuate termination in fewer than fourteen days, and the enrollee requests an earlier termination effective date.

(iv) If the enrollee is newly eligible for Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, the last day of enrollment in a QHP through the Exchange is the day before the individual is determined eligible for Medicaid, CHIP, or the BHP.

(v) 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.

(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 re-

sults 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]

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), or § 155.715(e) or (f), 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), or § 155.715(e) and (f).

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.

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§ 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;

(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 pursuant to paragraph (c)(2)(i) or this section.

(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

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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) *Judicial review.* An appellant may seek judicial review to the extent it is available by law.

[78 FR 54136, Aug. 30, 2013, as amended at 79 FR 30349, May 27, 2014]

§ 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;

(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 re-

quirements in §§ 155.260, 155.270, and 155.345(i); and

(2) Comply with all data sharing requests made by HHS.

§ 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 re-determination 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.

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(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 sec-

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tion, 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.

(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.

§ 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 re-determination 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.

(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]

§ 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, provided that—

(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 of the date, time, and location or format of the hearing no later than 15 days prior to the hearing date.

(c) *Conducting the hearing.* All hearings under this subpart must be conducted—

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(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.

§ 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 ap-

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peal 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 of 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 pending 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) or (3), if applicable; or

(ii) Retroactively, to the date the incorrect eligibility determination was made, 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.

§ 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, §155.505(f) through (g), and §155.510(a)(1), (a)(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, §§155.505(f) through (g), and 155.510(a)(1), (a)(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—

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(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)(3) 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 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.

(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]

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.

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(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), (f)(2), and (g) 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 reach-

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ing 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) *Membership in a health care sharing ministry.* (1) The Exchange must determine an applicant eligible for an exemption for a month if for such month the applicant is a member of a health care sharing ministry as defined in section 5000A(d)(2)(B)(ii) of the Code.

(2) The Exchange must make an exemption in this category available only retrospectively.

(e) *Incarceration.* (1) The Exchange must determine an applicant eligible for an exemption for a month if he or she meets the standards in section 5000A(d)(4) of the Code for such month.

(2) The Exchange must make an exemption in this category available only retrospectively.

(f) *Membership in an Indian tribe.* (1) The Exchange must determine an applicant eligible for an exemption for any month if he or she is a member of an Indian tribe, as defined in section 45A(c)(6) of the Code, for such month, as provided in section 5000A(e)(3) of the Code.

(2) *Duration of exemption for membership in an Indian tribe.* The Exchange must grant the exemption specified in this paragraph to an applicant who meets the standards specified in paragraph (f)(1) of this section for a month on a continuing basis, until such time that the applicant reports that he or she no longer meets the standards provided in paragraph (f)(1) of this section.

(3) The Exchange must make an exemption available in this category prospectively or retrospectively.

(g) *Hardship—(1) General.* The Exchange must grant a hardship exemption to an applicant eligible for an exemption for at least the month before, a month or months during which, and the month after, 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 (g)(2)(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 (g)(2)(ii) of this section; 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) *Filing threshold.* The IRS may allow an applicant to claim an exemption without obtaining an exemption certificate number from an Exchange for a taxable year if, for such year, the applicant could not be claimed as a dependent by another taxpayer and the applicant's gross income was less than the applicant's applicable return filing threshold described in section 5000A(e)(2) of the Code;

(4) *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 has been determined ineligible for Medicaid for one or more

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months during the benefit year solely as a result of a State not implementing section 2001(a) of the Affordable Care Act;

(5) *Self-only coverage in an eligible employer-sponsored plan.* The IRS may allow an applicant to claim an exemption for a calendar year if he or she, as well as one or more employed members of his or her family, as defined in 26 CFR 1.36B-1(d), has been determined eligible for affordable self-only employer-sponsored coverage pursuant to section 5000A(e)(1) of the Code through their respective employers for one or more months during the calendar year, but the aggregate cost of employer-sponsored coverage for all the employed members of the family exceeds the required contribution percentage of household income for that calendar year; or

(6) *Eligible for services through an Indian health care provider.* (i) The Exchange must determine an applicant eligible for an exemption for any month if he or she is an Indian eligible for services through an Indian health care provider, as defined in 42 CFR 447.51 and not otherwise eligible for an exemption under paragraph (f) of this section, or an individual eligible for services through the Indian Health Service in accordance with 25 U.S.C. 1680c(a), (b), or (d)(3).

(ii) The Exchange must grant the exemption specified in paragraph (g)(6) of this section to an applicant who meets the standards specified in paragraph (g)(6) of this section for a month on a continuing basis, until such time that the applicant reports that he or she no longer meets the standards provided in paragraph (g)(6) of this section.

(iii) The IRS may allow an applicant to claim the exemption specified in paragraph (g)(6) of this section without obtaining an exemption certificate number from an Exchange.

[78 FR 39523, July 1, 2013, as amended at 79 FR 30349, May 27, 2014; 80 FR 10868, Feb. 27, 2015]

§ 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 informa-

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tion 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), (f), and (g), after December 31 of a given calendar year, the Exchange will not 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(g)(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.

§ 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.

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(c) *Verification related to exemption for membership in a health care sharing ministry.* (1) For any applicant who requests an exemption based on membership in a health care sharing ministry, the Exchange must verify that the applicant meets the standards specified in §155.605(d) by, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, accepting his or her attestation; and verifying that the health care sharing ministry to which the applicant attests membership is known to the Exchange as a valid health care sharing ministry based on data provided by HHS—

(i) If information provided by an applicant regarding his or her membership in a health care sharing ministry 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. The Exchange may not consider an applicant's prior or current enrollment in health coverage as not reasonably compatible with an applicant's attestation of membership in a health care sharing ministry.

(ii) If an applicant attests to membership in a health care sharing ministry that is not known to the Exchange as a health care sharing ministry based on information provided by HHS, the Exchange must provide the applicant with information regarding how an organization can pursue recognition under §155.615(c)(2), and determine the applicant ineligible for this exemption until such time as HHS notifies the Exchange that the health care sharing ministry's meets the standards specified in section 5000A(d)(2)(B)(ii) of the Code.

(2) To be considered a health care sharing ministry for the purposes of this subpart, an organization must submit information to HHS that substantiates the organization's compliance with the standards specified in section 5000A(d)(2)(B)(ii) of the Code. If at any time HHS determines that an organization previously considered a health care sharing ministry for the purposes of this subpart no longer meets the standards specified in section 5000A(d)(2)(B)(ii) of the Code, HHS may revoke its earlier decision regarding

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the status of the health care sharing ministry.

(d) *Verification related to exemption for incarceration.* (1) For any applicant who provides information attesting that he or she was incarcerated for a given month in accordance with the standards specified in §155.605(e), the Exchange must verify his or her attestation through the same process as described in §155.315(e).

(2) To the extent that the Exchange is unable to verify an applicant's attestation that he or she was incarcerated for a given month in accordance with the standards specified in §155.605(e) through the process described in §155.315(e), the Exchange must follow the procedures specified in paragraph (g) of this section.

(e) *Verification related to exemption for members of Indian tribes.* (1) For any applicant who provides information attesting that he or she is a member of an Indian tribe, the Exchange must use the process outlined in §155.350(c) to verify that the applicant is a member of an Indian tribe.

(2) To the extent that the Exchange is unable to verify an applicant's status as a member of an Indian tribe through the process described in §155.350(c), the Exchange must follow the procedures specified in paragraph (g) of this section.

(f) *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(g)(3) and (5), 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) *Eligible for services through an Indian health care provider.* For any applicant who requests an exemption based on the hardship described in § 155.605(g)(6), the Exchange must verify whether he or she meets the standards specified in § 155.605(g)(6) through the same process described in § 155.615(e).

(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.

(g) *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.

(h) *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.

(i) *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

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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.

(j) *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.

(k) *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]

§ 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

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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) For an application submitted before the start of open enrollment for

2016, through the approach described in paragraph (b) of this section.

(b) *Use of HHS service.* Notwithstanding the requirements of this subpart, for an application submitted before the start of open enrollment for 2016, the Exchange may adopt an exemption eligibility determination made by HHS, provided that—

(1) The Exchange adheres to the eligibility determination made by HHS;

(2) The Exchange furnishes to HHS any information available through the Exchange that is necessary for an applicant to utilize the process administered by HHS; and

(3) The Exchange call center and Internet Web site specified in § 155.205(a) and (b), respectively, provide information to consumers regarding the exemption eligibility process.

[79 FR 30349, May 27, 2014]

§ 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.* 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.

(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]

§ 155.705 Functions of a SHOP.

(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.

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(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.

(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;

(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)(B)(I) 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

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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) The employer will select a level of coverage as described in paragraph (b)(2) and (b)(3) of this section.

(B) The employer will select a QHP within that level of coverage to serve as a reference plan on which contributions will be based.

(C) The employer will define a percentage contribution toward premiums for employee-only coverage under the reference plan and, if dependent coverage is offered, a percentage contribution toward premiums for dependent coverage under the reference plan. 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) Either State law or the employer may require that a Federally-facilitated SHOP base contributions on a calculated composite premium for the reference plan for employees, for adult

dependents, and for dependents below age 21.

(E) The resulting contribution amounts for each employee's coverage may then be applied toward the QHP selected by the employee.

(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.

[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]

§ 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.

(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

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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;

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(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 coverage of the employer's qualified employees enrolled in the 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.

[77 FR 18464, Mar. 27, 2012, as amended at 79 FR 13839, Mar. 11, 2014]

§ 155.720 Enrollment of employees into QHPs under SHOP.

(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.

[77 FR 18464, Mar. 27, 2012, as amended at 80 FR 10869, Feb. 27, 2015]

§ 155.725 Enrollment periods under SHOP.

(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

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case the plan year will end on December 31 of the calendar year in which coverage first became effective.

(c) *Annual employer election period.* (1) Notwithstanding any other paragraph in this section, for coverage beginning in 2015 in a Federally-facilitated SHOP, a qualified employer's annual election period may begin no sooner than November 15, 2014.

(2) 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—

(i) The method by which the qualified employer makes QHPs available to qualified employees pursuant to § 155.705(b)(2) and (3);

(ii) The employer contribution towards the premium cost of coverage;

(iii) The level of coverage offered to qualified employees as described in § 155.705(b)(2) and (3); and

(iv) 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.* 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.

(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) 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.

(2) 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 § 155.725(h), 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.

(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 QHP selection received by the Federally-facilitated SHOP from a qualified employee in his or her initial or annual open enrollment period:

(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.

(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.

(i) *Renewal of coverage.* (1) If a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, such 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), (2), (4), (5), (7), (8), (9), or (10);

(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).

(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).

[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]

§ 155.730 Application standards for SHOP.

(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

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(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.

[77 FR 18464, Mar. 27, 2012, as amended at 78 FR 54141, Aug. 30, 2013; 79 FR 13839, Mar. 11, 2014]

§ 155.735 Termination of SHOP enrollment or coverage.

(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—

(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 on the last day of the month in which the FF-SHOP receives notice of an event described in paragraph (d)(1) of this section, and notice must have been received by the FF-SHOP prior to the proposed date of termination.

(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 quali-

fied 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.

[78 FR 54141, Aug. 30, 2013, as amended at 80 FR 10870, Feb. 27, 2015]

§155.740 SHOP employer and employee eligibility appeals requirements.

(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, §§155.505(e) through (g), and 155.510(a)(1), (a)(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 of the SHOP to make an eligibility determination in a timely manner.

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(d) *Employee right to appeal.* An employer or employee may appeal—

(1) A notice of denial of eligibility under § 155.715(f); or

(2) A failure of the SHOP to make an eligibility determination in a timely manner.

(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 em-

ployer 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.

(1) *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 retroactive to the date the incorrect eligibility determination was made, if the decision finds the employer or employee eligible, or effective as of the date of the notice of the appeal decision, if eligibility is denied.

(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.

[78 FR 54141, Aug. 30, 2013, as amended at 79 FR 30350, May 27, 2014]

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]

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§ 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 accord-

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ance 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) An Exchange must ensure that the provider network of each QHP meets the standards specified in §156.230 of this subtitle, except for multi-State plans.

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(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.

§ 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

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(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]

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, the following data and information:

(1) A financial statement presented in accordance with GAAP by April 1 of each year,

(2) Eligibility and enrollment 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 governmental 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 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 requirements under this part;

(3) Processes and procedures designed to prevent improper eligibility determinations and enrollment transactions; and

(4) Identification of errors that have resulted in incorrect eligibility determinations.

§ 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:

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(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

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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;

(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, analysis, 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:

(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

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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;

(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;

(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; 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).

§ 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.

(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.

§ 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:

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(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.

§ 155.1320 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, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of the Treasury, as applicable, and the State to implement a section 1332 waiver.

(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.

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(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.

(1) 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) [Reserved]

(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.

§ 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 guidance published by the Secretary and the Secretary of the Treasury, as applicable, 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.

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 the quality rating information assigned to each QHP on its Web site, in accordance with § 155.205(b)(1)(v), as calculated by HHS and in a form and manner specified by HHS.

§ 155.1405 Enrollee satisfaction survey system.

The Exchange must prominently display results from the Enrollee Satisfaction Survey for each QHP on its Web site, in accordance with § 155.205(b)(1)(iv), as calculated by HHS and in a form and manner specified by HHS.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

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- 156.330 Changes of ownership of issuers of Qualified Health Plans in Federally-facilitated Exchanges.
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- 156.400 Definitions.
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- 156.500 Basis and scope.
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156.510 Eligibility.
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156.606 HHS audit authority.

Subpart H—Oversight and Financial Integrity Standards for Issuers of Qualified Health Plans in Federally-Facilitated Exchanges

156.705 Maintenance of records for Federally-facilitated Exchange.
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156.1105 Establishment of standards for HHS-approved enrollee satisfaction survey vendors for use by QHP issuers in Exchanges.
156.1110 Establishment of patient safety standards for QHP issuers.
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156.1210 Confirmation of HHS payment and collections reports.
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156.1240 Enrollment process for qualified individuals.
156.1250 Acceptance of certain third party payments.
156.1255 Renewal and re-enrollment notices.

AUTHORITY: Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

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.

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- (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 non-profit, 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:

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(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]

§ 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 Federally-facilitated Exchange user fee.* 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 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.

(d) *Adjustment of Federally-facilitated Exchange user fee*—(1) A participating

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issuer offering a plan through a Federally-facilitated Exchange may qualify for an adjustment in the Federally-facilitated Exchange user fee specified in paragraph (c) 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 the Federally-facilitated Exchange user fee adjustment—

(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) with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee, 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 in the Federally-facilitated Exchange user fee; and

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant

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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 for a participating issuer to seek an adjustment in the Federally-facilitated Exchange user fee with respect to the third party administrator for payments for contraceptive services must submit to HHS a notification of such intent, in a manner specified by HHS, by the later of January 1, 2014, or 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 in the Federally-facilitated Exchange user fee;

(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, and as long as an authorizing exception under OMB Circular No. A-25R is in effect, the participating issuer will be provided a reduction in its obligation to pay the Federally-facilitated Exchange user fee specified in paragraph (c) of this section 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.

(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) As long as an exception under OMB Circular No. A-25R is in effect, 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 Federally-facilitated Exchange user fee in a particular month, the partici-

pating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment in the Federally-facilitated Exchange 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 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 receiving an adjustment in the Federally-facilitated Exchange user fee 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, 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 with respect to which an adjustment in the Federally-facilitated Exchange user fee 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.

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(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]

§ 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 based on the total combined claims costs for providing essential health benefits within the single risk pool of that state market. The index rate must be adjusted on a market-wide basis for the state based on

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the total expected market-wide payments and charges under the risk adjustment and reinsurance programs, and Exchange user fees (expected to be remitted under § 156.50(b) or § 156.50(c) and (d) of this subchapter as applicable plus the dollar amount under § 156.50(d)(3)(i) and (ii) of this subchapter expected to be credited against user fees payable for that state market). 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) *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, or make the plan-level adjustments pursuant to paragraph (d)(2) of this section, more or less frequently than annually, except as provided in paragraph (d)(3)(ii) of this section.

(ii) Beginning the quarter after HHS issues notification that the FF-SHOP

can process quarterly rate updates, a health insurance issuer in the small group market (not including a merged market) may establish index rates and make the market-wide adjustments pursuant to paragraph (d)(1) of this section, and make the plan-level adjustments pursuant to paragraph (d)(2) of this section, no more frequently than quarterly, provided that any changes to rates must have effective dates of January 1, April 1, July 1, or October 1.

(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]

Subpart B—Essential Health Benefits Package

SOURCE: 78 FR 12866, Feb. 25, 2013, unless otherwise noted.

§ 156.100 State selection of benchmark.

Each State may identify a single EHB-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.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015]

§ 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

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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);

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(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]

§ 156.115 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) of this subpart, comply with the requirements of §146.136 of this subchapter.

(4) Include preventive health services described in §147.130 of this subchapter.

(5) If the EHB-benchmark plan does not include coverage for habilitative services, as described in §156.110(f) of this subpart, include habilitative services in a manner that meets one of the following—

(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) Unless prohibited by applicable State requirements, an issuer of a plan offering EHB may substitute benefits if the issuer meets the following conditions—

(1) Substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(2) of this section;

(ii) Is made only within the same essential health benefit category; and

(iii) Is not a prescription drug benefit.

(2) Submits 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 regardless of cost-sharing.

(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) 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.

[78 FR 12866, Feb. 25, 2013, as amended at 80 FR 10871, Feb. 27, 2015]

§ 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]

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§ 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.

(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 de-

nial 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.

(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.

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(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.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10871, Feb. 27, 2015]

§ 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.

(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.

§ 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 is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in sec-

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tion 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 will publish the annual premium adjustment percentage in the annual HHS notice of benefits and payment parameters.

(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.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 30350, May 27, 2014; 80 FR 10872, Feb. 27, 2015]

§ 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

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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 as follows, HHS will:

(1) Update the annual limit on cost sharing and related functions based on a projected estimate to enable the AV Calculator to comply with § 156.130(a)(2);

(2) Update the continuance tables to reflect more current enrollment data when HHS has determined that the enrolled population has materially changed;

(3) Update the algorithms when HHS has determined the need to adapt the AV Calculator for use by additional plan designs or to allow the AV Calculator to accommodate potential new types of plan designs, where such adaptations can be based on actuarially sound principles and will not have a substantial effect on the AV calculations performed by the then current AV Calculator;

(4) Update the continuance tables to reflect more current claims data no more than every 3 and no less than every 5 years and to annually trend the claims data when the trending factor is more than 5 percent different, calculated on a cumulative basis; and

(5) Update the AV Calculator user interface when a change would be useful to a broad group of users of the AV Calculator, would not affect the function of the AV Calculator, and would be technically feasible.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13839, Mar. 11, 2014]

§ 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 para-

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graph (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.* 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.

§ 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.

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135 of this subpart;

(2) Must demonstrate that the stand-alone dental plan offers the pediatric dental essential health benefit at either:

(i) A low level of coverage with an AV of 70 percent; or

(ii) A high level of coverage with an AV of 85 percent; and

(iii) Within a de minimis variation of ±2 percentage points of the level of coverage in paragraphs (b)(2)(i) or (ii) of this section.

(3) The level of coverage as defined in paragraph (b)(2) of this section must be certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

[78 FR 12866, Feb. 25, 2013, as amended at 79 FR 13840, Mar. 11, 2014]

§ 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) and (b) of this section) until the annual limitation on cost sharing in section 1302(c)(1) of the 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:

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(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) *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]

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 and, in the small group market, § 155.705 of this subchapter;

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20;

(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

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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 section 1302(d)(1) of the Affordable Care Act; 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, sex, gender identity or sexual orientation.

(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.* 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]

§ 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.

§ 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 ad-

vance 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.

§ 156.225 Marketing and Benefit Design of QHPs.

A QHP issuer and its officials, employees, agents and representatives must—

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(a) *State law applies.* Comply with any applicable State laws and regulations regarding marketing by health insurance issuers; and

(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.

§ 156.230 Network adequacy standards.

(a) *General requirement.* Each QHP issuer that uses a provider network must ensure that the provider network consisting of in-network providers, as available to all enrollees, meets the following standards—

(1) Includes essential community providers in accordance with § 156.235;

(2) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay; and,

(3) Is consistent with the network adequacy provisions of section 2702(c) of the PHS Act.

(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

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(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.

[77 FR 18469, Mar. 27, 2012, as amended at 80 FR 10873, Feb. 27, 2015]

§ 156.235 Essential community providers.

(a) *General requirement.* (1) A QHP issuer must have a sufficient number and geographic distribution of essential community providers, where available, to ensure reasonable and timely access to a broad range of such providers for low-income, medically underserved individuals in the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A QHP issuer 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.

(3) Nothing in this requirement shall be construed to require any QHP to provide coverage for any specific medical procedure provided by the essential community provider.

(b) *Alternate standard.* A QHP issuer described in paragraph (a)(2) 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, medically underserved individuals in the QHP's service area, in accordance with the Exchange's network adequacy standards.

(c) *Definition.* Essential community providers are providers that serve predominantly low-income, medically underserved individuals, including providers that meet the criteria of paragraph (c)(1) or (2) of this section, and providers that met the criteria under paragraph (c)(1) or (2) of this section on the publication date of this regulation unless the provider lost its status under paragraph (c)(1) or (2) of this section thereafter as a result of violating Federal law:

(1) Health care providers defined in section 340B(a)(4) of the PHS Act; and

(2) Providers described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Public Law 111-8.

(d) *Payment rates.* Nothing in paragraph (a) of this section shall be construed to require a QHP issuer to contract with an essential community provider if such provider refuses to accept the generally applicable payment rates of such issuer.

(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) would preclude a QHP issuer and federally-qualified health center from mutually 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 such mutually agreed upon rates are at least equal to the generally applicable payment rates of the issuer indicated in paragraph (d) of this section.

EFFECTIVE DATE NOTE: At 80 FR 10873, Feb. 27, 2015, §156.235 was revised, effective Jan. 1, 2016. For the convenience of the user, the revised text is set forth as follows:

§ 156.235 Essential community providers.

(a) *General ECP standard.* (1) A QHP issuer that uses a provider network 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 network includes as participating providers at least a minimum percentage, as specified by HHS, of available ECPs in each plan's service area with multiple providers at a single location counting 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; 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 ECP categories (Federally Qualified Health Centers, Ryan White Providers, Family Planning Providers, Indian Health Care Providers, Hospitals and other ECP providers) 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.

(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

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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 Line satisfies a minimum percentage, specified by HHS, of available ECPs in the plan's service area with multiple providers at a single location counting as a single ECP; 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

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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(1)(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.

§ 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 received an eligibility determination for coverage through the Exchange through the Exchange Internet Web site.

(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 no less than once a month in accordance with § 155.400(d).

(g) *Enrollment acknowledgement.* A QHP issuer must acknowledge receipt of enrollment information transmitted from the Exchange in accordance with Exchange standards established in accordance with § 155.400(b)(2) of this subchapter.

[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]

§ 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)(2)(i), (ii), or (iii) 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

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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 three consecutive months if an enrollee receiving advance payments of the premium tax credit has previously paid at least one full month's premium during the benefit year. 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.

(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 out-

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standing premiums, 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]

§ 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 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:

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(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.

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(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) 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 this subparagraph 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

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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 con-

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sent 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”).

§ 156.285 Additional standards specific to SHOP.

(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) Reconcile enrollment files with the SHOP at least monthly;

(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) Requirements for notices to be provided to enrollees and qualified employers in §§ 156.270(b) and 156.290(b); and

(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) If a qualified employer chooses to withdraw from participation in the SHOP, the QHP issuer must terminate coverage for all enrollees of the withdrawing qualified employer.

(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.

[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]

EFFECTIVE DATE NOTE: At 80 FR 10875, Feb. 27, 2015, § 156.285 was amended by revising paragraph (d)(1)(ii), effective Jan. 1, 2016. For the convenience of the user, the revised text is set forth as follows:

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§ 156.285 Additional standards specific to SHOP.

* * * * *

(d) * * *

(1) * * *

(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.

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§ 156.290 Non-renewal and decertification of QHPs.

(a) *Non-renewal of recertification.* If a QHP issuer elects not to seek recertification 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-renewal.* If a QHP issuer elects not to seek recertification with the Exchange for its QHP, the QHP issuer must provide written notice to each enrollee.

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(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]

§ 156.295 Prescription drug distribution and cost reporting.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a 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, broken down by pharmacy type, which includes an independent pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public, that is paid by the QHP issuer or the QHP issuer's contracted PBM;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer or its contracted 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) *Confidentiality.* Information disclosed by a QHP issuer or a PBM under this section is confidential and 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 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.

§ 156.298 Meaningful difference standard for Qualified Health Plans in the Federally-facilitated Exchanges.

(a) *General.* Subject to paragraph (b)(2) of this section, starting in the 2015 coverage year, in order to be certified as a QHP offered through a Federally-facilitated Exchange, a plan must be meaningfully different from all other QHPs offered by the same issuer of that plan within a service area and level of coverage in the Exchange, as defined in paragraph (b) of this section.

(b) *Meaningful difference standard.* A plan is considered meaningfully different from another plan in the same service area and metal tier (including catastrophic plans) if a reasonable consumer would be able to identify one or more material differences among the following characteristics between the plan and other plan offerings:

- (1) Cost sharing;
- (2) Provider networks;
- (3) Covered benefits;
- (4) Plan type;
- (5) Health Savings Account eligibility; or
- (6) Self-only, non-self-only, or child-only plan offerings.

(c) *Exception for limited plan availability.* If HHS determines that the plan offerings at a particular metal level (including catastrophic plans) within a county are limited, plans submitted for certification in that particular metal level (including catastrophic plans) within that county will not be subject to the meaningful difference requirement set forth in paragraph (b) of this section.

(d) *Two-year transition period for issuers with new acquisitions.* During the first 2 years after a merger or acquisition in which an acquiring issuer obtains or merges with another issuer, the FFEs may certify plans as QHPs that were previously offered by the acquired or merged issuer without those plans meeting the meaningful difference standard set forth in paragraph (b) of this section.

[79 FR 13840, Mar. 11, 2014]

Subpart D—Federally-Facilitated Exchange Qualified Health Plan Issuer Standards

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]

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§ 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, as applicable, with all applicable standards, including—

(1) Standards of subpart C of part 156 with respect to each of its QHPs on an ongoing basis;

(2) Exchange processes, procedures, and standards in accordance with subparts H and K of part 155 and, in the small group market, §155.705 of this subchapter;

(3) Standards of §155.220 of this subchapter with respect to assisting with enrollment in QHPs; and

(4) Standards of §§156.705 and 156.715 for maintenance of records and compliance reviews for QHP issuers operating in a Federally-facilitated Exchange or FF-SHOP.

(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 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

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paragraph (a) of this section until 10 years from the final date of the agreement period; and

(5) Contain specifications described in paragraph (b) of this section by no later than January 1, 2015, for existing agreements; and no later than the effective date of the agreement for agreements that are newly entered into as of October 1, 2013.

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 single percentage point.

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]

§ 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 in-

dividual 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

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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 applica-

ble), 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 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 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 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

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(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

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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]

§ 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) A QHP issuer will receive periodic advance payments based on the advance payment amounts 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

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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) *Reconciliation of amounts.* HHS will perform periodic reconciliations of any advance payments of cost-sharing reductions provided to a QHP issuer under paragraph (b) of this section against—

(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) *Payment of discrepancies.* If the actual amounts of cost-sharing reductions described in paragraphs (d)(1) and (2) of this section are—

(1) More than the amount of advance payments provided and the QHP issuer has timely provided the actual amounts of cost-sharing reductions as required under paragraph (c) of this section, HHS will reimburse the QHP issuer for the difference; and

(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).

[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]

§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 re-

fund 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—

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(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]

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§ 156.480 Oversight of the administration of the cost-sharing reductions and advance payments of the premium tax credit 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.* HHS or its designee may audit an issuer that offers a QHP in the individual market through an Exchange to assess compliance with the requirements of this subpart.

[78 FR 65100, Oct. 30, 2013]

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 that was in existence 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 individual who stands or acts for an organization or group of organizations through a formal agreement or financial compensation such as a contractor, broker, official, or employee.

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]

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§ 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 all of its 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 director on the organization's operational board;

(iii) Each member age 18 or older of the organization must have one vote in the election of each director of the organization's operational board;

(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 no later than two years after the same date;

(v) Elections of the directors on the organization's operational board must be contested so that the total number of candidates for vacant positions on the operational board exceeds the number of vacant positions, except in cases where a seat is vacated mid-term due to death, resignation, or removal; and

(vi) The majority of the voting directors on the operational board must be members of the organization.

(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 including that each director act in the sole interest of the CO-OP and, as appropriate, the health and wellbeing of its local geographic community;

(ii) Each director has one vote unless he or she is a non-voting director;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions);

(iv) Positions on the operational board that are designated for individuals with specialized expertise, experience, or affiliation cannot constitute a majority of the operational board even if the individuals in those positions are members of the CO-OP. This provision does not prevent any individual from seeking election to the operational board based on being a member of the CO-OP; and

(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) may serve on the CO-

OP's formation board or 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

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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.

§ 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

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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.* The loan recipient shall not convert or sell to a for-profit or non-consumer 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.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

Subpart G—Minimum Essential Coverage

SOURCE: 78 FR 39529, July 1, 2013, unless otherwise noted.

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§ 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]

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§ 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;

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(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.

Subpart I—Enforcement Remedies in Federally-Facilitated 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

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on QHP issuers in a Federally-facilitated Exchange that are not in compliance with Exchange standards applicable to issuers offering QHPs in the Federally-facilitated 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 only for non-compliance with QHP issuer participation standards and other standards applicable to issuers offering QHPs in a Federally-facilitated Exchange.

(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]

§ 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 a Federally-facilitated Exchange by HHS 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 non-compliance 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

(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 com-

plaints 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 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) *Notice of intent to issue civil money penalty.* If HHS proposes to assess a civil money penalty in accordance with this part, HHS will send a written notice of this decision to—

(1) The QHP issuer against whom the civil money penalty is being imposed, whose notice must include the following:

(i) A description of the basis for the determination;

(ii) The basis for the penalty;

(iii) The amount of the penalty;

(iv) The date the penalty is due;

(v) An explanation of the issuer's right to a hearing under an applicable administrative hearing process; and

(vi) Information about where to file the request for hearing.

(2) [Reserved]

(3) HHS will deliver notice under this paragraph by either hand delivery, certified mail, return receipt requested, or by overnight delivery service with signature upon delivery required.

(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),

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for failing to timely exercise its right to a hearing.

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 15245, Mar. 19, 2014; 79 FR 30351, May 27, 2014]

§ 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.

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(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; or

(13) The QHP issuer substantially fails to meet the requirements related to the offering of a QHP under subpart M of this part.

(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) *Appeals.* 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) *Effect of request for hearing.* If an issuer files a request for hearing under this paragraph,

(i) If the decertification is under paragraph (c) 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 the notice under paragraph (c)(1) of this section.

(ii) If the decertification is under paragraph (d) 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 deci-

sion that the QHP should not be decertified.

(2) [Reserved]

[78 FR 54143, Aug. 30, 2013, as amended at 79 FR 30351, May 27, 2014]

§ 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]

§ 156.901

Subpart J—Administrative Review of QHP Issuer Sanctions in Federally-Facilitated Exchanges

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 post-marked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone 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).

§ 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 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.

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§ 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

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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, or by telephone. 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.

§ 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,

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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 in triplicate, including one original of any signed documents, 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. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

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§ 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 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 letter to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

§ 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), in-

cluding 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

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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 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.

§ 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

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(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 or by telephone 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.

§ 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.

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(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.

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(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

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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

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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 Social Security Act, 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—

(1) A quality assessment and performance improvement program as specified in 42 CFR 482.21; and

(2) Discharge planning as specified in 42 CFR 482.43.

(b) *Documentation.* A QHP issuer must collect 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) 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.

(d) *Effective date.* A QHP issuer must ensure that each QHP meets patient safety standards in accordance with paragraph (a) of this section effective for plan years beginning on or after January 1, 2015.

[79 FR 13841, Mar. 11, 2014]

§ 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

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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 Confirmation of HHS payment and collections reports.

(a) *Responses to reports.* Within 15 calendar days of the date of a payment and collections report from HHS, the issuer must, in a format specified by HHS, either:

(1) Confirm to HHS that the amounts identified in the payment and collections report for the timeframe specified in the report accurately reflect applicable payments owed by the issuer to the Federal government and the payments owed to the issuer by the Federal government; or

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(2) Describe to HHS any inaccuracy it identifies in the payment and collections report.

(b) *Late discovery of a discrepancy.* If an issuer reports a discrepancy in a payment and collections report later than 15 calendar days after the date of the report, HHS will work with the issuer to resolve the discrepancy as long as the late reporting was not due to misconduct on the part of the issuer.

(c) *Discrepancies to be addressed in future reports.* Discrepancies in payment and collections reports identified to HHS under this section will be addressed in subsequent payment and collections reports, and will not be used to change debts determined pursuant to invoices generated under previous payment and collections reports.

[78 FR 65105, Oct. 30, 2013, as amended at 79 FR 13841, Mar. 11, 2014]

§ 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.* In 2015 and 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, and risk adjustment, reinsurance, and risk corridors payments and charges.

(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, risk adjustment, reinsurance, and risk corridors, after HHS nets amounts owed by the Federal government under these programs, is a determination of a debt.

[79 FR 13841, Mar. 11, 2014]

§ 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; or

(vi) The amount of a risk corridors payment or charge for a benefit year.

(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 (vi) of this section, as applicable, is equal to or exceeds 1 percent of the applicable payment or charge listed in that subparagraph 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, or Federally-facilitated Exchange user fee charges, 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, and Federally-facilitated Exchange user fees for the applicable benefit year;

(ii) For a risk adjustment payment or charge, including an assessment of risk adjustment user fees, within 60 calendar days of the date of the notification provided by HHS under §153.310(e) of this subchapter;

(iii) For a reinsurance payment, within 60 calendar days of the date of the notification provided by HHS under §153.240(b)(1)(ii) of this subchapter;

(iv) For a default risk adjustment charge, within 60 calendar days of the date of the notification of the default risk adjustment charge;

(v) For reconciliation of cost-sharing reductions, within 60 calendar days of the date of the notification provided by HHS of the cost-sharing reduction reconciliation payment or charge; and

(vi) For a risk corridors payment or charge, within 60 calendar days of the date of the notification provided by HHS 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 by the issuer to HHS under §153.710(d)(2) or (e)(2) of this subchapter, 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

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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.

(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]

§ 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) *QHP issuer application assister eligibility application assistance requirements.* If permitted by the Exchange pursuant to § 155.415 of this subchapter, and to the extent permitted by State law, a QHP issuer may permit its issuer 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 issuer ensures that each of its application assisters at least—

(i) Receives training on QHP options and insurance affordability programs, eligibility, and benefits rules and regulations;

(ii) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260 of this subchapter; and

(iii) Complies with applicable State law related to the sale, solicitation, and negotiation of health insurance products, including applicable State law related to agent, broker, and producer licensure; confidentiality; and conflicts of interest.

(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.

§ 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.

(b) [Reserved]

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§ 156.1250 Acceptance of certain third party payments.

Issuers offering individual market QHPs, including stand-alone dental plans, must accept premium and cost-sharing payments from the following third-party entities on behalf of plan enrollees:

- (a) Ryan White HIV/AIDS Program under title XXVI of the Public Health Service Act;
- (b) Indian tribes, tribal organizations or urban Indian organizations; and
- (c) State and Federal Government programs.

[79 FR 15245, Mar. 19, 2014]

§ 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

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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]

PART 157—EMPLOYER INTER-ACTIONS 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.

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.

(a) *General requirements*. When joining the SHOP, a qualified employer must comply with the requirements, proc-

esses, 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) A period to seek coverage in a QHP beginning on the first day of becoming a qualified employee; 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 employees; 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.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

- Sec.
- 158.101 Basis and scope.
- 158.102 Applicability.
- 158.103 Definitions.

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Subpart A—Disclosure and Reporting

- 158.110 Reporting requirements related to premiums and expenditures.
- 158.120 Aggregate reporting.
- 158.121 Newer experience.
- 158.130 Premium revenue.
- 158.140 Reimbursement for clinical services provided to enrollees.
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- 158.160 Other non-claims costs.
- 158.161 Reporting of Federal and State licensing and regulatory fees.
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- 158.170 Allocation of expenses.

Subpart B—Calculating and Providing the Rebate

- 158.210 Minimum medical loss ratio.
- 158.211 Requirement in States with a higher medical loss ratio.
- 158.220 Aggregation of data in calculating an issuer's medical loss ratio.
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- 158.241 Form of rebate.
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- 158.301 Standard for adjustment to the medical loss ratio.
- 158.310 Who may request adjustment to the medical loss ratio.
- 158.311 Duration of adjustment to the medical loss ratio.
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- 158.323 State contact information.
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- 158.340 Process for submitting request for adjustment to the medical loss ratio.
- 158.341 Treatment as a public document.
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- 158.343 Optional State hearing.
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Subpart D—HHS Enforcement

- 158.401 HHS enforcement.
- 158.402 Audits.
- 158.403 Circumstances in which a State is conducting audits of issuers.

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- 158.501 Access to facilities and records.
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- 158.601 General rule regarding the imposition of civil penalties.
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- 158.603 Notice to responsible entities.
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- 158.610 Determining the amount of the penalty—other matters as justice may require.
- 158.611 Settlement authority.
- 158.612 Limitations on penalties.
- 158.613 Notice of proposed penalty.
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- 158.615 Failure to request a hearing.

AUTHORITY: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg-18), as amended.

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 ex-

ceeds 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 section 2791(e)(2) of the PHS Act and section 1304(b)(1) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute "51" employees for "101" employees in the definition.

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.

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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 section 2791(e)(4) of the PHS Act and section 1304(b)(2) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute “50” employees for “100” employees in the definition.

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]

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

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complies with the requirements of this Part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

(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]

§ 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 experi-

ence 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 and with less than 12 months of experience in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 of this subpart 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.

§ 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:

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(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 in-

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tended 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 withheld 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) Prescription drug rebates received by the issuer.

(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 on census based assessments.

(ii) State subsidies based on a stop-loss payment methodology.

(iii) The amount of incentive and bonus payments made 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]

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in §158.110 of this subpart must include expenditures for activities that improve health care quality, as 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.

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(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;

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(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) Actual rewards, incentives, bonuses, 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;

(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]

§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

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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]

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§ 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.

§ 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 which include Federal income taxes on investment income and capital gains 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.

(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

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(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]

EFFECTIVE DATE NOTE: At 80 FR 10876, Feb. 27, 2015, §158.162 was amended by revising paragraph (a)(2) and adding paragraph (b)(2)(iv), effective Jan. 1, 2016. For the convenience of the user, the added and revised text is set forth as follows:

§ 158.162 Reporting of Federal and State taxes.

(a) * * *

(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) * * *

(2) * * *

(iv) State employment and similar taxes and assessments.

* * * * *

§ 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 of this subpart 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.

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

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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.

(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]

§ 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-

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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 de-

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ductible 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) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under §158.210 in this subpart.

(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) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under § 158.210 in this subpart.

[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]

§ 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 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) *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

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provide any rebate owing to an enrollee no later than September 30 following the end of the MLR reporting year.

(e) *Late payment interest.* An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (d) 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 (d) of this section.

[75 FR 74921, Dec. 1, 2010, as amended at 78 FR 15540, Mar. 11, 2013; 79 FR 13842, Mar. 11, 2014]

§ 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.

(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

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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]

§ 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

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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 re-

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spect 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

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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

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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 her discretion, she determines that application of the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act may destabilize the individual market in that State. Application of the 80 percent MLR standard may destabilize the individual market in a State only if there is a reasonable likelihood that application of the requirement will do so.

§ 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) *State MLR standard.* The State must describe its current MLR standard for the individual market, if any, and the formula used to assess compliance with such standard.

(b) *State market withdrawal requirements.* The State must describe any requirements it has with respect to withdrawals from the State's individual health insurance market. Such requirements include, but are not limited to, any notice that must be provided and any authority the State regulator may have to approve a withdrawal plan or ensure that enrollees of the exiting issuer have continuing coverage, as well as any penalties or sanctions that may be levied upon exit or limitations on re-entry.

(c) *Mechanisms to provide options to consumers.* The State must describe the mechanisms available to the State to provide consumers with options in the event an issuer withdraws from the individual market. Such mechanisms include, but are not limited to, a guaranteed issue requirement, limits on health status rating, an issuer of last resort, or a State-operated high risk pool. A description of each mechanism should include detail on the issuers participating in and products available under such mechanism, as well as any limitations with respect to eligibility, enrollment period, total enrollment, and coverage for pre-existing conditions.

(d) *Issuers in the State's individual market.* Subject to § 158.320 of this subpart, the State must provide:

(1) For each issuer who offers coverage in the individual market in the State its number of individual enrollees by product, available individual premium data by product, and individual health insurance market share within the State; and

(2) For each issuer who offers coverage in the individual market in the

State to more than 1,000 enrollees, the following additional information:

(i) Total earned premium on individual market health insurance products in the State;

(ii) Reported MLR pursuant to State law for the individual market business in the State;

(iii) Estimated MLR for the individual market business in the State, as determined in accordance with § 158.221 of this part;

(iv) Total agents' and brokers' commission expenses on individual health insurance products;

(v) Estimated rebate for the individual market business in the State, as determined in accordance with §§ 158.221 and 158.240 of this part;

(vi) Net underwriting profit for the individual market business and consolidated business in the State;

(vii) After-tax profit and profit margin for the individual market business and consolidated business in the State;

(viii) Risk-based capital level; and

(ix) Whether the issuer has provided notice of exit to the State's insurance commissioner, superintendent, or comparable State authority.

§ 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:

(a) An explanation and justification of how the proposed adjustment to the MLR was determined;

(b) An explanation of how an adjustment to the MLR standard for the State's individual market will permit issuers to adjust current business models and practices in order to meet an 80 percent MLR as soon as is practicable;

(c) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet an 80 percent MLR for the applicable MLR reporting years; and

(d) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet the adjusted MLR proposed by the State for the applicable MLR reporting years.

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§ 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 application of an 80 percent MLR, as calculated in accordance with this subpart, may destabilize the individual market in a State that has requested an adjustment to the 80 percent MLR:

(a) The number of issuers reasonably likely to exit the State or to cease offering coverage in the State absent an adjustment to the 80 percent MLR and the resulting impact on competition in the State. In making this determination the Secretary may consider as to each issuer that is reasonably likely to exit the State:

(1) Each issuer's MLR relative to an 80 percent MLR;

(2) Each issuer's solvency and profitability, as measured by factors such as surplus level, risked-based capital ratio, net income, and operating or underwriting gain;

(3) The requirements and limitations within the State with respect to market withdrawals; and

(4) Whether each issuer covers less than 1,000 life-years in the State's individual insurance market.

(b) The number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent an adjustment to the 80 percent MLR.

(c) Whether absent an adjustment to the 80 percent MLR standard consumers may be unable to access agents and brokers.

(d) The alternate coverage options within the State available to individual market enrollees in the event an issuer exits the market, including:

(1) Any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer;

(2) The issuers that may remain in the State subsequent to the implemen-

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tation of the 80 percent MLR, as calculated in accordance with this Part, and the nature, terms, and price of the products offered by such issuers;

(3) The capacity of remaining issuers to write additional business, as measured by their risk based capital ratios;

(4) The mechanisms, such as guaranteed issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers in the event of an issuer withdrawing from the market, and the affordability of these options compared to the coverage provided by exiting or potentially exiting issuers; and

(5) Any authority the State's insurance commissioner, superintendent, or comparable official may exercise with respect to stabilization of the individual insurance market.

(e) The impact on premiums charged, and on benefits and cost-sharing provided, to consumers by issuers remaining in the market in the event one or more issuers were to withdraw from the market.

(f) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

§ 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

and will be posted promptly on the Secretary's Internet Web site devoted to health care coverage.

§ 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 initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market.

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

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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

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(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

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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

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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 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.

§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 non-compliance 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 non-compliance 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

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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

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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.