SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

PARTS 140–143 [RESERVED]

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

Subpart A—General Provisions

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

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 or the requirements of part 148 of this subchapter concerning individual health insurance.

(2) Insurance issuers in States described in paragraph (c)(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]

§ 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 (set forth in 45 CFR part 146) and the individual market (set forth in 45 CFR part 148). 45 CFR part 146 limits the group market to insurance sold to employment-related group health plans and further divides the group market into the large group market and the small group market. Federal law further defines the small group market as insurance sold to employer plans with 2 to 50 employees. State law, however, may expand the definition of the small group market to include certain coverage that would otherwise, under the Federal law, be considered coverage in the large group market or the individual 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. Small employers, and individuals who are eligible to enroll under the employer's plan, are guaranteed availability of insurance coverage sold in the small group market. Small and large employers are guaranteed the right to renew their group coverage, subject to certain exceptions. Eligible individuals are guaranteed availability of coverage sold in the individual market, and all coverage in the individual market must be guaranteed renewable. All coverage issued in the small or large group market, and in the individual market, must provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth.

(c) Coverage that is provided to associations, but is not related to employment, is not considered group coverage under 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.

(d) Provisions relating to CMS enforcement of one or more provisions of part 146 or the requirements of part 148, or both, are contained in part 150 of this subchapter.

[62 FR 16955, Apr. 8, 1997, as amended at 63 FR 57558, Oct. 27, 1998; 64 FR 45795, Aug. 20, 1999]

§ 144.103 Definitions.

For purposes of parts 146 (group 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 actively in existence for at least 5 years.

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

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

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

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

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

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

COBRA definitions:

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

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

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

(4) *Continuation coverage* means coverage under a COBRA continuation provision or a similar State program. Coverage provided by a plan that is subject to a COBRA continuation provision or similar State program, but that does not satisfy all the requirements of that provision or program, will be deemed to be continuation coverage if it allows an individual to elect to continue coverage for a period of at least 18 months. Continuation coverage does not include coverage under a conversion policy required to be offered to an individual upon exhaustion of continuation coverage, nor does it include continuation coverage under the Federal Employees Health Benefits Program.

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

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

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

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

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

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

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

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

Condition means a *medical condition*.

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

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

Eligible individual, for purposes of—

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

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

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

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

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

Enrollment date definitions (*enrollment date*, *first day of coverage*, and *waiting*

period) are set forth in 45 CFR 146.111(a)(3)(i) through (iii).

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.

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. (However, certain very small plans may be treated as being in the individual market, rather than the group market; see the definition of *individual market* in this section.)

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. Unless a State elects otherwise in accordance with section 2791(e)(1)(B)(ii) of the PHS Act, such term also includes coverage offered in connection with a group health plan that has fewer than two participants who are current employees on the first day of the plan year.

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

Issuer means a *health insurance issuer*.

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

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 enrollment definitions (*late enrollee* and *late enrollment*) are set forth in 45 CFR 146.111(a)(3)(v) and (vi).

Medical care means amounts paid for—

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

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

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

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

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

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

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

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

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

Plan 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 in the individual health insurance market the 12-month period that is designated as the policy year in the policy documents of the individual 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.

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.

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.

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 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

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 several States, the District of Columbia, 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).

Waiting period has the meaning given the term in 45 CFR 146.111(a)(3)(iii).

[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]

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

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

§ 144.200 Basis.

This subpart implements—

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

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

§ 144.202 Definitions.

As used in this Subpart—

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

Qualified long-term care insurance policy means an insurance policy that has

been determined by a State insurance commissioner to meet the requirements of sections 1917(b)(1)(C)(iii)(I) through (IV) and 1917(b)(5) of the Act. It includes a certificate issued under a group insurance contract.

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

§ 144.204 Applicability of regulations.

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

§ 144.206 Reporting requirements.

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

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

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

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

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

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

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

(A) Current identifying information on the insured individual;

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

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

(D) The annual premium.

(E) The coverage period.

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

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

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

(ii) Include, but are not limited to—

(A) Current identifying information on the insured individual;

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

(C) Remaining lifetime benefits;

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

§ 144.208 Deadlines for submission of reports.

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

The first reports required for these insurers will be the reports that pertain to the reporting period that begins

no more than 120 days after the effective date of the final regulations.

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

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

§144.210 Form and manner of reports.

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

§144.212 Confidentiality of information.

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

§144.214 Notifications of noncompliance with reporting requirements.

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

PART 145 [RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

Subpart A—General Provisions

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

Subpart C—Requirements Related to Benefits

Subpart D—Preemption and Special Rules

Subpart E—Provisions Applicable to Only Health Insurance Issuers

Subpart F—Exclusion of Plans and Enforcement

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 health insurance issuers offering group health insurance coverage concerning:

(i) Limitations on a preexisting condition exclusion period.

(ii) Certificates and disclosure of previous coverage.

(iii) Methods of counting creditable coverage.

(iv) Special enrollment periods.

(v) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

(vi) Prohibiting discrimination against participants and beneficiaries based on a health factor.

(vii) 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]

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

§ 146.111 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion*—(1) *Defined* (i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in §144.103 of this part.

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

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

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for any prosthesis if the body part was lost before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. (Therefore, the exclusion of benefits is required to comply with the limitations on preexisting condition exclusions in this section. For an example illustrating the application of these limitations to a succeeding insurance policy, see *Example 3* of paragraph (a)(3)(iv) of this section.)

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 subject to the limitations on preexisting condition exclusions in this section.

Example 3. (i) *Facts*. A group health plan provides coverage for the treatment of diabetes, generally not subject to any lifetime dollar limit. However, if an individual was diagnosed with diabetes before the effective date of coverage under the plan, diabetes coverage is subject to a lifetime limit of $10,000.

(ii) *Conclusion*. In this *Example 3*, the $10,000 lifetime limit 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 subject to the limitations on preexisting condition exclusions in this section.

Example 4. (i) *Facts*. A group health plan provides coverage for the treatment of acne, subject to a lifetime limit of $2,000. The plan counts against this $2,000 lifetime limit acne treatment 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 lifetime 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 subject to the limitations on preexisting condition exclusions in this section.

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

(ii) *Conclusion*. In this *Example 5*, the requirement to be covered under the plan for 12 months to be eligible for pregnancy benefits is a subterfuge for a preexisting condition exclusion because it is designed to exclude benefits for a condition (pregnancy) that arose before the effective date of coverage. Because a plan is prohibited under paragraph (b)(5) of this section from imposing any preexisting condition exclusion on pregnancy, the plan provision is prohibited. However, if the plan provision included an exception for women who were pregnant before the effective date of coverage under the plan (so that the provision applied only to women who became pregnant on or after the effective date of coverage) the plan provision would not be a preexisting condition exclusion (and would not be prohibited by paragraph (b)(5) of this section).

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 subject to the limitations on preexisting condition exclusions in this section.

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 subject to the limitations on preexisting condition exclusions in this section.

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 subject to the limitations on preexisting condition exclusions in this section.

(2) *General rules*. Subject to paragraph (b) of this section (prohibiting the imposition of a preexisting condition exclusion with respect to certain individuals and conditions), a group health plan, and a health insurance issuer offering group health insurance coverage, may impose, with respect to a participant or beneficiary, a preexisting condition exclusion only if the requirements of this paragraph (a)(2) are satisfied.

(i) *6-month look-back rule.* A preexisting condition exclusion must relate to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period (or such shorter period as applies under the plan) ending on the enrollment date.

(A) For purposes of this paragraph (a)(2)(i), medical advice, diagnosis, care, or treatment is taken into account only if it is recommended by, or received from, an individual licensed or similarly authorized to provide such services under State law and operating within the scope of practice authorized by State law.

(B) For purposes of this paragraph (a)(2)(i), the 6-month period ending on the enrollment date begins on the 6-month anniversary date preceding the enrollment date. For example, for an enrollment date of August 1, 1998, the 6-month period preceding the enrollment date is the period commencing on February 1, 1998 and continuing through July 31, 1998. As another example, for an enrollment date of August 30, 1998, the 6-month period preceding the enrollment date is the period commencing on February 28, 1998 and continuing through August 29, 1998.

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

Example 1. (i) *Facts.* Individual *A* is diagnosed with a medical condition 8 months before *A*'s enrollment date in Employer *R*'s group health plan. *A*'s doctor recommends that *A* take a prescription drug for 3 months, and *A* follows the recommendation.

(ii) *Conclusion.* In this *Example 1,* Employer *R*'s plan may impose a preexisting condition exclusion with respect to *A*'s condition because A received treatment during the 6-month period ending on *A*'s enrollment date in Employer *R*'s plan by taking the prescription medication during that period. However, if *A* did not take the prescription drug during the 6-month period, Employer *R*'s plan would not be able to impose a preexisting condition exclusion with respect to that condition.

Example 2. (i) *Facts.* Individual *B* is treated for a medical condition 7 months before the enrollment date in Employer *S*'s group health plan. As part of such treatment, *B*'s physician recommends that a follow-up examination be given 2 months later. Despite this recommendation, *B* does not receive a follow-up examination, and no other medical advice, diagnosis, care, or treatment for that condition is recommended to *B* or received by *B* during the 6-month period ending on *B*'s enrollment date in Employer *S*'s plan.

(ii) *Conclusion.* In this *Example 2,* Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date.

Example 3. (i) *Facts.* Same facts as *Example 2,* except that Employer *S*'s plan learns of the condition and attaches a rider to *B*'s certificate of coverage excluding coverage for the condition. Three months after enrollment, *B*'s condition recurs, and Employer *S*'s plan denies payment under the rider.

(ii) *Conclusion.* In this *Example 3,* the rider is a preexisting condition exclusion and Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date. (In addition, such a rider would violate the provisions of §146.121, even if *B* had received treatment for the condition within the 6-month period ending on the enrollment date.)

Example 4. (i) *Facts.* Individual *C* has asthma and is treated for that condition several times during the 6-month period before *C*'s enrollment date in Employer *T*'s plan. Three months after the enrollment date, *C* begins coverage under Employer *T*'s plan. Two months later, *C* is hospitalized for asthma.

(ii) *Conclusion.* In this *Example 4,* Employer *T*'s plan may impose a preexisting condition exclusion with respect to *C*'s asthma because care relating to *C*'s asthma was received during the 6-month period ending on *C*'s enrollment date (which, under the rules of paragraph (a)(3)(i) of this section, is the first day of the waiting period).

Example 5. (i) *Facts.* Individual *D,* who is subject to a preexisting condition exclusion imposed by Employer *U*'s plan, has diabetes, as well as retinal degeneration, a foot condition, and poor circulation (all of which are conditions that may be directly attributed to diabetes). *D* receives treatment for these conditions during the 6-month period ending on *D*'s enrollment date in Employer *U*'s plan. After enrolling in the plan, *D* stumbles and breaks a leg.

(ii) *Conclusion.* In this *Example 5,* the leg fracture is not a condition related to D's diabetes, retinal degeneration, foot condition, or poor circulation, even though they may have contributed to the accident. Therefore, benefits to treat the leg fracture cannot be subject to a preexisting condition exclusion. However, any additional medical services that may be needed because of *D*'s preexisting diabetes, poor circulation, or retinal degeneration that would not be needed by another patient with a broken leg who does not have these conditions may be subject to

the preexisting condition exclusion imposed under Employer *U*'s plan.

(ii) *Maximum length of preexisting condition exclusion.* A preexisting condition exclusion is not permitted to extend for more than 12 months (18 months in the case of a late enrollee) after the enrollment date. For example, for an enrollment date of August 1, 1998, the 12-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through July 31, 1999; the 18-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through January 31, 2000.

(iii) *Reducing a preexisting condition exclusion period by creditable coverage*—(A) The period of any preexisting condition exclusion that would otherwise apply to an individual under a group health plan is reduced by the number of days of creditable coverage the individual has as of the enrollment date, as counted under §146.113. Creditable coverage may be evidenced through a certificate of creditable coverage (required under §146.115(a)), or through other means in accordance with the rules of §146.115(c).

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

Example. (i) *Facts.* Individual *D* works for Employer *X* and has been covered continuously under *X*'s group health plan. *D*'s spouse works for Employer *Y*. *Y* maintains a group health plan that imposes a 12-month preexisting condition exclusion (reduced by creditable coverage) on all new enrollees. *D* enrolls in *Y*'s plan, but also stays covered under *X*'s plan. *D* presents *Y*'s plan with evidence of creditable coverage under *X*'s plan.

(ii) *Conclusion.* In this *Example*, *Y*'s plan must reduce the preexisting condition exclusion period that applies to *D* by the number of days of coverage that *D* had under *X*'s plan as of *D*'s enrollment date in *Y*'s plan (even though *D*'s coverage under *X*'s plan was continuing as of that date).

(iv) *Other standards.* See §146.121 for other standards in this Subpart A that may apply with respect to certain benefit limitations or restrictions under a group health plan. Other laws may also apply, such as the Uniformed Services Employment and Reemployment Rights Act (USERRA), which can affect the application of a preexisting condition exclusion to certain individuals who are reinstated in a group health plan following active military service.

(3) *Enrollment definitions*—(i) *Enrollment date* means the first day of coverage (as described in paragraph (a)(3)(ii) of this section) 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.

(ii) *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.

(iii) *Waiting period* means the period that must pass before coverage for an employee or dependent who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an employee or dependent enrolls as a late enrollee or special enrollee, any period before such late or special enrollment is not a waiting period. If an individual seeks coverage in the individual market, a waiting period begins on the date the individual submits a substantially complete application for coverage and ends on—

(A) If the application results in coverage, the date coverage begins;

(B) If the application does not result in coverage, the date on which the application is denied by the issuer or the date on which the offer of coverage lapses.

(iv) The rules of paragraphs (a)(3)(i), (ii), and (iii) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period following the date an employee is hired and completes the applicable enrollment forms, or on any subsequent January 1 after completion of the applicable enrollment forms. Employer *V*'s plan imposes a preexisting condition exclusion for 12 months (reduced by the individual's creditable coverage) following an individual's enrollment date. Employee *E* is hired by Employer *V* on October 13, 1998 and on October 14, 1998 *E* completes and files all the forms necessary to enroll in

the plan. *E*'s coverage under the plan becomes effective on October 25, 1998 (which is the beginning of the first payroll period after *E*'s date of hire).

(ii) *Conclusion.* In this *Example 1*, *E*'s enrollment date is October 13, 1998 (which is the first day of the waiting period for *E*'s enrollment and is also *E*'s date of hire). Accordingly, with respect to *E*, the permissible 6-month period in paragraph (a)(2)(i) is the period from April 13, 1998 through October 12, 1998, the maximum permissible period during which Employer *V*'s plan can apply a preexisting condition exclusion under paragraph (a)(2)(ii) is the period from October 13, 1998 through October 12, 1999, and this period must be reduced under paragraph (a)(2)(iii) by *E*'s days of creditable coverage as of October 13, 1998.

Example 2. (i) *Facts.* A group health plan has two benefit package options, Option 1 and Option 2. Under each option a 12-month preexisting condition exclusion is imposed. Individual *B* is enrolled in Option 1 on the first day of employment with the employer maintaining the plan, remains enrolled in Option 1 for more than one year, and then decides to switch to Option 2 at open season.

(ii) *Conclusion.* In this *Example 2, B* cannot be subject to any preexisting condition exclusion under Option 2 because any preexisting condition exclusion period would have to begin on *B*'s enrollment date, which is *B*'s first day of coverage, rather than the date that *B* enrolled in Option 2. Therefore, the preexisting condition exclusion period expired before B switched to Option 2.

Example 3. (i) *Facts.* On May 13, 1997, Individual *E* is hired by an employer and enrolls in the employer's group health plan. The plan provides benefits solely through an insurance policy offered by Issuer *S*. On December 27, 1998, *E*'s leg is injured in an accident and the leg is amputated. On January 1, 1999, the plan switches coverage to a policy offered by Issuer *T*. Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 3, E*'s enrollment date is May 13, 1997, *E*'s first day of coverage. Therefore, the permissible 6-month look-back period for the preexisting condition exclusion imposed under Issuer *T*'s policy begins on November 13, 1996 and ends on May 12, 1997. In addition, the 12-month maximum permissible preexisting condition exclusion period begins on May 13, 1997 and ends on May 12, 1998. Accordingly, because no medical advice, diagnosis, care, or treatment was recommended to or received by *E* for the leg during the 6-month look-back period (even though medical care was provided within the 6-month period preceding the effective date of *E*'s coverage under Issuer *T*'s policy), Issuer *T* may not impose any preexisting condition exclusion with respect to *E*. Moreover, even if *E* had received treatment during the 6-month look-back period, Issuer *T* still would not be permitted to impose a preexisting condition exclusion because the 12-month maximum permissible preexisting condition exclusion period expired on May 12, 1998 (before the effective date of *E*'s coverage under Issuer *T*'s policy).

Example 4. (i) *Facts.* A group health plan limits eligibility for coverage to full-time employees of Employer *Y*. Coverage becomes effective on the first day of the month following the date the employee becomes eligible. Employee *C* begins working full-time for Employer *Y* on April 11. Prior to this date, *C* worked part-time for *Y*. *C* enrolls in the plan and coverage is effective May 1.

(ii) *Conclusion.* In this *Example 4*, *C*'s enrollment date is April 11 and the period from April 11 through April 30 is a waiting period. The period while *C* was working part-time, and therefore not in an eligible class of employees, is not part of the waiting period.

Example 5. (i) *Facts.* To be eligible for coverage under a multiemployer group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the previous quarter. If the hours requirement is satisfied, coverage becomes effective on the first day of the current calendar quarter. Employee *D* begins work on January 28 and does not work 250 hours in covered employment during the first quarter (ending March 31). *D* works at least 250 hours in the second quarter (ending June 30) and is enrolled in the plan with coverage effective July 1 (the first day of the third quarter).

(ii) *Conclusion.* In this *Example 5*, *D*'s enrollment date is the first day of the quarter during which *D* satisfies the hours requirement, which is April 1. The period from April 1 through June 30 is a waiting period.

(v) *Late enrollee* means an individual whose enrollment in a plan is a late enrollment.

(vi) (A) *Late enrollment* means enrollment of an individual under a group health plan other than—

(*1*) On the earliest date on which coverage can become effective for the individual under the terms of the plan; or

(*2*) Through special enrollment. (For rules relating to special enrollment, see §146.117.)

(B) If an individual ceases to be eligible for coverage under the 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.

(vii) *Examples.* The rules of paragraphs (a)(3)(v) and (vi) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* Employee *F* first becomes eligible to be covered by Employer *W*'s group health plan on January 1, 1999 but elects not to enroll in the plan until a later annual open enrollment period, with coverage effective January 1, 2001. *F* has no special enrollment right at that time.

(ii) *Conclusion.* In this *Example 1*, *F* is a late enrollee with respect to *F*'s coverage that became effective under the plan on January 1, 2001.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *F* terminates employment with Employer *W* on July 1, 1999 without having had any health insurance coverage under the plan. *F* is rehired by Employer *W* on January 1, 2000 and is eligible for and elects coverage under Employer *W*'s plan effective on January 1, 2000.

(ii) *Conclusion.* In this *Example 2*, *F* would not be a late enrollee with respect to *F*'s coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions*—(1) *Newborns*—(i) *In general.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who, within 30 days after birth, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after birth and subsequently enrolls in another group health plan without a significant break in coverage (as described in §146.113(b)(2)(iii)), the other plan may not impose any preexisting condition exclusion on the child.

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

Example 1. (i) *Facts.* Individual *E,* who has no prior creditable coverage, begins working for Employer *W* and has accumulated 210 days of creditable coverage under Employer *W*'s group health plan on the date *E* gives birth to a child. Within 30 days after the birth, the child is enrolled in the plan. Ninety days after the birth, both *E* and the child terminate coverage under the plan. Both *E* and the child then experience a break in coverage of 45 days before *E* is hired by Employer *X* and the two are enrolled in Employer *X*'s group health plan.

(ii) *Conclusion.* In this *Example 1,* because *E*'s child is enrolled in Employer *W*'s plan within 30 days after birth, no preexisting condition exclusion may be imposed with respect to the child under Employer *W*'s plan. Likewise, Employer *X*'s plan may not impose any preexisting condition exclusion on *E*'s child because the child was covered under creditable coverage within 30 days after birth and had no significant break in coverage before enrolling in Employer *X*'s plan. On the other hand, because *E* had only 300 days of creditable coverage prior to *E*'s enrollment date in Employer *X*'s plan, Employer *X*'s plan may impose a preexisting condition exclusion on *E* for up to 65 days (66 days if the 12-month period after *E*'s enrollment date in *X*'s plan includes February 29).

Example 2. (i) *Facts.* Individual *F* is enrolled in a group health plan in which coverage is provided through a health insurance issuer. *F* gives birth. Under State law applicable to the health insurance issuer, health care expenses incurred for the child during the 30 days following birth are covered as part of *F*'s coverage. Although *F* may obtain coverage for the child beyond 30 days by timely requesting special enrollment and paying an additional premium, the issuer is prohibited under State law from recouping the cost of any expenses incurred for the child within the 30-day period if the child is not later enrolled.

(ii) *Conclusion.* In this *Example 2,* the child is covered under creditable coverage within 30 days after birth, regardless of whether the child enrolls as a special enrollee under the plan. Therefore, no preexisting condition exclusion may be imposed on the child unless the child has a significant break in coverage.

(2) *Adopted children.* Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who is adopted or placed for adoption before attaining 18 years of age and who, within 30 days after the adoption or placement for adoption, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after adoption or placement for adoption and subsequently enrolls in another group health plan without a significant break in coverage (as described in §146.113(b)(2)(iii)), the other plan may

not impose any preexisting condition exclusion on the child. This rule does not apply to coverage before the date of such adoption or placement for adoption.

(3) *Significant break in coverage.* Paragraphs (b)(1) and (2) of this section no longer apply to a child after a significant break in coverage. (*See* §146.113(b)(2)(iii) for rules relating to the determination of a significant break in coverage.)

(4) *Special enrollment.* For special enrollment rules relating to new dependents, see §146.117(b).

(5) *Pregnancy.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to pregnancy.

(6) *Genetic information*—(i) A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to a condition based solely on genetic information. However, if an individual is diagnosed with a condition, even if the condition relates to genetic information, the plan may impose a preexisting condition exclusion with respect to the condition, subject to the other limitations of this section.

(ii) The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* enrolls in a group health plan that imposes a 12-month maximum preexisting condition exclusion. Three months before *A*'s enrollment, *A*'s doctor told *A* that, based on genetic information, *A* has a predisposition towards breast cancer. *A* was not diagnosed with breast cancer at any time prior to *A*'s enrollment date in the plan. Nine months after *A*'s enrollment date in the plan, *A* is diagnosed with breast cancer.

(ii) *Conclusion.* In this *Example,* the plan may not impose a preexisting condition exclusion with respect to *A*'s breast cancer because, prior to *A*'s enrollment date, *A* was not diagnosed with breast cancer.

(c) *General notice of preexisting condition exclusion.* A group health plan imposing a preexisting condition exclusion, and a health insurance issuer offering group health insurance coverage subject to a preexisting condition exclusion, must provide a written general notice of preexisting condition exclusion to participants under the plan and cannot impose a preexisting condition exclusion with respect to a participant or a dependent of the participant until such a notice is provided.

(1) *Manner and timing.* A plan or issuer must provide the general notice of preexisting condition exclusion as part of any written application materials distributed by the plan or issuer for enrollment. If the plan or issuer does not distribute such materials, the notice must be provided by the earliest date following a request for enrollment that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content.* The general notice of preexisting condition exclusion must notify participants of the following:

(i) The existence and terms of any preexisting condition exclusion under the plan. This description includes the length of the plan's look-back period (which is not to exceed 6 months under paragraph (a)(2)(i) of this section); the maximum preexisting condition exclusion period under the plan (which cannot exceed 12 months (or 18-months for late enrollees) under paragraph (a)(2)(ii) of this section); and how the plan will reduce the maximum preexisting condition exclusion period by creditable coverage (described in paragraph (a)(2)(iii) of this section).

(ii) A description of the rights of individuals to demonstrate creditable coverage, and any applicable waiting periods, through a certificate of creditable coverage (as required by §146.115(a)) or through other means (as described in §146.115(c)). This must include a description of the right of the individual to request a certificate from a prior plan or issuer, if necessary, and a statement that the current plan or issuer will assist in obtaining a certificate from any prior plan or issuer, if necessary.

(iii) A person to contact (including an address or telephone number) for obtaining additional information or assistance regarding the preexisting condition exclusion.

(3) *Duplicate notices not required.* If a notice satisfying the requirements of this paragraph (c) is provided to an individual, the obligation to provide a general notice of preexisting condition

exclusion with respect to that individual is satisfied for both the plan and the issuer.

(4) *Example with sample language.* The rules of this paragraph (c) are illustrated by the following example, which includes sample language that plans and issuers can use as a basis for preparing their own notices to satisfy the requirements of this paragraph (c):

Example. (i) *Facts.* A group health plan makes coverage effective on the first day of the first calendar month after hire and on each January 1 following an open season. The plan imposes a 12-month maximum preexisting condition exclusion (18 months for late enrollees) and uses a 6-month look-back period. As part of the enrollment application materials, the plan provides the following statement:

This plan imposes a preexisting condition exclusion. This means that if you have a medical condition before coming to our plan, you might have to wait a certain period of time before the plan will provide coverage for that condition. This exclusion applies only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within a six-month period. Generally, this six-month period ends the day before your coverage becomes effective. However, if you were in a waiting period for coverage, the six-month period ends on the day before the waiting period begins. The preexisting condition exclusion does not apply to pregnancy nor to a child who is enrolled in the plan within 30 days after birth, adoption, or placement for adoption.

This exclusion may last up to 12 months (18 months if you are a late enrollee) from your first day of coverage, or, if you were in a waiting period, from the first day of your waiting period. However, you can reduce the length of this exclusion period by the number of days of your prior ''creditable coverage.'' Most prior health coverage is creditable coverage and can be used to reduce the preexisting condition exclusion if you have not experienced a break in coverage of at least 63 days. To reduce the 12-month (or 18-month) exclusion period by your creditable coverage, you should give us a copy of any certificates of creditable coverage you have. If you do not have a certificate, but you do have prior health coverage, we will help you obtain one from your prior plan or issuer. There are also other ways that you can show you have creditable coverage. Please contact us if you need help demonstrating creditable coverage.

All questions about the preexisting condition exclusion and creditable coverage should be directed to Individual *B* at Address *M* or Telephone Number *N*.

(ii) *Conclusion.* In this *Example,* the plan satisfies the general notice requirement of this paragraph (c), and thus also satisfies this requirement for any issuer providing the coverage.

(d) *Determination of creditable coverage*—(1) *Determination within reasonable time.* If a group health plan or health insurance issuer offering group health insurance coverage receives creditable coverage information under §146.115, the plan or issuer is required, within a reasonable time following receipt of the information, to make a determination regarding the amount of the individual's creditable coverage and the length of any exclusion that remains. Whether this determination is made within a reasonable time depends on the relevant facts and circumstances. Relevant facts and circumstances include whether a plan's application of a preexisting condition exclusion would prevent an individual from having access to urgent medical care.

(2) *No time limit on presenting evidence of creditable coverage.* A plan or issuer may not impose any limit on the amount of time that an individual has to present a certificate or other evidence of creditable coverage.

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

Example. (i) *Facts.* A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *H* develops an urgent health condition before receiving a certificate of creditable coverage from *H*'s prior group health plan. *H* attests to the period of prior coverage, presents corroborating documentation of the coverage period, and authorizes the plan to request a certificate on *H*'s behalf in accordance with the rules of §146.115.

(ii) *Conclusion.* In this *Example,* the plan must review the evidence presented by *H* and make a determination of creditable coverage within a reasonable time that is consistent with the urgency of *H*'s health condition. (This determination may be modified as permitted under paragraph (f) of this section.)

(e) *Individual notice of period of preexisting condition exclusion.* After an individual has presented evidence of creditable coverage and after the plan or issuer has made a determination of creditable coverage under paragraph

(d) of this section, the plan or issuer must provide the individual a written notice of the length of preexisting condition exclusion that remains after offsetting for prior creditable coverage. This individual notice is not required to identify any medical conditions specific to the individual that could be subject to the exclusion. A plan or issuer is not required to provide this notice if the plan or issuer does not impose any preexisting condition exclusion on the individual or if the plan's preexisting condition exclusion is completely offset by the individual's prior creditable coverage.

(1) *Manner and timing.* The individual notice must be provided by the earliest date following a determination that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content.* A plan or issuer must disclose—

(i) Its determination of any preexisting condition exclusion period that applies to the individual (including the last day on which the preexisting condition exclusion applies);

(ii) The basis for such determination, including the source and substance of any information on which the plan or issuer relied;

(iii) An explanation of the individual's right to submit additional evidence of creditable coverage; and

(iv) A description of any applicable appeal procedures established by the plan or issuer.

(3) *Duplicate notices not required.* If a notice satisfying the requirements of this paragraph (e) is provided to an individual, the obligation to provide this individual notice of preexisting condition exclusion with respect to that individual is satisfied for both the plan and the issuer.

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

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *G* presents a certificate of creditable coverage indicating 240 days of creditable coverage. Within seven days of receipt of the certificate, the plan determines that *G* is subject to a preexisting condition exclusion of 125 days, the last day of which is March 5. Five days later, the plan notifies *G* that, based on the certificate *G* submitted, *G* is subject to a preexisting condition exclusion period of 125 days, ending on March 5. The notice also explains the opportunity to submit additional evidence of creditable coverage and the plan's appeal procedures. The notice does not identify any of *G*'s medical conditions that could be subject to the exclusion.

(ii) *Conclusion.* In this *Example 1*, the plan satisfies the requirements of this paragraph (e).

Example 2. (i) *Facts.* Same facts as in *Example 1*, except that the plan determines that *G* has 430 days of creditable coverage based on *G*'s certificate indicating 430 days of creditable coverage under *G*'s prior plan.

(ii) *Conclusion.* In this *Example 2*, the plan is not required to notify *G* that *G* will not be subject to a preexisting condition exclusion.

(f) *Reconsideration.* Nothing in this section prevents a plan or issuer from modifying an initial determination of creditable coverage if it determines that the individual did not have the claimed creditable coverage, provided that —

(1) A notice of the new determination (consistent with the requirements of paragraph (e) of this section) is provided to the individual; and

(2) Until the notice of the new determination is provided, the plan or issuer, for purposes of approving access to medical services (such as a pre-surgery authorization), acts in a manner consistent with the initial determination.

[69 FR 78783, Dec. 30, 2004, as amended at 75 FR 37235, June 28, 2010]

§ 146.113 Rules relating to creditable coverage.

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

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

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

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

(iv) Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under section 1928 of the Social Security Act (the program for distribution of pediatric vaccines).

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under §146.111(a)(2)(iii), the amount of an individual's creditable coverage generally is determined by using the standard method described in paragraph (b) of this section. A plan or issuer may use the alternative method under paragraph (c) of this section with respect to any or all of the categories of benefits described under paragraph (c)(3) of this section.

(b) *Standard method*—(1) *Specific benefits not considered.* Under the standard method, the amount of creditable coverage is determined without regard to the specific benefits included in the coverage.

(2) *Counting creditable coverage*—(i) *Based on days.* For purposes of reducing the preexisting condition exclusion period that applies to an individual, the amount of creditable coverage is determined by counting all the days on which the individual has one or more types of creditable coverage. Accordingly, if on a particular day an individual has creditable coverage from more than one source, all the creditable coverage on that day is counted as one day. Any days in a waiting period for coverage are not creditable coverage.

(ii) *Days not counted before significant break in coverage.* Days of creditable coverage that occur before a significant break in coverage are not required to be counted.

(iii) *Significant break in coverage defined*—A significant break in coverage means a period of 63 consecutive days during each of which an individual does not have any creditable coverage. (See also §146.143(c)(2)(iii) regarding the applicability to issuers of State insurance laws that require a break of more than

63 days before an individual has a significant break in coverage for purposes of State insurance law.)

(iv) *Periods that toll a significant break.* Days in a waiting period and days in an affiliation period are not taken into account in determining whether a significant break in coverage has occurred. In addition, for an individual who elects COBRA continuation coverage during the second election period provided under the Trade Act of 2002, the days between the date the individual lost group health plan coverage and the first day of the second COBRA election period are not taken into account in determining whether a significant break in coverage has occurred.

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

Example 1. (i) *Facts.* Individual *A* has creditable coverage under Employer *P*'s plan for 18 months before coverage ceases. *A* is provided a certificate of creditable coverage on *A*'s last day of coverage. Sixty-four days after the last date of coverage under *P*'s plan, *A* is hired by Employer *Q* and enrolls in *Q*'s group health plan. *Q*'s plan has a 12-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 1*, *A* has a break in coverage of 63 days. Because *A*'s break in coverage is a significant break in coverage, *Q*'s plan may disregard *A*'s prior coverage and *A* may be subject to a 12-month preexisting condition exclusion.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *A* is hired by *Q* and enrolls in *Q*'s plan on the 63rd day after the last date of coverage under *P*'s plan.

(ii) *Conclusion.* In this *Example 2*, *A* has a break in coverage of 62 days. Because *A*'s break in coverage is not a significant break in coverage, *Q*'s plan must count *A*'s prior creditable coverage for purposes of reducing the plan's preexisting condition exclusion period that applies to *A*.

Example 3. (i) *Facts.* Same facts as *Example 1*, except that *Q*'s plan provides benefits through an insurance policy that, as required by applicable State insurance laws, defines a significant break in coverage as 90 days.

(ii) *Conclusion.* In this *Example 3*, under State law, the issuer that provides group health insurance coverage to *Q*'s plan must count *A*'s period of creditable coverage prior to the 63-day break. (However, if *Q*'s plan was a self-insured plan, the coverage would not be subject to State law. Therefore, the health coverage would not be governed by the longer break rules and *A*'s previous health coverage could be disregarded.)

Example 4. [Reserved]

Example 5. (i) *Facts.* Individual *C* has creditable coverage under Employer *S*'s plan for 200 days before coverage ceases. *C* is provided a certificate of creditable coverage on *C*'s last day of coverage. *C* then does not have any creditable coverage for 51 days before being hired by Employer *T*. *T*'s plan has a 3-month waiting period. *C* works for *T* for 2 months and then terminates employment. Eleven days after terminating employment with *T*, *C* begins working for Employer *U*. *U*'s plan has no waiting period, but has a 6-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 5*, *C* does not have a significant break in coverage because, after disregarding the waiting period under *T*'s plan, *C* had only a 62-day break in coverage (51 days plus 11 days). Accordingly, *C* has 200 days of creditable coverage, and *U*'s plan may not apply its 6-month preexisting condition exclusion with respect to *C*.

Example 6. [Reserved]

Example 7. (i) *Facts.* Individual *E* has creditable coverage under Employer *X*'s plan. *E* is provided a certificate of creditable coverage on *E*'s last day of coverage. On the 63rd day without coverage, *E* submits a substantially complete application for a health insurance policy in the individual market. *E*'s application is accepted and coverage is made effective 10 days later.

(ii) *Conclusion.* In this *Example 7*, because *E* applied for the policy before the end of the 63rd day, the period between the date of application and the first day of coverage is a waiting period and no significant break in coverage occurred even though the actual period without coverage was 73 days.

Example 8. (i) *Facts.* Same facts as *Example 7*, except that *E*'s application for a policy in the individual market is denied.

(ii) *Conclusion.* In this *Example 8*, even though *E* did not obtain coverage following application, the period between the date of application and the date the coverage was denied is a waiting period. However, to avoid a significant break in coverage, no later than the day after the application for the policy is denied *E* would need to do one of the following: submit a substantially complete application for a different individual market policy; obtain coverage in the group market; or be in a waiting period for coverage in the group market.

(vi) *Other permissible counting methods*—(A) *Rule.* Notwithstanding any other provisions of this paragraph (b)(2), for purposes of reducing a preexisting condition exclusion period (but not for purposes of issuing a certificate under §146.115), a group health

plan, and a health insurance issuer offering group health insurance coverage, may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

(B) *Example.* The rule of this paragraph (b)(2)(vi) is illustrated by the following example:

Example. (i) *Facts.* Individual *F* has coverage under Group Health Plan *Y* from January 3, 1997 through March 25, 1997. *F* then becomes covered by Group Health Plan *Z*. *F*'s enrollment date in Plan *Z* is May 1, 1997. Plan *Z* has a 12-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example,* Plan *Z* may determine, in accordance with the rules prescribed in paragraphs (b)(2)(i), (ii), and (iii) of this section, that *F* has 82 days of creditable coverage (29 days in January, 28 days in February, and 25 days in March). Thus, the preexisting condition exclusion will no longer apply to *F* on February 8, 1998 (82 days before the 12-month anniversary of *F*'s enrollment (May 1)). For administrative convenience, however, Plan *Z* may consider that the preexisting condition exclusion will no longer apply to *F* on the first day of the month (February 1).

(c) *Alternative method*—(1) *Specific benefits considered.* Under the alternative method, a group health plan, or a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage based on coverage within any category of benefits described in paragraph (c)(3) of this section and not based on coverage for any other benefits. The plan or issuer may use the alternative method for any or all of the categories. The plan or issuer may apply a different preexisting condition exclusion period with respect to each category (and may apply a different preexisting condition exclusion period for benefits that are not within any category). The creditable coverage determined for a category of benefits applies only for purposes of reducing the preexisting condition exclusion period with respect to that category. An individual's creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method of paragraph (b) of this section.

(2) *Uniform application.* A plan or issuer using the alternative method is required to apply it uniformly to all participants and beneficiaries under the plan or health insurance coverage. The use of the alternative method is required to be set forth in the plan.

(3) *Categories of benefits.* The alternative method for counting creditable coverage may be used for coverage for the following categories of benefits—

(i) Mental health;

(ii) Substance abuse treatment;

(iii) Prescription drugs;

(iv) Dental care; or

(v) Vision care.

(4) *Plan notice.* If the alternative method is used, the plan is required to—

(i) State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan; and

(ii) Include in these statements a description of the effect of using the alternative method, including an identification of the categories used.

(5) *Issuer notice.* With respect to health insurance coverage offered by an issuer in the small or large group market, if the insurance coverage uses the alternative method, the issuer states prominently in any disclosure statement concerning the coverage, that the issuer is using the alternative method, and includes in such statements a description of the effect of using the alternative method. This applies separately to each type of coverage offered by the health insurance issuer.

(6) *Disclosure of information on previous benefits.* See §146.115(b) for special rules concerning disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage under this paragraph (c).

(7) *Counting creditable coverage*—(i) *In general.* Under the alternative method, the group health plan or issuer counts creditable coverage within a category if any level of benefits is provided within the category. Coverage under a reimbursement account or arrangement, such as a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code),

does not constitute coverage within any category.

(ii) *Special rules.* In counting an individual's creditable coverage under the alternative method, the group health plan, or issuer, first determines the amount of the individual's creditable coverage that may be counted under paragraph (b) of this section, up to a total of 365 days of the most recent creditable coverage (546 days for a late enrollee). The period over which this creditable coverage is determined is referred to as the determination period. Then, for the category specified under the alternative method, the plan or issuer counts within the category all days of coverage that occurred during the determination period (whether or not a significant break in coverage for that category occurs), and reduces the individual's preexisting condition exclusion period for that category by that number of days. The plan or issuer may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, that is at least as favorable to the individual.

(iii) *Example.* The rules of this paragraph (c)(7) are illustrated by the following example:

Example. (i) *Facts.* Individual *D* enrolls in Employer *V*'s plan on January 1, 2001. Coverage under the plan includes prescription drug benefits. On April 1, 2001, the plan ceases providing prescription drug benefits. *D*'s employment with Employer *V* ends on January 1, 2002, after *D* was covered under Employer *V*'s group health plan for 365 days. *D* enrolls in Employer *Y*'s plan on February 1, 2002 (*D*'s enrollment date). Employer *Y*'s plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) *Conclusion.* In this *Example*, Employer *Y*'s plan may impose a 275-day preexisting condition exclusion with respect to *D* for prescription drug benefits because *D* had 90 days of creditable coverage relating to prescription drug benefits within *D*'s determination period.

[69 FR 78788, Dec. 30, 2004]

§ 146.115 Certification and disclosure of previous coverage.

(a) *Certificate of creditable coverage*—(1) *Entities required to provide certificate*—(i) *In General.* A group health plan, and each health insurance issuer offering group health insurance coverage under a group health plan, is required to furnish certificates of creditable coverage in accordance with this paragraph (a).

(ii) *Duplicate certificates not required.* An entity required to provide a certificate under this paragraph (a) with respect to an individual satisfies that requirement if another party provides the certificate, but only to the extent that the certificate contains the information required in paragraph (a)(3) of this section. For example, in the case of a group health plan funded through an insurance policy, the issuer satisfies the certification requirement with respect to an individual if the plan actually provides a certificate that includes all the information required under paragraph (a)(3) of this section with respect to the individual.

(iii) *Special rule for group health plans.* To the extent coverage under a plan consists of group health insurance coverage, the plan satisfies the certification requirements under this paragraph (a) if any issuer offering the coverage is required to provide the certificates pursuant to an agreement between the plan and the issuer. For example, if there is an agreement between an issuer and a plan sponsor under which the issuer agrees to provide certificates for individuals covered under the plan, and the issuer fails to provide a certificate to an individual when the plan would have been required to provide one under this paragraph (a), then the issuer, but not the plan, violates the certification requirements of this paragraph (a).

(iv) *Special rules for issuers*—(A)(*1*) *Responsibility of issuer for coverage period.* An issuer is not required to provide information regarding coverage provided to an individual by another party.

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(A) is illustrated by the following example:

Example. (i) *Facts.* A plan offers coverage with an HMO option from one issuer and an indemnity option from a different issuer. The HMO has not entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option and later ceases to be

covered under the plan, any certificate provided by the HMO is not required to provide information regarding the employee's coverage under the indemnity option.

(B)(*1*) *Cessation of issuer coverage prior to cessation of coverage under a plan.* If an individual's coverage under an issuer's policy or contract ceases before the individual's coverage under the plan ceases, the issuer is required to provide sufficient information to the plan (or to another party designated by the plan) to enable the plan (or other party), after cessation of the individual's coverage under the plan, to provide a certificate that reflects the period of coverage under the policy or contract. By providing that information to the plan, the issuer satisfies its obligation to provide an automatic certificate for that period of creditable coverage with respect to the individual under paragraph (a)(2)(ii) of this section. The issuer, however, must still provide a certificate upon request as required under paragraph (a)(2)(iii) of this section. In addition, the issuer is required to cooperate with the plan in responding to any request made under paragraph (b)(2) of this section (relating to the alternative method of counting creditable coverage). Moreover, if the individual's coverage under the plan ceases at the time the individual's coverage under the issuer's policy or contract ceases, the issuer must still provide an automatic certificate under paragraph (a)(2)(ii) of this section. If an individual's coverage under an issuer's policy or contract ceases on the effective date for changing enrollment options under the plan, the issuer may presume (absent information to the contrary) that the individual's coverage under the plan continues. Therefore, the issuer is required to provide information to the plan in accordance with this paragraph (a)(1)(iv)(B)(*1*) (and is not required to provide an automatic certificate under paragraph (a)(2)(ii) of this section).

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(B) is illustrated by the following example:

Example. (i) *Facts.* A group health plan provides coverage under an HMO option and an indemnity option through different issuers, and only allows employees to switch on each January 1. Neither the HMO nor the indemnity issuer has entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option on January 1, the indemnity issuer must provide the plan (or a person designated by the plan) with appropriate information with respect to the individual's coverage with the indemnity issuer. However, if the individual's coverage with the indemnity issuer ceases at a date other than January 1, the issuer is instead required to provide the individual with an automatic certificate.

(2) *Individuals for whom certificate must be provided; timing of issuance*—(i) *Individuals.* A certificate must be provided, without charge, for participants or dependents who are or were covered under a group health plan upon the occurrence of any of the events described in paragraph (a)(2)(ii) or (iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(ii) are referred to as automatic certificates.

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 607(3) of ERISA, section 4980(B)(g)(1) of the Internal Revenue Code, or section 2208 of the PHS Act) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of ERISA, section 4980(B)(f)(6) of the Internal Revenue Code, and section 2206 of the PHS Act (relating to notices required under COBRA).

(B) *Other individuals when coverage ceases.* In the case of an individual who is not a qualified beneficiary entitled to elect COBRA continuation coverage, an automatic certificate must be provided at the time the individual ceases to be covered under the plan. A plan or issuer satisfies the requirement to provide an automatic certificate at the

time the individual ceases to be covered if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums).

(*1*) The cessation of temporary continuation coverage (TCC) under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefit Program) is a cessation of coverage upon which an automatic certificate must be provided.

(*2*) In the case of an individual who is entitled to elect to continue coverage under a State program similar to COBRA and who receives the automatic certificate not later than the time a notice is required to be furnished under the State program, the certificate is deemed to be provided within a reasonable time after coverage ceases under the plan.

(*3*) If an individual's coverage ceases due to the operation of a lifetime limit on all benefits, coverage is considered to cease for purposes of this paragraph (a)(2)(ii)(B) on the earliest date that a claim is denied due to the operation of the lifetime limit.

(C) *Qualified beneficiaries when COBRA ceases.* In the case of an individual who is a qualified beneficiary and has elected COBRA continuation coverage (or whose coverage has continued after the individual became entitled to elect COBRA continuation coverage), an automatic certificate is to be provided at the time the individual' s coverage under the plan ceases. A plan, or issuer, satisfies this requirement if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums). An automatic certificate is required to be provided to such an individual regardless of whether the individual has previously received an automatic certificate under paragraph (a)(2)(ii)(A) of this section.

(iii) *Any individual upon request.* A certificate must be provided in response to a request made by, or on behalf of, an individual at any time while the individual is covered under a plan and up to 24 months after coverage ceases. Thus, for example, a plan in which an individual enrolls may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from a plan in which the individual was formerly enrolled. After the request is received, a plan or issuer is required to provide the certificate by the earliest date that the plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate is required to be provided under this paragraph (a)(2)(iii) even if the individual has previously received a certificate under this paragraph (a)(2)(iii) or an automatic certificate under paragraph (a)(2)(ii) of this section.

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

Example 1. (i) *Facts.* Individual *A* terminates employment with Employer *Q*. *A* is a qualified beneficiary entitled to elect COBRA continuation coverage under Employer *Q*'s group health plan. A notice of the rights provided under COBRA is typically furnished to qualified beneficiaries under the plan within 10 days after a covered employee terminates employment.

(ii) *Conclusion.* In this *Example 1,* the automatic certificate may be provided at the same time that *A* is provided the COBRA notice.

Example 2. (i) *Facts.* Same facts as *Example 1,* except that the automatic certificate for *A* is not completed by the time the COBRA notice is furnished to *A*.

(ii) *Conclusion.* In this *Example 2,* the automatic certificate may be provided after the COBRA notice but must be provided within the period permitted by law for the delivery of notices under COBRA.

Example 3. (i) *Facts.* Employer *R* maintains an insured group health plan. *R* has never had 20 employees and thus *R*'s plan is not subject to the COBRA continuation provisions. However, *R* is in a State that has a State program similar to COBRA. *B* terminates employment with *R* and loses coverage under *R*'s plan.

(ii) *Conclusion.* In this *Example 3,* the automatic certificate must be provided not later than the time a notice is required to be furnished under the State program.

Example 4. (i) *Facts.* Individual *C* terminates employment with Employer *S* and receives both a notice of *C*'s rights under COBRA and an automatic certificate. *C* elects COBRA continuation coverage under Employer *S*'s group health plan. After four months of COBRA continuation coverage and the expiration of a 30-day grace period, *S*'s group health plan determines that *C*'s COBRA continuation coverage has ceased

due to a failure to make a timely payment for continuation coverage.

(ii) *Conclusion.* In this *Example 4*, the plan must provide an updated automatic certificate to *C* within a reasonable time after the end of the grace period.

Example 5. (i) *Facts.* Individual *D* is currently covered under the group health plan of Employer *T*. *D* requests a certificate, as permitted under paragraph (a)(2)(iii) of this section. Under the procedure for *T*'s plan, certificates are mailed (by first class mail) 7 business days following receipt of the request. This date reflects the earliest date that the plan, acting in a reasonable and prompt fashion, can provide certificates.

(ii) *Conclusion.* In this *Example 5*, the plan's procedure satisfies paragraph (a)(2)(iii) of this section.

(3) *Form and content of certificate*—(i) *Written certificate*—(A) *In General.* Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (or any other medium approved by the Secretary).

(B) *Other permissible forms.* No written certificate is required to be provided under this paragraph (a) with respect to a particular event described in paragraph (a)(2)(ii) or (iii) of this section, if—

(*1*) An individual who is entitled to receive the certificate requests that the certificate be sent to another plan or issuer instead of to the individual;

(*2*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in this paragraph (a)(3) through means other than a written certificate (such as by telephone); and

(*3*) The receiving plan or issuer receives the information from the sending plan or issuer through such means within the time required under paragraph (a)(2) of this section.

(ii) *Required information.* The certificate must include the following—

(A) The date the certificate is issued;

(B) The name of the group health plan that provided the coverage described in the certificate;

(C) The name of the participant or dependent with respect to whom the certificate applies, and any other information necessary for the plan providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the plan and the name of the participant if the certificate is for (or includes) a dependent;

(D) The name, address, and telephone number of the plan administrator or issuer required to provide the certificate;

(E) The telephone number to call for further information regarding the certificate (if different from paragraph (a)(3)(ii)(D) of this section);

(F) Either—

(*1*) A statement that an individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage, or

(*2*) The date any waiting period (and affiliation period, if applicable) began and the date creditable coverage began;

(G) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate; and

(H) An educational statement regarding HIPAA, which explains:

(*1*) The restrictions on the ability of a plan or issuer to impose a preexisting condition exclusion (including an individual's ability to reduce a preexisting condition exclusion by creditable coverage);

(*2*) Special enrollment rights;

(*3*) The prohibitions against discrimination based on any health factor;

(*4*) The right to individual health coverage;

(*5*) The fact that State law may require issuers to provide additional protections to individuals in that State; and

(*6*) Where to get more information.

(iii) *Periods of coverage under the certificate.* If an automatic certificate is provided pursuant to paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate pursuant to paragraph (a)(2)(iii) of this section, the certificate provided must include each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be

provided for each such period of continuous coverage.

(iv) *Combining information for families.* A certificate may provide information with respect to both a participant and the participant's dependents if the information is identical for each individual. If the information is not identical, certificates may be provided on one form if the form provides all the required information for each individual and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (a)(3)(ii) of this section are satisfied if the plan or issuer provides a certificate in accordance with a model certificate authorized by the Secretary.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §146.145(c). In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in §146.113(c) (relating to the alternative method of counting creditable coverage). However, if excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (b) of this section.

(4) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided to each individual described in paragraph (a)(2) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the participant and the participant's spouse at the participant's last known address, then the requirements of this paragraph (a)(4) are satisfied with respect to all individuals residing at that address. If a dependent's last known address is different than the participant's last known address, a separate certificate is required to be provided to the dependent at the dependent's last known address. If separate certificates are being provided by mail to individuals who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* A plan or issuer must establish a written procedure for individuals to request and receive certificates pursuant to paragraph (a)(2)(iii) of this section. The written procedure must include all contact information necessary to request a certificate (such as name and phone number or address).

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (a)(2)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is permitted to provide the certificate to the designated individual or entity. If a certificate is required to be provided upon request under paragraph (a)(2)(iii) of this section and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is required to provide the certificate to the designated individual or entity.

(5) *Special rules concerning dependent coverage*—(i)(A) *Reasonable efforts.* A plan or issuer is required to use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. In any case in which an automatic certificate is required to be furnished with respect to a dependent under paragraph (a)(2)(ii) of this section, no individual certificate is required to be furnished until the plan or issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

(B) *Example.* The rules of this paragraph (a)(5)(i) are illustrated by the following example:

Example. (i) *Facts.* A group health plan covers employees and their dependents. The plan annually requests all employees to provide updated information regarding dependents, including the specific date on which an employee has a new dependent or on which a person ceases to be a dependent of the employee.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the standard in this paragraph (a)(5)(i) of this section that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent covered by the certificate, the procedures described in paragraph (c)(5) of this section may be used to demonstrate dependent status. In addition, these procedures may be used to demonstrate that a child was covered under any creditable coverage within 30 days after birth, adoption, or placement for adoption. See also §146.111(b), under which such a child cannot be subject to a preexisting condition exclusion.

(6) *Special certification rules*—(i) *Issuers.* Issuers of group and individual health insurance are required to provide certificates of any creditable coverage they provide in the group or individual health insurance market, even if the coverage is provided in connection with an entity or program that is not itself required to provide a certificate because it is not subject to the group market provisions of this part, part 7 of subtitle B of title I of ERISA, or chapter 100 of subtitle K of the Internal Revenue Code. This would include coverage provided in connection with any of the following:

(A) Creditable coverage described in sections 2701(c)(1)(G), (I) and (J) of the PHS Act (coverage under a State health benefits risk pool, a public health plan, and a health benefit plan under section 5(e) of the Peace Corps Act).

(B) Coverage subject to section 2722(a)(1)(B) of the PHS Act (requiring certificates by issuers offering health insurance coverage in connection with any group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program).

(C) Coverage subject to section 2743 of the PHS Act applicable to health insurance issuers in the individual market. (However, this section does not require a certificate to be provided with respect to short-term limited duration insurance, which is excluded from the definition of ''individual health insurance coverage'' in 45 CFR 144.103 that is not provided in connection with a group health plan, as described in paragraph (a)(6)(i)(B) of this section.)

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to this part, provide certificates consistent with the rules of this section, see section 2791(a)(3) of the PHS Act applicable to entities described in sections 2701(c)(1)(C), (D), (E), and (F) of the PHS Act (relating to Medicare, Medicaid, TRICARE, and Indian Health Service), section 2722(a)(1)(A) of the PHS Act applicable to non-Federal governmental plans generally, section 2721(b)(2)(C)(ii) of the PHS Act applicable to non-Federal governmental plans that elect to be excluded from the requirements of subparts 1 through 3 of part A of title XXVII of the PHS Act, and section 9805(a) of the Internal Revenue Code applicable to group health plans, which includes church plans (as defined in section 414(e) of the Internal Revenue Code).

(b) *Disclosure of coverage to a plan or issuer using the alternative method of counting creditable coverage*—(1) *In general.* After an individual provides a certificate of creditable coverage to a plan or issuer using the alternative method under §146.113(c), that plan or issuer (requesting entity) must request that the entity that issued the certificate (prior entity) disclose the information set forth in paragraph (b)(2) of this section. The prior entity is required to disclose this information promptly.

(2) *Information to be disclosed.* The prior entity is required to identify to the requesting entity the categories of benefits with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs in order to determine the individual's creditable coverage with respect to any such category.

(3) *Charge for providing information.* The prior entity may charge the requesting entity for the reasonable cost of disclosing such information.

(c) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *Purpose.* The rules in this paragraph (c) implement section 2701(c)(4) of the PHS Act, which permits individuals to demonstrate the duration of creditable coverage

through means other than certificates, and section 2701(e)(3) of the PHS Act, which requires the Secretary to establish rules designed to prevent an individual's subsequent coverage under a group health plan or health insurance coverage from being adversely affected by an entity's failure to provide a certificate with respect to that individual.

(2) *In general.* If the accuracy of a certificate is contested or a certificate is unavailable when needed by an individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make such a demonstration when—

(i) An entity has failed to provide a certificate within the required time;

(ii) The individual has creditable coverage provided by an entity that is not required to provide a certificate of the coverage pursuant to paragraph (a) of this section;

(iii) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan; or

(iv) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(3) *Evidence of creditable coverage*—(i) *Consideration of evidence*—(A) A plan or issuer is required to take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether an individual has creditable coverage. A plan or issuer shall treat the individual as having furnished a certificate under paragraph (a) of this section if—

(*1*) The individual attests to the period of creditable coverage;

(*2*) The individual also presents relevant corroborating evidence of some creditable coverage during the period; and

(*3*) The individual cooperates with the plan's or issuer's efforts to verify the individual's coverage.

(B) For purposes of this paragraph (c)(3)(i), cooperation includes providing (upon the plan's or issuer's request) a written authorization for the plan or issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While a plan or issuer may refuse to credit coverage where the individual fails to cooperate with the plan's or issuer's efforts to verify coverage, the plan or issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that corroborate creditable coverage (and waiting or affiliation periods) include explanations of benefits (EOBs) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting or affiliation periods) may also be corroborated through means other than documentation, such as by a telephone call from the plan or provider to a third party verifying creditable coverage.

(iv) *Example.* The rules of this paragraph (c)(3) are illustrated by the following example:

Example. (i) *Facts.* Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. *X*'s group health plan imposes a preexisting condition exclusion of 12 months on new enrollees under the plan and uses the standard method of determining creditable coverage. *F* fails to receive a certificate of prior coverage from the self-insured group health plan maintained by *F*'s prior employer, *W*, and requests a certificate. However, *F* (and *X*'s plan, on *F*'s behalf and with *F*'s cooperation) is unable to obtain a certificate from *W*'s plan. *F* attests that, to the best of *F*'s knowledge, *F* had at least 12 months of continuous coverage under *W*'s plan, and that the coverage ended no earlier than *F*'s termination of employment from *W*. In addition, *F* presents evidence of coverage, such as an explanation of benefits for a claim that was made during the relevant period.

(ii) *Conclusion.* In this *Example*, based solely on these facts, *F* has demonstrated creditable coverage for the 12 months of coverage

under *W*'s plan in the same manner as if *F* had presented a written certificate of creditable coverage.

(4) *Demonstrating categories of creditable coverage.* Procedures similar to those described in this paragraph (c) apply in order to determine the duration of an individual's creditable coverage with respect to any category under paragraph (b) of this section (relating to determining creditable coverage under the alternative method).

(5) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the group health plan or issuer is required to treat the individual as having furnished a certificate showing the dependent status if the individual attests to such dependency and the period of such status and the individual cooperates with the plan's or issuer's efforts to verify the dependent status.

[69 FR 78790, Dec. 30, 2004, as amended at 75 FR 27138, May 13, 2010]

§ 146.117 Special enrollment periods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

They then lose eligibility for coverage under *Q*.

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

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

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

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

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

(3) *Conditions for special enrollment*—(i) *Loss of eligibility for coverage.* In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(i) are satisfied at the time the coverage is terminated as a result of loss of eligibility (regardless of whether the individual is eligible for or elects COBRA continuation coverage). Loss of eligibility under this paragraph (a)(3)(i) does not include a loss due to the failure of the employee or dependent to pay premiums on a timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). Loss of eligibility for coverage under this paragraph (a)(3)(i) includes (but is not limited to)—

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

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

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

(D) A situation in which an individual incurs a claim that would meet or exceed a lifetime limit on all benefits; and

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

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

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

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

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

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

(ii) *Conclusion.* In this *Example 1*, employer contributions towards *D*'s coverage ceased on January 1 and the conditions of paragraph (a)(3)(ii) of this section are satisfied on this date (regardless of whether *D* elects to pay the total cost and continue coverage under *Y*'s plan).

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

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

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

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

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

(a)(3)(i)(D) of this section (relating to loss of eligibility for coverage due to the operation of a lifetime limit on all benefits), a plan or issuer must allow an employee a period of at least 30 days after a claim is denied due to the operation of a lifetime limit on all benefits.

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

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

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

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

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

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

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

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

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

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

(iv) *Dependent of a participant only.* An individual is described in this paragraph (b)(2)(iv) if the individual is a dependent (as defined in §144.103 of this chapter) of a participant and the individual has become a dependent of the participant through marriage, birth, adoption, or placement for adoption.

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

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

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

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

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

(B) *Birth, adoption, or placement for adoption.* Coverage must begin in the case of a dependent's birth on the date

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

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

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

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

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

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

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

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

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance or group health plan coverage, you may be able to enroll yourself and your dependents in this plan if you or your dependents lose eligibility for that other coverage (or if the employer stops contributing towards your or your dependents' other coverage). However, you must request enrollment within [insert ''30 days'' or any longer period that applies under the plan] after your or your dependents' other coverage ends (or after the employer stops contributing toward the other coverage).

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

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

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

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

(2) Special enrollees must be offered all the benefit packages available to similarly situated individuals who enroll when first eligible. For this purpose, any difference in benefits or cost-

sharing requirements for different individuals constitutes a different benefit package. In addition, a special enrollee cannot be required to pay more for coverage than a similarly situated individual who enrolls in the same coverage when first eligible. The length of any preexisting condition exclusion that may be applied to a special enrollee cannot exceed the length of any preexisting condition exclusion that is applied to similarly situated individuals who enroll when first eligible. For rules prohibiting the application of a preexisting condition exclusion to certain newborns, adopted children, and children placed for adoption, see §146.111(b).

(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]

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

(a) *In general.* A group health plan offering health insurance coverage through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, may impose an affiliation period only if each of the following requirements is satisfied—

(1) No preexisting condition exclusion is imposed with respect to any coverage offered by the HMO in connection with the particular group health plan.

(2) No premium is charged to a participant or beneficiary for the affiliation period.

(3) The affiliation period for the HMO coverage is imposed consistent with the requirements of §146.121 (prohibiting discrimination based on a health factor).

(4) The affiliation period does not exceed 2 months (or 3 months in the case of a late enrollee).

(5) The affiliation period begins on the enrollment date, or in the case of a late enrollee, the affiliation period begins on the day that would be the first day of coverage but for the affiliation period.

(6) The affiliation period for enrollment in the HMO under a plan runs concurrently with any waiting period.

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

Example 1. (i) *Facts.* An employer sponsors a group health plan. Benefits under the plan are provided through an HMO, which imposes a two-month affiliation period. In order to be eligible under the plan, employees must have worked for the employer for six months. Individual *A* begins working for the employer on February 1.

(ii) *Conclusion.* In this *Example 1,* Individual *A*'s enrollment date is February 1 (see §146.111(a)(2)), and both the waiting period and the affiliation period begin on this date and run concurrently. Therefore, the affiliation period ends on March 31, the waiting period ends on July 31, and *A* is eligible to have coverage begin on August 1.

Example 2. (i) *Facts.* A group health plan has two benefit package options, a fee-for-service option and an HMO option. The HMO imposes a 1-month affiliation period. Individual *B* is enrolled in the fee-for-service option for more than one month and then decides to switch to the HMO option at open season.

(ii) *Conclusion.* In this *Example 2*, the HMO may not impose the affiliation period with respect to *B* because any affiliation period would have to begin on *B*'s enrollment date in the plan rather than the date that *B* enrolled in the HMO option. Therefore, the affiliation period would have expired before *B* switched to the HMO option.

Example 3. (i) *Facts.* An employer sponsors a group health plan that provides benefits through an HMO. The plan imposes a two-month affiliation period with respect to salaried employees, but it does not impose an affiliation period with respect to hourly employees.

(ii) *Conclusion.* In this *Example 3*, the plan may impose the affiliation period with respect to salaried employees without imposing any affiliation period with respect to hourly employees (unless, under the circumstances, treating salaried and hourly employees differently does not comply with the requirements of §146.121).

(c) *Alternatives to affiliation period.* An HMO may use alternative methods in lieu of an affiliation period to address adverse selection, as approved by the State insurance commissioner or other official designated to regulate HMOs. However, an arrangement that is in the nature of a preexisting condition exclusion cannot be an alternative to an affiliation period. Nothing in this part requires a State to receive proposals for or approve alternatives to affiliation periods.

[69 FR 78797, Dec. 30, 2004]

§ 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*—(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 (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

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

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

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

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

(G) Continued eligibility; and

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

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

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

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

more health factors and thus violates this paragraph (b)(1).

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

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

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

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

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

(ii) *Conclusion.* In this *Example 4,* the issuer's exclusion of A and A's dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

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

(B) However, benefits provided under a plan or through group health insurance coverage 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 or issuer may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may impose annual, lifetime, or other limits on benefits and 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 any other provision of ERISA, 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 $500,000 lifetime limit on all benefits 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 $500,000 of benefits are 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 $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000 lifetime limit 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. (This example does not address whether the plan provision is permissible under the Americans with Disabilities Act or any other applicable law.)

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

(ii) *Conclusion.* In this *Example 5*, the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

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.

Example 8. (i) *Facts.* An employer sponsors a group health plan that is available to all current employees. Under the plan, the medical care expenses of each employee (and the employee's dependents) are reimbursed up to an annual maximum amount. The maximum reimbursement amount with respect to an employee for a year is $1500 multiplied by the number of years the employee has participated in the plan, reduced by the total reimbursements for prior years.

(ii) *Conclusion.* In this *Example 8*, the variable annual limit does not violate this paragraph (b)(2)(i). Although the maximum reimbursement amount for a year varies among employees within the same group of similarly situated individuals based on prior claims experience, employees who have participated in the plan for the same length of time are eligible for the same total benefit over that length of time (and the restriction on the maximum reimbursement amount is not directed at any individual participants or beneficiaries based on any health factor).

(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.)

(3) *Relationship to §146.111.* (i) A preexisting condition exclusion is permitted under this section if it —

(A) Complies with §146.111;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or

beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion 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.

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

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with §146.111. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with §146.111 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2*, the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

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

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

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

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

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

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage

from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

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

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

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

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

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

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

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

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

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

(C) Marital status;

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

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

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

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

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

Example 1. (i) *Facts.* An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's usual business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

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

Example 2. (i) *Facts.* Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 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 dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent 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 dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 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 lower lifetime dollar limit than in the benefit package made available to the other six employees.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

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

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

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

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

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

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

(f) *Wellness programs.* A wellness program is any program designed to promote health or prevent disease. 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). 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, paragraph (f)(1) of this section clarifies that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If any 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, the wellness program does not violate this section if the requirements of paragraph (f)(2) of this section are met.

(1) *Wellness programs not subject to requirements.* If none of the conditions for obtaining a reward under a wellness program are 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 does not violate this section, if participation in the program is made available to all similarly situated individuals. Thus, for example, the following programs need not satisfy the requirements of paragraph (f)(2) of this section, if participation in the program is made available to all similarly situated individuals:

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

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

(iii) 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.

(iv) A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly health education seminar.

(2) *Wellness programs subject to requirements.* If any 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, the wellness program does not violate this section if the requirements of this paragraph (f)(2) are met.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed 20 percent of the 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 20 percent of the cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(2), the cost of coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.

(ii) 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.

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

(iv) The reward under the program must be available to all similarly situated individuals. (A) A reward is not available to all similarly situated individuals for a period unless the program allows —

(1) 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) 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) A plan or issuer may seek verification, such as a statement from an individual's physician, that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(v)(A) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under paragraph (f)(2)(iv) of this section. However, if plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the requirement of this paragraph (f)(2)(v): ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 3, 4, and 5 of paragraph (f)(3) of this section.

(3) *Examples.* The rules of paragraph (f)(2) of this section 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 $3,600 (of which the employer pays $2,700 per year and the employee pays $900 per year). The annual premium for family coverage is $9,000 (of which the employer pays $4,500 per year and the employee pays $4,500 per year). The plan offers a wellness program with an annual premium rebate of $360. The program is available only to employees.

(ii) *Conclusion.* In this *Example 1*, the program satisfies the requirements of paragraph (f)(2)(i) of this section because the reward for the wellness program, $360, does not exceed 20 percent of the total annual cost of employee-only coverage, $720. ($3,600 × 20% = $720.) If any class of dependents is allowed to participate in the program and the employee is enrolled in family coverage, the plan could offer the employee a reward of up to 20 percent of the cost of family coverage, $1,800. ($9,000 × 20% = $1,800.)

Example 2. (i) *Facts.* A group health plan gives an annual premium discount of 20 percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion.* In this *Example 2*,the program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard or waive the cholesterol standard. (In addition, plan materials describing the program are required to disclose the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) for obtaining the premium discount. Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that the plan provides that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count) within a 60-day period, the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* begins a diet and exercise program but is unable to achieve a cholesterol count under 200 within the prescribed period. D's doctor determines D requires prescription medication to achieve a medically advisable cholesterol count. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates *D* by making the discount available to *D*, but only if *D* follows the advice of D's doctor regarding medication and blood tests.

(ii) *Conclusion.* In this *Example 3*, the program is a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 4. (i) *Facts.* A group health plan will waive the $250 annual deductible (which is less than 20 percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable in the burden it imposes and is reasonable taking into consideration the individual's medical situation. All

plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived.'' Due to a medical condition, Individual E is unable to achieve a BMI of between 19 and 26 and is also unable to follow the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the discount available to *E* if *E* follows the physician's recommendations.

(ii) *Conclusion.* In this *Example 4*, the program satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 5. (i) *Facts.* In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is 20 percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *F* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *F* by requiring *F* to participate in a smoking cessation program to avoid the surcharge. *F* can avoid the surcharge for as long as *F* participates in the program, regardless of whether *F* stops smoking (as long as *F* continues to be addicted to nicotine).

(ii) *Conclusion.* In this *Example 5*, the premium surcharge is permissible as a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

Example 6. (i) *Facts.* Same facts as *Example 5*, except the plan accommodates *F* by requiring *F* to view, over a period of 12 months, a 12-hour video series on health problems associated with tobacco use. *F* can avoid the surcharge by complying with this requirement.

(ii) *Conclusion.* In this *Example 6*, the requirement to watch the series of video tapes is a reasonable alternative method for avoiding the surcharge.

(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 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1*, the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

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

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

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

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

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

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

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

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

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the PHS Act (including the COBRA continuation provisions) or any other State or Federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other Federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA

qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

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

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

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

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

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

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

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

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

Example 1. (i) *Facts.* Individual *D* was hired by a nonfederal governmental employer in June 1999. The employer maintains a self-funded group health plan with a plan year beginning on October 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section for the plan year beginning October 1, 2005, and renewed the exemption election for the plan year beginning October 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual could enroll effective October 1 of any plan year if the individual could pass a physical examination. The evidence-of-good-health requirement for late enrollees, absent an exemption election under §146.180 of this part, would have been in violation of this section. *D* chose not to enroll for coverage when first hired. In February of 2006, *D* was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 2006, because *D* assumed *D* could not meet the evidence-of-good-health requirement. With the plan year beginning October 1, 2007 the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. The plan notifies individual *D* (and all other employees) that it will be coming into compliance with the requirements of this section. The notice specifies that the effective date of compliance will be October 1, 2007, explains the applicable enrollment restrictions that will apply under the plan, states that individuals will have at least 30 days to enroll, and explains that coverage for those who choose to enroll will be effective as of October 1, 2007. Individual *D* timely requests enrollment in the plan, and coverage commences under the plan on October 1, 2007.

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

Example 2. (i) *Facts.* Individual *E* was hired by a nonfederal governmental employer in February 1999. The employer maintains a self-funded group health plan with a plan year beginning on September 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section and ''§146.111 (limitations on preexisting condition exclusion periods) for the plan year beginning September 1, 2002, and renews the exemption election for the plan years beginning September 1, 2003, September 1, 2004, September 1, 2005, and September 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declined to enroll when first eligible, the individual could enroll effective September 1 of any plan year if the individual could pass a physical examination. Also under the terms

of the plan, all enrollees were subject to a 12-month preexisting condition exclusion period, regardless of whether they had creditable coverage. *E* chose not to enroll for coverage when first hired. In June of 2006, *E* is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2007, the plan sponsor chooses to bring the plan into compliance with this section, but renews its exemption election with regard to limitations on preexisting condition exclusion periods. The plan notifies *E* of her opportunity to enroll, without a physical examination, effective September 1, 2007. The plan gives *E* 30 days to enroll. *E* is subject to a 12-month preexisting condition exclusion period with respect to any treatment *E* receives that is related to *E*'s MS, without regard to any prior creditable coverage *E* may have. Beginning September 1, 2008, the plan will cover treatment of *E*'s MS.

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

[71 FR 75046, Dec. 13, 2006, as amended at 74 FR 51688, Oct. 7, 2009]

§ 146.122 Additional requirements prohibiting discrimination based on genetic information.

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

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

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

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

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

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

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

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

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

(3) *Genetic information* means—

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

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

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

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

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

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

(iii) The term *genetic information* includes—

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

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

(4) *Genetic services* means —

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

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

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of

proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that Employee *A* has made claims for treatment of polycystic kidney disease. *A* also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both *A*'s claims experience and the family medical history of *A*'s children (that is, the fact that *A* has the disease).

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

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

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional

who is providing health care services to an individual to request that the individual undergo a genetic test.

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

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

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

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

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

(4) *Determination regarding payment.*

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

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

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

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

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

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

(A) Compliance with the request is voluntary; and

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

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

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

the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

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

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

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

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

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

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

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

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

(ii) *Incidental collection exception.*

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

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

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

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

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

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

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

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

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

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

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

Example 5. (i) *Facts.* A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

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

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

(ii) *Conclusion.* In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to

the question is not within the incidental collection exception and is prohibited under this paragraph (d).

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

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

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

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

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

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

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

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

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

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

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

payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C*.

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

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

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

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

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

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

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

[74 FR 51688, Oct. 7, 2009]

§ 146.125 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 determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

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

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital

stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1*, because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, a group health plan that provides benefits for hospital lengths of stay in connection with childbirth must meet the following requirements:

(1) *Required statement.* The plan document that provides a description of plan benefits to participants and beneficiaries, or that notifies participants and beneficiaries of plan benefit changes, must disclose information that notifies participants and beneficiaries of their rights under this section.

(2) *Disclosure notice.* To meet the disclosure requirement set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, group health plans and health insurance issuers offering group health insurance coverage generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the plan or issuer may pay for a shorter stay if the attending provider (*e.g.*, your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, plans and issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, a plan or issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up

to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your plan administrator.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to each participant covered under a group health plan, and each beneficiary receiving benefits under a group health plan, not later than 60 days after the first day of the first plan year beginning on or after January 1, 2009. Each time a plan distributes one or both of the documents described in paragraph (d)(1) to participants and beneficiaries after providing this initial notice, the disclosure notice in paragraph (d)(2) must appear in at least one of those documents.

(4) *Exceptions.* The requirements of this paragraph (d) do not apply in the following situations.

(i) *Self-insured plans that have already provided notice.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has already provided an initial notice that complies with paragraphs (d)(1) and (d)(2) of this section, the group health plan is not automatically required to provide another such notice to participants and beneficiaries who have been provided with the initial notice. However, following the effective date of these regulations, whenever such a plan provides one or both of the documents described in paragraph (d)(1) of this section to participants and beneficiaries, the disclosure notice in paragraph (d)(2) of this section must appear in at least one of those documents.

(ii) *Self-insured plans that have elected exemption from this section.* If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has made the election described in Sec. 146.180 to be exempted from the requirements of this section, the group health plan is not subject to this paragraph (d).

(iii) *Insured plans.* If benefits for hospital lengths of stay in connection with childbirth are provided through health insurance coverage, and the coverage is regulated under a State law described in paragraph (e) of this section, the group health plan is not subject to this paragraph (d).

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2725 of the PHS Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans.* For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section do not apply.

(ii) *Self-insured plans.* For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 2725 of the PHS Act and this section apply.

(iii) *Partially-insured plans.* For a group health plan that provides some

benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 2724 (a) of the PHS Act.* The preemption provisions contained in section 2724 (a)(1) of the PHS Act and Sec. 146.143(a) do not supersede a state law described in paragraph (e)(1) of this section.

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

Example 1. (i) *Facts.* A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion.* In this Example 1, the coverage is subject to state law, and the requirements of section 2725 of the PHS Act and this section do not apply.

Example 2. (i) *Facts.* A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion.* In this Example 2, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 2725 of the PHS Act and this section.

(f) *Applicability date.* Section 2725 of the PHS Act applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 1998. This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

[73 FR 62424, Oct. 20, 2008, as amended at 75 FR 27138, May 13, 2010]

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms.* For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but does not include mental health or substance use disorder benefits. Any condition defined by the plan 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 services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan 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 services for substance use disorders, as defined under the terms of the plan 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. (*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.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits*—(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)(6) 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) *Examples.* The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1,* each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) *Facts.* A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) *Conclusion.* In this *Example 2,* each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) *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.

(6) *Plan not described in paragraph (b)(2) or (b)(3) of this section*—(i) *In general.* A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(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)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) *Example.* The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/

surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40% of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60% of payments for medical/surgical benefits.

(ii) *Conclusion.* In this *Example,* the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% × $100,000 + 60% × $1,000,000 = $640,000).

(c) *Parity requirements with respect to financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits.* When reference is made in this paragraph (c) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) *Coverage unit.* When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) *General parity requirement*—(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) *Classifications of benefits used for applying rules*—(A) *In general.* If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided

in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. 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.

(*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.

(*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.

(*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, 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 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.

(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 rule for 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 nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) *Examples.* The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0%	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level.	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) *Conclusion.* In this *Example 1,* the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) *Facts.* For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments.	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x + $300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) *Conclusion.* In this *Example 2*, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels—the $50 copayment, the $20 copayment, and the $15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) *Facts.* A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3*, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) *Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as ''generic'', ''preferred brand name'', ''non-preferred brand name'', or ''specialty'' complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

Tier description	Tier 1	Tier 2	Tier 3	Tier 4
	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).

(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, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(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) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) 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); and

(F) Exclusions based on failure to complete a course of treatment.

(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 group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) *Conclusion.* In this *Example 1,* the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (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. 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 2,* 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, 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 3. (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 may differ based on clinically appropriate standards of care for a condition.

(ii) *Conclusion.* In this *Example 3,* the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation—medical appropriateness—is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, 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 4. (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 4,* 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 antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) *Facts.* An employer maintains both a major medical program 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 program 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 program.

(ii) *Conclusion.* In this *Example 5*, 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.

(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 denial.* The reason for any denial under a non-Federal governmental 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 within a reasonable time and in a reasonable manner by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary upon request. 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).

(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; or

(ii) 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.

(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. For purposes of this paragraph (f), the term *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 two but not more than 50 employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year (except that for purposes of this paragraph, a small employer shall include an employer with one employee in the case of an employer residing in a State that permits small groups to include a single individual). See also section 2721(a) of the PHS Act and §146.145(b) of this Part, which provide that this section (and certain other sections) does not apply to any group health plan (and health insurance issuer offering coverage in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(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 of 1986 (26 U.S.C. 414) 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* [Reserved]

(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, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(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 later of either—

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

[75 FR 5444, Feb. 2, 2010]

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—

(i) Shortens the period of time from the ''6-month period'' described in section 2701(a)(1) of the PHS Act and §146.111(a)(2)(i) (for purposes of identifying a preexisting condition);

(ii) Shortens the period of time from the ''12 months'' and ''18 months'' described in section 2701(a)(2) of the PHS Act and §146.111(a)(2)(ii) (for purposes of applying a preexisting condition exclusion period);

(iii) Provides for a greater number of days than the ''63-day period'' described in sections 2701(c)(2)(A) and (d)(4)(A) of the PHS Act and §§146.111(a)(2)(iii) and 146.113 (for purposes of applying the break in coverage rules);

(iv) Provides for a greater number of days than the ''30-day period'' described in sections 2701(b)(2) and (d)(1) of the PHS Act and §146.111(b) (for purposes of the enrollment period and preexisting condition exclusion periods for certain newborns and children that are adopted or placed for adoption);

(v) Prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) of the PHS Act or expands the exceptions described therein;

(vi) Requires special enrollment periods in addition to those required under section 2701(f) of the PHS Act; or

(vii) Reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B) of the PHS 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]

§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) *General exception for certain small group health plans.* The requirements of this part, other than §146.130 and the provisions with respect to genetic nondiscrimination (found in §146.111(b)(6), §146.121(b), §146.121(c), §146.121(e), §146.122(b), §146.122(c), §146.122(d), and §146.122(e)) do not apply to any group health plan (and group health insurance coverage) for any plan year, if on the first day of the plan year, the plan has fewer than two participants who are current employees.

(c) *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 (c)(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 (c)(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 (c)(3)(v) of this section.

(ii) *Not an integral part of a group health plan.* For purposes of this paragraph (c)(3), benefits are not an integral part of a group health plan (whether the benefits are provided through the same plan or a separate plan) only if the following two requirements are satisfied—

(A) Participants must have the right to elect not to receive coverage for the benefits; and

(B) If a participant elects to receive coverage for the benefits, the participant must pay an additional premium or contribution for that coverage.

(iii) *Limited scope*—(A) *Dental benefits.* Limited scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth).

(B) *Vision benefits.* Limited scope vision benefits are benefits substantially all of which are for treatment of the eye.

(iv) *Long-term care.* Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(v) *Health flexible spending arrangements.* Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) are excepted for a class of participants only if they satisfy the following two requirements—

(A) Other group health plan coverage, not limited to excepted benefits, is made available for the year to the class of participants by reason of their employment; and

(B) The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement).

(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 (c)(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 (c)(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 (c)(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 (c)(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 (c)(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 (c)(5) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage for both active employees and retirees. The coverage for retirees supplements benefits provided by Medicare, but does not meet the requirements for a supplemental policy under section 1882(g)(1) of the Social Security Act.

(ii) *Conclusion.* In this *Example,* the coverage provided to retirees does not meet the definition of supplemental excepted benefits under this paragraph (c)(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.

(d) *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 (d)) 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 (d)(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 (d)(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.

(e) *Determining the average number of employees.* [Reserved]

[69 FR 78798, Dec. 30, 2004, as amended at 74 FR 51692, Oct. 7, 2009]

Subpart E—Provisions Applicable to Only Health Insurance Issuers

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

(a) *Issuance of coverage in the small group market.* Subject to paragraphs (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State must—

(1) Offer, to any small employer in the State, all products that are approved for sale in the small group market and that the issuer is actively marketing, and must accept any employer that applies for any of those products; and

(2) Accept for enrollment under the coverage every eligible individual (as defined in paragraph (b) of this section) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan, or during a special enrollment period, and may not impose any restriction on an eligible individual's being a participant or beneficiary, which is inconsistent with the nondiscrimination provisions of § 146.121.

(b) *Eligible individual defined.* For purposes of this section, the term ''eligible individual'' means an individual who is eligible—

(1) To enroll in group health insurance coverage offered to a group health plan maintained by a small employer, in accordance with the terms of the group health plan;

(2) For coverage under the rules of the health insurance issuer which are uniformly applicable in the State to small employers in the small group market; and

(3) For coverage in accordance with all applicable State laws governing the issuer and the small group market.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(i) Limit the employers that may apply for the coverage to those with eligible individuals who live, work, or reside in the service area for the network plan; and

(ii) Within the service area of the plan, deny coverage to employers if the issuer has demonstrated to the applicable State authority (if required by the State authority) that—

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees; and

(B) It is applying this paragraph (c)(1) uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies health insurance coverage to an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the small group market within the service area to any employer for a period of 180 days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable State authority (if required by the State authority) that it—

(i) Does not have the financial reserves necessary to underwrite additional coverage; and

(ii) Is applying this paragraph (d)(1) uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies group health insurance coverage to any small employer in a State under paragraph (d)(1) of this section may not offer coverage in connection with group health plans

in the small group market in the State before the later of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable State authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Exception to requirement for failure to meet certain minimum participation or contribution rules.* (1) Paragraph (a) of this section does not preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) For purposes of paragraph (e)(1) of this section—

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) *Exception for coverage offered only to bona fide association members.* Paragraph (a) of this section does not apply to health insurance coverage offered by a health insurance issuer if that coverage is made available in the small group market only through one or more bona fide associations (as defined in 45 CFR 144.103).

(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 plan.* The issuer is ceasing to offer coverage in the market in accordance with paragraphs (c) and (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c).

(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 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.* 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—

(1) Large group market; and

(2) 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.

(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.

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[62 FR 16958, Apr. 8, 1997; 62 FR 31670, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See §146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

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[62 FR 16958, Apr. 8, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart F—Exclusion of Plans and Enforcement

§146.180 Treatment of non-Federal governmental plans.

(a) *Requirements subject to exemption—*(1) *Basic rule.* A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), from any or all of the following requirements:

(i) Limitations on preexisting condition exclusion periods described in §146.111.

(ii) Special enrollment periods for individuals and dependents described in §146.117.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in §146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from the requirements in §146.121(a)(1)(vi) and §146.122 that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns described in §146.130.

(v) Parity in the application of certain limits to mental health benefits described in §146.136.

(vi) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2706 of the PHS Act.

(2) *Limitations.* (i) An election under this section cannot circumvent a requirement of this part 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 2706 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 2706 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) *Example 2.* An individual is hired by a non-Federal governmental employer and reports to work on August 6. The individual has diabetes. Under the terms of the plan in effect on August 6, if an individual files an enrollment application within the first 30 days of employment, enrollment in the plan is effective as of the first day of employment. The individual timely files an enrollment application. The application is processed on September 10. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from §146.121, which prohibits enrollment discrimination based on health status-related factors, by requiring new enrollees to pass medical underwriting. The plan cannot decline to enroll the individual effective August 6, even if he would not pass medical underwriting under the terms of the plan in effect on September 1.

(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.

(3) *Stop-loss or excess risk coverage.* For purposes of this section. (i) Subject to paragraph (a)(3)(ii), 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 of this part.

(4) *Construction.* Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election*—(1) *Election requirements.* The election must meet the following requirements:

(i) Be made in writing.

(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) 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.

(2) *''Term of the agreement'' defined.* Except as provided in paragraphs (b)(2)(i) and (b)(2)(ii), 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 of this part 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) *Mailing address.* The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Private Health Insurance Group, CMSO, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21244–1850.

(d) *Filing a timely election*—(1) *Plan not governed by collective bargaining.* Subject to paragraph (d)(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, 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) *Verifying timely filing.* CMS uses the postmark on the envelope in which the election is submitted to determine that the election is timely filed as specified under paragraphs (d)(1) or (d)(2) of this section, as applicable. 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.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (d)(1) and (d)(2) of this section for good cause if the plan substantially complies with the requirements of paragraph (f) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (d)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (d)(1) or (d)(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.

(e) *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.* 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 (e)(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 (e)(1) of this section.

(f) *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 this paragraph (f), 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 (f)(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 this paragraph (f) 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 (including a self-funded non-Federal governmental plan that has been exempted from requirements of this part under §146.125(a)(2)), 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.

(v) A statement informing plan enrollees that the plan provides for certification and disclosure of creditable coverage for covered employees and their dependents who lose coverage under the plan.

(g) *Subsequent elections*—(1) *Election renewal.* A plan sponsor may renew an

election under this section through subsequent elections. The timeliness standards described in paragraph (d) apply to election renewals under this paragraph (g).

(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 (b)(1)(viii), the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (f) 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) 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 (f)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) 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)) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (f)(1), and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (d)(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 (d)(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.

(h) *Requirements not subject to exemption.*

(1) *Certification and disclosure of creditable coverage.* Without regard to an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents as specified under §146.115 of this part.

(2) *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 of this part, the exemption election must not be construed to exempt the plan from any provisions of this part 146 that pertain to genetic information.

(3) *Enforcement.* CMS enforces these requirements as provided under paragraph (k) of this section.

(4) *Examples.*

(i)

Example 1. (A) Individual *A* is hired by a county that has elected to exempt its self-funded group health plan from certain requirements of paragraph (a)(1) of this section, including prohibitions against enrollment discrimination based on health status-related factors. Individual *A* applies for enrollment in the county's group health plan. Applicants must pass medical underwriting before being allowed to enroll in the plan. The plan requires an applicant to complete a medical history form and to authorize the plan to contact physicians regarding any medical treatments the applicant has received in the past 5 years. Individual *A* has Type 2 diabetes. He submits the required form, which reflects that condition. The plan also receives information from Individual *A*'s physicians. While the plan's request to Individual *A's* physicians did not include a request for genetic information, the plan received information from a physician in response to its request for health information about Individual *A*, that one of Individual *A*'s parents has Huntington's Disease. The Plan denies enrollment to Individual *A*.

(B) Individual *A* files a complaint with CMS that he has been denied enrollment in the plan because of genetic information the plan received. CMS investigates the complaint and determines that the plan uniformly denies enrollment to anyone who has Type II diabetes. CMS resolves the complaint in favor of the plan on the basis that the plan permissibly denied enrollment to Individual *A* under its exemption election because of the existence of a medical condition that uniformly disqualifies individuals from participating in the plan.

(ii)

Example 2. (A) Same facts as in *Example 1*, except Individual *A* does not have diabetes or any other preexisting medical condition; that is, there is no manifestation of a disease

or disorder with respect to Individual *A* at the time of his application for enrollment in the county's group health plan.

(B) In these circumstances, CMS resolves the complaint in favor of Individual *A* because CMS determines that the plan impermissibly denied enrollment to Individual *A* on the basis of genetic information. CMS instructs the plan to permit Individual *A* to enroll in the plan retroactive to the earliest date coverage would be effective under the terms of the plan based on the date of Individual *A*'s enrollment application or hire, as applicable. CMS may impose a civil money penalty, as determined under subpart C of part 150.

(i) *Effect of failure to comply with certification and notification requirements*—(1) *Substantial failure.* (i) *General rule.* Except as provided in paragraph (i)(1)(iii) of this section, a substantial failure to comply with paragraphs (f) or (h)(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 (f) or paragraph (h)(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 paragraphs (f) or (h)(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 (f) 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 (f) 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:* Same facts as in Example 1, except the noncompliant school district failed to notify any enrollees regarding an election under this section. That is, the school district failed to provide the annual notice to current plan enrollees as well as the notice at the time of enrollment to new enrollees. The school district has substantially failed to comply with the requirements of paragraph (f) of this section. At a minimum, the election is invalidated with respect to all enrollees

of the noncompliant school district for the plan year for which the substantial failure has occurred. In this example, the plan decides not to cancel its election entirely. The election with regard to the other nine school districts remains in effect.

(iii) *Example 3.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (f) 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.

(iv) *Example 4:* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from certain requirements of this part. The collective bargaining agreement applies to five plan years, 2001 through 2005. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2001 through December 31, 2005. Prior to the dissemination of the annual notice for the 2004 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2001 through December 31, 2005. Accordingly, CMS would not invalidate the election for the 2004 plan year.

(v) *Example 5:* A non-Federal governmental employer has elected to exempt its self-funded plan from certain requirements of this part. An individual terminates employment with the governmental employer, which fails to automatically provide a certificate of creditable coverage within the period specified in §146.115(a)(2)(ii)(A). (The governmental employer generally provides certificates to terminated employees on an automatic basis, but neglected to do so in this case.) The oversight is brought to the employer's attention when the individual inquires as to why he has not received his certificate of creditable coverage. The governmental employer promptly (within 30 days) forwards a certificate to the individual. CMS would not view that situation as constituting a substantial failure and would not invalidate the election under this section.

(j) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and states the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (d)(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.

(k) *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.

(l) *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.

[67 FR 48811, July 26, 2002, as amended at 74 FR 51693, Oct. 7, 2009]

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

Sec.

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.

§147.108 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 enrolling 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]

§147.120 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, 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 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 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 eligible 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.

(ii) *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 written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect; 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 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, 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 deductible) with respect to those items or 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 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, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(A) In developing the binding health plan coverage guidelines specified in this paragraph (a)(1)(iv), the Health Resources and Services Administration shall be informed by evidence and may establish exemptions from such guidelines with respect to group health plans established or maintained by religious employers and health insurance coverage provided in connection with group health plans established or maintained by religious employers with respect to any requirement to cover contraceptive services under such guidelines.

(B) For purposes of this subsection, a ''religious employer'' is an organization that meets all of the following criteria:

(*1*) The inculcation of religious values is the purpose of the organization.

(*2*) The organization primarily employs persons who share the religious tenets of the organization.

(*3*) The organization serves primarily persons who share the religious tenets of the organization.

(*4*) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* 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.

(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 recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *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.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(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; 76 FR 46626, Aug. 3, 2011]

§ 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.

(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 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. Accordingly, 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;

(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]

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *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 accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider.

You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount 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 *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section 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 patient protections do not apply to grandfathered health plans).

[75 FR 37238, 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 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 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 contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *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 condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2,* the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered 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 ÷ 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 ÷ 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 ÷ 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 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 ($5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* 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 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 ÷ 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 ÷ 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 × 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) 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 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 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 subsequent 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]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

Subpart A—General Provisions

Sec.

AUTHORITY: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–41 through 300gg–63, 300gg–91, and 300gg–92).

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

Subpart A—General Provisions

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain eligible individuals who previously had group coverage, and 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.

[63 FR 57561, Oct. 27, 1998, as amended at 74 FR 51693, Oct. 7, 2009]

§ 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) 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. In some cases, coverage that may be considered group coverage under State law (such as coverage sold through certain associations) is considered individual coverage.

(2) The requirements of this part that pertain to guaranteed availability of individual health insurance coverage for certain eligible individuals apply to all issuers of individual health insurance coverage in a State, unless the State implements an acceptable alternative mechanism as described in §148.128. 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, regardless of whether a State implements an alternative mechanism under §148.128 of this part.

(b) *Effective date.* Except as provided in §148.124 (certificate of creditable coverage), §148.128 (alternative State mechanisms), §148.170 (standards relating to benefits for mothers and newborns), and §148.180 (prohibition of health discrimination based on genetic information) of this part, 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,

regardless of when a period of creditable coverage occurs.

[62 FR 16995, Apr. 8, 1997; 62 FR 31695, June 10, 1997, as amended at 63 FR 57562, Oct. 27, 1998; 74 FR 51693, Oct. 7, 2009]

§ 148.103 Definitions.

Unless otherwise provided, the following definition applies:

Eligible individual means an individual who meets the following conditions:

(1) The individual has at least 18 months of creditable coverage (as determined under §146.113 of this subchapter) as of the date on which the individual seeks coverage under this part.

(2) The individual's most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any of these plans).

(3) The individual is not eligible for coverage under any of the following:

(i) A group health plan.

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

(iii) A State plan under Title XIX (Medicaid) of the Social Security Act (or any successor program).

(4) The individual does not have other health insurance coverage.

(5) The individual's most recent coverage was not terminated because of nonpayment of premiums or fraud. (For more information about nonpayment of premiums or fraud, see §146.152(b)(1) and (b)(2) of this subchapter.)

(6) If the individual has been offered the option of continuing coverage under a COBRA continuation provision or a similar State program, the individual has both elected and exhausted the continuation coverage.

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.

(a) *General rule.* Except as provided for in paragraph (c) of this section, an issuer that furnishes health insurance coverage in the individual market must meet the following requirements with respect to any eligible individual who requests coverage:

(1) May not decline to offer coverage or deny enrollment under any policy forms that it actively markets in the individual market, except as permitted in paragraph (c) of this section concerning alternative coverage when no State mechanism exists. An issuer is deemed to meet this requirement if, upon the request of an eligible individual, it acts promptly to do the following:

(i) Provide information about all available coverage options.

(ii) Enroll the individual in any coverage option the individual selects.

(2) May not impose any preexisting condition exclusion on the individual.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply to health insurance coverage offered in the individual market in a State that chooses to implement an acceptable alternative mechanism described in §148.128.

(c) *Alternative coverage permitted where no State mechanism exists*—(1) *General rule.* If the State does not implement an acceptable alternative mechanism under §148.128, an issuer may elect to limit the coverage required under paragraph (a) of this section if it offers eligible individuals at least two policy forms that meet the following requirements:

(i) Each policy form must be designed for, made generally available to, and actively marketed to, and enroll, both eligible and other individuals.

(ii) The policy forms must be either the issuer's two most popular policy forms (as described in paragraph (c)(2) of this section) or representative samples of individual health insurance offered by the issuer in the State (as described in paragraph (c)(3) of this section).

(2) *Most popular policies.* The *two most popular policy forms* means the policy forms with the largest, and the second largest, premium volume for the last reporting year, for policies offered in that State. In the absence of applicable State standards, *premium volume* means earned premiums for the last reporting year. In the absence of applicable State

standards, the last reporting year is the period from October 1 through September 30 of the preceding year. Blocks of business closed under applicable State law are not included in calculating premium volume.

(3) *Representative policy forms*—(i) *Definition of weighted average.* Weighted average means the average actuarial value of the benefits provided by all the health insurance coverage issued by one of the following:

(A) An issuer in the individual market in a State during the previous calendar year, weighted by enrollment for each policy form, but not including coverage issued to eligible individuals.

(B) All issuers in the individual market in a State if the data are available for the previous calendar year, weighted by enrollment for each policy form.

(ii) *Requirements.* The two representative policy forms must meet the following requirements:

(A) Include a lower-level coverage policy form under which the actuarial value of benefits under the coverage is at least 85 percent but not greater than 100 percent of the weighted average.

(B) Include a higher-level coverage policy form under which the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the lower-level coverage policy form offered by an issuer in that State and at least 100 percent, but not greater than 120 percent, of the weighted average.

(C) Include benefits substantially similar to other individual health insurance coverage offered by the issuer in the State.

(D) Provide for risk adjustment, risk spreading, or a risk spreading mechanism, or otherwise provide some financial subsidization for eligible individuals.

(E) Meet all applicable State requirements.

(iii) *Actuarial value of benefits.* The actuarial value of benefits provided under individual health insurance coverage must be calculated based on a standardized population, and a set of standardized utilization and cost factors under applicable State law.

(4) *Election.* All issuer elections must be applied uniformly to all eligible individuals in the State and must be effective for all policies offered during a period of at least 2 years.

(5) *Documentation.* The issuer must document the actuarial calculations it makes as follows:

(i) *Enforcement by State.* In a State that elects to enforce the provisions of this section in lieu of an alternative mechanism under §148.128, the issuer must provide the appropriate State authorities with the documentation required by the State.

(ii) *Enforcement by CMS.* If CMS acts to enforce the provisions of this section under part 150, the issuer must provide to CMS, within the following time frames, any documentation CMS requests:

(A) For policy forms already being marketed as of July 1, 1997—no later than September 1, 1997.

(B) For other policy forms—90 days before the beginning of the calendar year in which the issuer wants to market the policy form.

(d) *Special rules for network plans.* (1) An issuer that offers coverage in the individual market through a network plan may take the following actions:

(i) Specify that an eligible individual may only enroll if he or she lives, resides, or works within the service area for the network plan.

(ii) Deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(A) It does not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to provide services to current group contract holders and enrollees, and to current individual enrollees.

(B) It uniformly denies coverage to individuals without regard to any health status-related factor, and without regard to whether the individuals are eligible individuals.

(iii) Not offer any coverage in the individual market, within the service area identified for purposes of paragraph (d)(1)(ii) of this section, for a period of 180 days after the coverage is denied.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with part 150, the issuer must make the

demonstration described in paragraph (d)(1)(ii) of this section to CMS rather than to the State, and the issuer may not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(e) *Application of financial capacity limits.* (1) An issuer may deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(i) It does not have the financial reserves necessary to underwrite additional coverage.

(ii) It uniformly denies coverage to all individuals in the individual market, consistent with applicable State law, without regard to any health status-related factor of the individuals, and without regard to whether the individuals are eligible individuals.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with part 150, the issuer must make the demonstration described in paragraph (e)(1) of this section to CMS rather than to the State, and the issuer may not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(3) An issuer that denies coverage in any service area according to paragraph (e)(1) of this section is prohibited from offering that coverage in the individual market for a period of 180 days after the later of the date—

(i) The coverage is denied; or

(ii) 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.

(4) A State may apply the 180-day suspension described in paragraph (e)(3) of this section on a service-area-specific basis.

(f) *Rules for dependents*—(1) *General rule.* Except as prohibited by §148.180, if an eligible individual elects to enroll in individual health insurance coverage that provides coverage for dependents, the issuer may apply a preexisting condition exclusion on any dependent who is not an eligible individual.

(2) *Exception for certain children.* A child is deemed to be an eligible individual if the following conditions are met:

(i) The child was covered under any creditable coverage within 30 days of birth, adoption, or placement for adoption (or longer if the State provides for a longer special enrollment period than required under §146.117(a)(6) of this subchapter).

(ii) The child has not had a significant break in coverage.

(3) *Examples.* The following examples illustrate the requirements of this paragraph (f) for certain children:

Example 1: Individual *A* had self-only coverage under his employer's group health plan for five years. *A* has two children, ages 11 and 15, but never enrolled in family coverage. *A* leaves his job to become self-employed, and qualifies as an eligible individual because he is not entitled to any continuation coverage, Medicare or Medicaid, and has no other health insurance coverage. He applies to Issuer *R* for coverage in the individual market under a policy with family coverage that *R* makes available to eligible individuals. *R* must sell *A* the policy, but he may refuse coverage to *A*'s children, or may apply a preexisting condition exclusion to them if allowed under applicable State law, because they did not have prior creditable coverage, and therefore do not qualify as eligible individuals.

Example 2: Individual *B* was also covered under a group health plan for 5 years before losing his job. He originally had coverage only for himself and his wife, but 3 months before his employment ended, his wife had a baby. *B* took advantage of the special enrollment period that applied, changed to family coverage, and enrolled the baby in the group health plan within 20 days. Immediately after losing his job, *B* applied to Issuer *R* for family coverage. *B* and his wife qualify as eligible individuals, and the baby is deemed to be an eligible individual even though she has less than 3 months of creditable coverage. Therefore *R* must make the policy available to all three members of the family, and cannot impose any preexisting condition exclusions.

(g) *Clarification of applicability.* (1) An issuer in the individual market is not required to offer a family coverage option with any policy form.

(2) An issuer offering health insurance coverage only in connection with group health plans, or only through one or more bona fide associations, or both, is not required to offer that type of coverage in the individual market.

(3) An issuer offering health insurance coverage in connection with a group health plan is not deemed to be a health insurance issuer offering individual health insurance coverage solely because the issuer offers a conversion policy.

(4) Except as prohibited by §148.180, this section does not restrict the amount of the premium rates that an issuer may charge an individual under State law for health insurance coverage provided in the individual market.

(5) This section does not prevent an issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates, or modifying otherwise applicable copayments or deductibles, in return for adherence to programs of health promotion and disease prevention.

(6) This section does not require issuers to reopen blocks of business closed under applicable State law.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16996, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 74 FR 51693, Oct. 7, 2009]

§ 148.122 Guaranteed renewability of individual health insurance coverage.

(a) *Applicability*. This section applies to all health insurance coverage in the individual market.

(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 plan*. The issuer is ceasing to offer coverage in the individual market in accordance with paragraphs (d) and (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.

(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 to each individual provided coverage of that type of health insurance at least 90 days before the date the coverage will be discontinued.

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(e) *Discontinuing all coverage*. An issuer may discontinue offering all health insurance coverage in the individual market in a State only if it meets the following requirements.

(1) Provides notice in writing to the applicable State authority and to each individual of the discontinuation at

least 180 days before the date the coverage will expire.

(2) Discontinues and does not renew all health insurance policies it issues or delivers for issuance in the State in the individual market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(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.* An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a policy form offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that policy form.

(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.

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[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 148.124 Certification and disclosure of coverage.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to all issuers of health insurance coverage.

(2) *Exception.* The provisions of this section do not apply to issuers of the following types of coverage:

(i) Health insurance coverage furnished in connection with a group health plan defined in §144.103 of this subchapter. (These issuers are required under §146.115 of this subchapter to provide a certificate of coverage.)

(ii) Excepted benefits described in §148.220.

(iii) Short-term, limited duration coverage defined in §144.103 of this subchapter.

(b) *General rules*—(1) *Individuals for whom a certificate must be provided; timing of issuance.* A certificate must be provided, without charge, for individuals and dependents who are or were covered under an individual health insurance policy as follows:

(i) *Issuance of automatic certificates.* An automatic certificate must be provided within a reasonable time period consistent with State law after the individual ceases to be covered under the policy.

(ii) *Any individual upon request.* Requests for certificates may be made by, or on behalf of, an individual within 24 months after coverage ends. For example, an entity that provides coverage to an individual in the future may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from the issuer of the individual's prior coverage. After the request is received, an issuer must provide the certificate by the earliest date the issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate must be provided under this paragraph even if the individual has previously received a certificate under this paragraph (b)(1)(ii) or an automatic certificate under paragraph (a)(l)(i) of this section.

(2) *Form and content of certificate*—(i) *Written certificate*—(A) *General rule.* Except as provided in paragraph (b)(2)(i)(B) of this section, the issuer must provide the certificate in writing (including any form approved by CMS).

(B) *Other permissible forms.* No written certificate must be provided if all of the following occur:

(*1*) An individual is entitled to receive a certificate.

(*2*) The individual requests that the certificate be sent to another plan or issuer instead of to the individual.

(*3*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in paragraph (a)(3) of this section through means other than a written certificate (for example, by telephone).

(*4*) The receiving plan or issuer receives the information from the sending issuer in the prescribed form within the time periods required under paragraph (b)(1) of this section.

(ii) *Required information.* The certificate must include the following:

(A) The date the certificate is issued.

(B) The name of the individual or dependent for whom the certificate applies, and any other information necessary for the issuer providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the policy and the name of the policyholder if the certificate is for (or includes) a dependent.

(C) The name, address, and telephone number of the issuer required to provide the certificate.

(D) The telephone number to call for further information regarding the certificate (if different from paragraph (b)(2)(ii)(C) of this section).

(E) Either one of the following:

(*1*) A statement that the individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage as defined in §146.113(b)(2)(iii) of this subchapter.

(*2*) Both the date the individual first sought coverage, as evidenced by a substantially complete application, and the date creditable coverage began.

(F) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate.

(iii) *Periods of coverage under a certificate.* If an automatic certificate is provided under paragraph (b)(1)(i) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate under paragraph (b)(1)(ii) of this section, a certificate must be provided for each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be provided for each period of continuous coverage.

(iv) *Single certificate permitted for families.* An issuer may provide a single certificate for both an individual and the individual's dependents if it provides all the required information for each individual and dependent, and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (b)(2)(ii) of this section are satisfied if the issuer provides a certificate in accordance with a model certificate as provided by CMS.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §148.220. If excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (c) of this section.

(3) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided, without charge, to each individual described in paragraph (b)(1) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the individual and the individual's spouse at the individual's last known address, the requirements of this paragraph (b)(3) are satisfied with respect to all individuals and dependents residing at that address. If a dependent's last known address is different than the individual's last known address, a separate certificate must be provided to the dependent at the dependent's last known address. If separate certificates are provided by mail to individuals and dependents who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* An issuer must establish a procedure for individuals and dependents to request and receive certificates under paragraph (b)(1)(ii) of this section.

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (b)(1)(i) of this section, and the individual or dependent entitled to receive the certificate designates another individual or entity

to receive the certificate, the issuer responsible for providing the certificate may provide the certificate to the designated party. If a certificate must be provided upon request under paragraph (b)(1)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the issuer responsible for providing the certificates must provide the certificate to the designated party.

(4) *Special rules concerning dependent coverage*—(i) *Reasonable efforts.* An issuer must use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. If an automatic certificate must be furnished with respect to a dependent under paragraph (b)(1)(i) of this section, no individual certificate must be furnished until the issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the policy.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by an issuer does not provide the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for demonstrating dependent status. An individual may, if necessary, use these procedures to demonstrate that a child was enrolled within 30 days of birth, adoption, or placement for adoption, in which case the child would not be subject to a preexisting condition exclusion under §148.120(f)(2).

(iii) *Transition rule for dependent coverage through June 30, 1998*—(A) *General rule.* An issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (b)(2)(ii)(C) of this section by providing the name of the policyholder and specifying that the type of coverage described in the certificate is for dependent coverage (for example, family coverage or individual-plus-spouse coverage).

(B) *Certificates provided on request.* For purposes of certificates provided on the request of, or on behalf of, an individual under paragraph (b)(1)(ii) of this section, an issuer must make reasonable efforts to obtain and provide the names of any dependent covered by the certificate if the information is requested. If a certificate does not include the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for submitting documentation to establish that the creditable coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's creditable coverage.* See paragraph (d)(3) of this section for special rules to demonstrate dependent status.

(D) *Duration.* The transitional rules of this paragraph (b)(4)(iii) are effective for certifications provided with respect to an event occurring before July 1, 1998.

(5) *Optional notice.* This paragraph applies to events described in paragraph (b)(1)(i) of this section, that occur after September 30, 1996, but before June 30, 1997. An issuer offering individual health insurance coverage is deemed to satisfy paragraphs (b)(1) and (b)(2) of this section if a notice is provided in accordance with the provisions of §146.125(e)(3)(ii) through (e)(3)(iv) of this subchapter.

(c) *Disclosure of coverage to a plan, or issuer, electing the alternative method of creating coverage*—(1) *General rule.* If an individual enrolls in a group health plan and the plan or issuer uses the alternative method of determining creditable coverage described in §146.113(c) of this subchapter, the individual provides a certificate of coverage under paragraph (b) of this section or demonstrates creditable coverage under paragraph (d) of this section, and the plan or coverage in which the individual enrolls requests from the prior entity, the prior entity must disclose promptly to the requesting plan or issuer (''requesting entity'') the information set forth in paragraph (c)(2) of this section.

(2) *Information to be disclosed.* The prior entity must identify to the requesting entity the categories of benefits under which the individual was covered and with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity

may identify specific information that the requesting entity reasonably needs to determine the individual's creditable coverage with respect to any of those categories. The prior entity must promptly disclose to the requesting entity the creditable coverage information that was requested.

(3) *Charge for providing information.* The prior entity furnishing the information under paragraph (c)(2) of this section may charge the requesting entity for the reasonable cost of disclosing the information.

(d) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *General rule.* Individuals may establish creditable coverage through means other than certificates. If the accuracy of a certificate is contested or a certificate is unavailable when needed by the individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make a demonstration if one of the following occurs:

(i) An entity has failed to provide a certificate within the required time period.

(ii) The individual has creditable coverage but an entity may not be required to provide a certificate of the coverage.

(iii) The coverage is for a period before July 1, 1996.

(iv) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan.

(v) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(2) *Evidence of creditable coverage*—(i) *Consideration of evidence.* An issuer must take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether or not an individual has 18 months of creditable coverage. An issuer must treat the individual as having furnished a certificate if the individual attests to the period of creditable coverage, the individual presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the issuer's efforts to verify the individual's coverage. For this purpose, cooperation includes providing (upon the issuer's request) a written authorization for the issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While an issuer may refuse to credit coverage if the individual fails to cooperate with the issuer's efforts to verify coverage, the issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (EOB) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting period or affiliation period information) may be established through means other than documentation, such as by a telephone call from the issuer to a third party verifying creditable coverage.

(3) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the issuer must treat the individual as having furnished a certificate showing the dependent status if the individual attests to the dependency and the period of the status and the individual cooperates with the issuer's efforts to verify the dependent status.

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[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 148.126 Determination of an eligible individual.

(a) *General rule.* Each issuer offering health insurance coverage in the individual market is responsible for determining whether an applicant for coverage is an eligible individual as defined in § 148.103.

(b) *Specific requirements.* (1) The issuer must exercise reasonable diligence in making this determination.

(2) The issuer must promptly determine whether an applicant is an eligible individual.

(3) If an issuer determines that an individual is an eligible individual, the issuer must promptly issue a policy to that individual.

(c) *Insufficient information*—(1) *General rule.* If the information presented in or with an application is substantially insufficient for the issuer to make the determination described in paragraph (b)(2) of this section, the issuer may immediately request additional information from the individual, and must act promptly to make its determination after receipt of the requested information

(2) *Failure to provide a certification of creditable coverage.* If an entity fails to provide the certificate that is required under this part or part 146 of this subchapter to the applicant, the issuer is subject to the procedures set forth in § 148.124(d)(1) concerning an individual's right to demonstrate creditable coverage.

[62 FR 17000, Apr. 8, 1997]

EFFECTIVE DATE NOTE: At 62 FR 17000, Apr. 8, 1997, § 148.126 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 148.128 State flexibility in individual market reforms—alternative mechanisms.

(a) *Waiver of requirements.* The requirements of § 148.120, which set forth Federal requirements for guaranteed availability in the individual market, do not apply in a State that implements an acceptable alternative mechanism in accordance with the following criteria:

(1) The alternative mechanism meets the following conditions:

(i) Offers health insurance coverage to all eligible individuals.

(ii) Prohibits imposing preexisting condition exclusions and affiliation periods for coverage of an eligible individual.

(iii) Offers an eligible individual a choice of coverage that includes at least one policy form of coverage that is comparable to either one of the following:

(A) Comprehensive coverage offered in the individual market in the State.

(B) A standard option of coverage available under the group or individual health insurance laws of the State.

(2) The State is implementing one of the following provisions relating to risk:

(i) One of the following model acts, as adopted by the NAIC on June 3, 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.

(A) The Small Employer and Individual Health Insurance Availability Model Act to the extent it applies to individual health insurance coverage.

(B) The Individual Health Insurance Portability Model Act.

(ii) A qualified high risk pool, which, for purposes of this section, is a high risk pool that meets the following conditions:

(A) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion or affiliation periods for coverage of an eligible individual.

(B) Provides for premium rates and covered benefits for the coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of 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.

(iii) One of the following mechanisms:

(A) Any other mechanism that provides for risk adjustment, risk spreading, or a risk-spreading mechanism (among issuers or policies of an issuer)

or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers.

(B) A mechanism that provides a choice for each eligible individual of all individual health insurance coverage otherwise available.

(b) *Permissible forms of mechanisms.* A private or public individual health insurance mechanism (such as a health insurance coverage pool or program, a mandatory group conversion policy, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of these mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State, in accordance with this section, may constitute an acceptable alternative mechanism.

(c) *Establishing an acceptable alternative mechanism—transition rules.* CMS presumes a State to be implementing an acceptable alternative mechanism as of July 1, 1997 if the following conditions are met:

(1) By not later than April 1, 1997, as evidenced by a postmark date, or other such date, the chief executive officer of the State takes the following actions:

(i) Notifies CMS that the State has enacted or intends to enact by not later than January 1, 1998 (unless it is a State described in paragraph (d) of this section), any legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(ii) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(2) CMS has not made a determination, in accordance with the procedure in paragraph (e)(4) of this section, that the State will not be implementing a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(d) *Delay permitted for certain States.* If a State notifies CMS that its legislature is not meeting in a regular session between August 21, 1996 and August 20, 1997, CMS continues to presume until July 1, 1998 that the State is implementing an acceptable alternative mechanism, if the chief executive officer of the State takes the following actions:

(1) Notifies CMS by April 1, 1997, that the State intends to submit an alternative mechanism and intends to enact any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(2) Notifies CMS by April 1, 1998, that the State has enacted any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(3) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(e) *Submitting an alternative mechanism after April 1, 1997*—(1) *Notice with information.* A State that wishes to implement an acceptable alternative mechanism must take the following actions:

(i) Notify CMS that it has enacted legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism, and

(ii) Provide CMS with the information necessary for CMS to review the mechanism and its implementation (or proposed implementation).

(2) *An acceptable alternative mechanism.* If the State takes the actions described in paragraph (e)(1) of this section, the mechanism is considered to be an acceptable alternative mechanism unless CMS makes a preliminary determination (under paragraph (e)(4)(i) of this section), within the review period (defined in paragraph (e)(3) of this section), that the mechanism is not an acceptable alternative mechanism.

(3) *Review period*—(i) *General.* The review period begins on the date the State's notice and information are received by CMS, and ends 90 days later, not counting any days during which the review period is suspended under paragraph (e)(3)(ii) of this section.

(ii) *Suspension of review period.* During any review period, if CMS notifies the

State of the need for additional information or further discussion on its submission, CMS suspends the review period until the State provides the necessary information.

(4) *Determination by CMS*—(i) *Preliminary determination.* If CMS finds after reviewing the submitted information, and after consultation with the chief executive officer of the State and the chief insurance regulatory official of the State, that the mechanism is not an acceptable alternative mechanism, CMS takes the following actions:

(A) Notifies the State, in writing, of the preliminary determination.

(B) Informs the State that if it fails to implement an acceptable alternative mechanism, the Federal guaranteed availability provisions of §148.120 will take effect.

(C) Permits the State a reasonable opportunity to modify the mechanism (or to adopt another mechanism).

(ii) *Final determination.* If, after providing notice and a reasonable opportunity for the State to modify its mechanism, CMS makes a final determination that the design of the State's alternative mechanism is not acceptable or that the State is not substantially enforcing an acceptable alternative mechanism, CMS notifies the State in writing of the following:

(A) CMS's final determination.

(B) That the requirements of §148.120 concerning guaranteed availability apply to health insurance coverage offered in the individual market in the State as of a date specified in the notice from CMS.

(iii) *State request for early notice.* A State may request that CMS notify the State before the end of the review period if CMS is not making a preliminary determination.

(5) *Effective date.* If CMS does not make a preliminary determination within the review period, the acceptable alternative mechanism is effective 90 days after the end of the 90-day review period described in paragraph (e)(3)(i) of this section.

(f) *Continued application.* A State alternative mechanism may continue to be presumed to be acceptable, if the State provides information to CMS that meets the following requirements:

(1) If the State makes a significant change to its alternative mechanism, it provides the information before making a change.

(2) Every 3 years from the later of implementing the alternative mechanism or implementing a significant change, it provides CMS with information.

(g) *Review criteria.* CMS reviews each State's submission to determine whether it addresses all of the following requirements:

(1) Is the mechanism reasonably designed to provide all eligible individuals with a choice of health insurance coverage?

(2) Does the choice offered to eligible individuals include at least one policy form that meets one of the following requirements?

(i) Is the policy form comparable to comprehensive health insurance coverage offered in the individual market in the State?

(ii) Is the policy form comparable to a standard option of coverage available under the group or individual health insurance laws of the State?

(3) Does the mechanism prohibit preexisting condition exclusions for all eligible individuals?

(4) Is the State implementing one of the following:

(i) The NAIC Small Employer and Individual Health Insurance Availability Model Act (Availability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

(ii) The Individual Health Insurance Portability Model Act (Portability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

(iii) A qualified high-risk pool that provides eligible individuals health insurance or comparable coverage without a preexisting condition exclusion, and with premiums and benefits consistent with the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect August 21, 1996), revised to reflect HIPAA requirements.

(iv) A mechanism that provides for risk spreading or provides eligible individuals with a choice of all available individual health insurance coverage.

(5) Has the State enacted all legislation necessary for implementing the alternative mechanism?

(6) If the State has not enacted all legislation necessary for implementing the alternative mechanism, will the necessary legislation be enacted by January 1, 1998?

(h) *Limitation of CMS's authority.* CMS does not make a preliminary or final determination on any basis other than that a mechanism is not considered an acceptable alternative mechanism or is not being implemented.

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Subpart C—Requirements Related to Benefits

§ 148.170 Standards relating to benefits for mothers and newborns.

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

(i) 48 hours following a vaginal delivery; or

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

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

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

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

Example 1. (i) *Facts.* A pregnant woman covered under a policy issued in the individual market goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

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

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

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

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

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

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

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

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

(ii) *Conclusion.* In this *Example*, the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours

and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, an issuer, plan, hospital, or managed care organization is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a policy offered by an issuer subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The issuer pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example*, the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* An issuer subject to the requirements of this section may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll in or renew coverage solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under a policy issued in the individual market are discharged within 24 hours after the delivery, the issuer will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the issuer violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the issuer provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2,* because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, an issuer may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* An issuer subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the issuer automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the covered individual must call the issuer to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the issuer will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example,* the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit an issuer from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the issuer based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* An issuer may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a covered individual in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a covered individual in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any issuer that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent an issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The issuer covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1,* the issuer violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the issuer also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* An issuer generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the issuer will cover 80 percent of the cost of the stay if the covered individual notifies the issuer of the pregnancy in advance of admission and uses whatever hospital the issuer may designate.

(ii) *Conclusion.* In this *Example 2,* the issuer does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the issuer does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent an issuer from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(5) *Applicability.* This section applies to all health insurance coverage issued in the individual market, and is not limited in its application to coverage that is provided to eligible individuals as defined in section 2741(b) of the PHS Act.

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, an issuer offering health insurance in the individual market must meet the following requirements with respect to benefits for hospital lengths of stay in connection with childbirth:

(1) Required statement. The insurance contract must disclose information that notifies covered individuals of their rights under this section.

(2) Disclosure notice. To meet the disclosure requirements set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, health insurance issuers generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the issuer may pay for a shorter stay if the attending provider (*e.g.* , your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, an issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your issuer.

(3) *Timing of disclosure.* The disclosure notice in paragraph (d)(2) of this section shall be furnished to the covered individuals in the form of a copy of the contract, or a rider (or equivalent amendment to the contract) no later than December 19, 2008. To the extent an issuer has already provided the disclosure notice in paragraph (d)(2) of this section to covered individuals, it need not provide another such notice by December 19, 2008.

(4) *Exception.* The requirements of this paragraph (d) do not apply with respect to coverage regulated under a state law described in paragraph (e) of this section.

(e) *Applicability in certain states*—(1) *Health insurance coverage.* The requirements of section 2751 of the PHS Act and this section do not apply with respect to health insurance coverage in the individual market if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Relation to section 2762(a) of the PHS Act.* The preemption provisions contained in section 2762(a) of the PHS Act and §148.210(b) do not supersede a state law described in paragraph (e)(1) of this section.

(f) *Applicability date.* Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

[73 FR 62427, Oct. 20, 2008]

§ 148.180 Prohibition of discrimination based on genetic information.

(a) *Definitions.* For purposes of this section, the following definitions as set forth in § 146.122 of this subchapter pertain to health insurance issuers in the individual market to the extent that those definitions are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in effect or operated in the individual market:

Collect has the meaning set forth at § 146.122(a).

Family member has the meaning set forth at § 146.122(a).

Genetic information has the meaning set forth at § 146.122(a).

Genetic services has the meaning set forth at § 146.122(a).

Genetic test has the meaning set forth at § 146.122(a).

Manifestation or manifested has the meaning set forth at § 146.122(a).

Preexisting condition exclusion has the meaning set forth at § 144.103.

Underwriting purposes has the meaning set forth at § 148.180(f)(1).

(b) *Prohibition on genetic information as a condition of eligibility.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section precludes an issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of that individual when the family member is covered under the policy that covers the individual.

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

Example 1. (i) *Facts.* A State implements the HIPAA guaranteed availability requirement in the individual health insurance market in accordance with § 148.120. Individual *A* and his spouse *S* are not ''eligible individuals'' as that term is defined at § 148.103 and, therefore, they are not entitled to obtain individual health insurance coverage on a guaranteed available basis. They apply for individual coverage with Issuer *M*. As part of the application for coverage, *M* receives health information about *A* and *S*. Although *A* has no known medical conditions, *S* has high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 1*, *M* permissibly may decline to offer coverage to *S* because *S* has a manifested disorder (high blood pressure) that makes her ineligible for coverage under the policy's rules for eligibility.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *S* does not have high blood pressure or any other known medical condition. The only health information relevant to *S* that *M* receives in the application indicates that both of *S*'s parents are overweight and have high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 2*, *M* cannot decline to offer coverage to *S* because *S* does not have a manifested disease or disorder. The only health information *M* has that relates to her pertains to a manifested disease or disorder of family members, which as family medical history constitutes genetic information with respect to *S*. If *M* denies eligibility to *S* based on genetic information, the denial will violate this paragraph (b).

(c) *Prohibition on genetic information in setting premium rates.*

(1) *In general.* An issuer offering health insurance coverage in the individual market must not adjust premium amounts for an individual on the basis of genetic information regarding the individual or a family member of the individual.

(2) *Rule of construction.* (i) Nothing in paragraph (c)(1) of this section precludes an issuer from adjusting premium amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or on the basis of a manifestation of a disease or disorder in a family member of that individual when the family member is covered under the policy that covers the individual.

(ii) The manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to that individual and to further increase premium amounts.

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

Example 1. (i) *Facts.* Individual *B* is covered under an individual health insurance policy through Issuer *N*. Every other policy year,

before renewal, *N* requires policyholders to submit updated health information before the policy renewal date for purposes of determining an appropriate premium, in excess of any increases due to inflation, based on the policyholders' health status. *B* complies with that requirement. During the past year, *B*'s blood glucose levels have increased significantly. *N* increases its premium for renewing *B*'s policy to account for *N*'s increased risk associated with *B*'s elevated blood glucose levels.

(ii) *Conclusion.* In this *Example 1*, *N* is permitted to increase the premium for *B*'s policy on the basis of a manifested disorder (elevated blood glucose) in *B*.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *B*'s blood glucose levels have not increased and are well within the normal range. In providing updated health information to *N*, *B* indicates that both his mother and sister are being treated for adult onset diabetes mellitus (Type 2 diabetes). *B* provides this information voluntarily and not in response to a specific request for family medical history or other genetic information. *N* increases *B*'s premium to account for *B*'s genetic predisposition to develop Type 2 diabetes in the future.

(ii) *Conclusion.* In this *Example 2*, *N* cannot increase *B*'s premium on the basis of *B*'s family medical history of Type 2 diabetes, which is genetic information with respect to *B*. Since there is no manifestation of the disease in *B* at this point in time, *N* cannot increase *B*'s premium.

(d) *Prohibition on genetic information as preexisting condition.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion with respect to that coverage.

(2) *Rule of construction.* Nothing in paragraph (d)(1) of this section precludes an issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

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

Example 1. (i) *Facts.* Individual *C* has encountered delays in receiving payment from the issuer of his individual health insurance policy for covered services. He decides to switch carriers and applies for an individual health insurance policy through Issuer *O*. *C* is generally in good health, but has arthritis for which he has received medical treatment. *O* offers *C* an individual policy that excludes coverage for a 12-month period for any services related to *C*'s arthritis.

(ii) *Conclusion.* In this *Example 1*, *O* is permitted to impose a preexisting condition exclusion with respect to *C* because *C* has a manifested disease (arthritis).

Example 2. (i) *Facts.* Individual *D* applies for individual health insurance coverage through Issuer *P*. *D* has no known medical conditions. However, in response to *P*'s request for medical information about *D*, *P* receives information from *D*'s physician that indicates that both of *D*'s parents have adult onset diabetes mellitus (Type 2 diabetes). *P* offers *D* an individual policy with a rider that permanently excludes coverage for any treatment related to diabetes that *D* may receive while covered by the policy, based on the fact that both of *D*'s parents have the disease.

(ii) *Conclusion.* In this *Example 2*, the rider violates this paragraph (d) because the preexisting condition exclusion is based on genetic information with respect to *D* (family medical history of Type 2 diabetes).

(e) *Limitation on requesting or requiring genetic testing.*

(1) *General rule.* Except as otherwise provided in this paragraph (e), an issuer offering health insurance coverage in the individual market must not request or require an individual or a family member of the individual to undergo a genetic test.

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

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

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

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

Example 2. (i) *Facts.* Individual *F* is covered by a health maintenance organization

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

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

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

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

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

(5) *Research exception.* Notwithstanding paragraph (e)(1) of this section, an issuer may request, but not require, that an individual or family member covered under the same policy undergo a genetic test if all of the conditions of this paragraph (e)(5) are met:

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

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

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in paragraph (b) of this section) or premium amounts (as described in paragraph (c) of this section).

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

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

(f) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* An issuer offering health insurance coverage in the individual market must not collect (as defined in paragraph (a) of this section) genetic information for underwriting purposes. *See* paragraph (g) of this section for examples illustrating the rules of this paragraph (f)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (f)(1)(iii) of this section, *underwriting purposes* means, with respect to any issuer offering health insurance coverage in the individual market—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the coverage;

(B) The computation of premium amounts under the coverage;

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

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

(iii) *Medical appropriateness.* An issuer in the individual market may limit or exclude a benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an issuer conditions a benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on a covered individual's genetic information, the issuer is permitted to condition the benefit on the genetic information. An issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness, and may deny the benefit if the covered individual does not provide the genetic information required to determine medical appropriateness. *See* paragraph (g) of this section for examples illustrating the applicability of this paragraph (f)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.*

(i) *In general.* An issuer offering health insurance coverage in the individual market must not collect genetic information with respect to any individual prior to that individual's enrollment under the coverage or in connection with that individual's enrollment. Whether or not an individual's information is collected prior to that individual's enrollment is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.

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

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

Example 1. (i) *Facts.* Individual *G* applies for a health insurance policy through Issuer *Q*. *Q*'s application materials ask for the applicant's medical history, but not for family medical history. The application's instructions state that no genetic information, including family medical history, should be provided. *G* answers the questions in the application completely and truthfully, but volunteers certain health information about diseases his parents had, believing that *Q* also needs this information.

(ii) *Conclusion.* In this *Example 1*, *G*'s family medical history is genetic information with respect to *G*. However, since *Q* did not request this genetic information, and *Q*'s instructions stated that no genetic information should be provided, *Q*'s collection is an incidental collection under paragraph (f)(2)(ii). However, *Q* may not use the genetic information it obtained incidentally for underwriting purposes.

Example 2. (i) *Facts.* Individual *H* applies for a health insurance policy through Issuer *R*. *R*'s application materials request that an applicant provide information on his or her individual medical history, including the names and contact information of physicians from whom the applicant sought treatment. The application includes a release which authorizes the physicians to furnish information to *R*. *R* forwards a request for health information about *H*, including the signed release, to his primary care physician. Although the request for information does not ask for genetic information, including family medical history, it does not state that no genetic information should be provided. The physician's office administrator includes part of *H*'s family medical history in the package to *R*.

(ii) *Conclusion.* In this *Example 2*, *R*'s request was for health information solely about its applicant, *H*, which is not genetic information with respect to *H*. However, *R*'s materials did not state that genetic information should not be provided. Therefore, *R*'s collection of *H*'s family medical history (which is genetic information with respect to

H), violates the rule against collection of genetic information and does not qualify for the incidental collection exception under paragraph (f)(2)(ii).

Example 3. (i) *Facts.* Issuer *S* acquires Issuer *T*. *S* requests *T*'s records, stating that *S* should not provide genetic information and should review the records to excise any genetic information. *T* assembles the data requested by *S* and, although *T* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *S* receives genetic information about some of *T*'s covered individuals.

(ii) *Conclusion.* In this *Example 3*, *S*'s request for health information explicitly stated that genetic information should not be provided. Therefore, its collection of genetic information was within the incidental collection exception. However, *S* may not use the genetic information it obtained incidentally for underwriting purposes.

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

Example 1. (i) *Facts.* Individual *I* has an individual health insurance policy through Issuer *U* that covers genetic testing for celiac disease for individuals who have family members with this condition. *I*'s policy includes dependent coverage. After *I*'s son is diagnosed with celiac disease, *I* undergoes a genetic test and promptly submits a claim for the test to *U* for reimbursement. *U* asks *I* to provide the results of the genetic test before the claim is paid.

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

Example 2. (i) *Facts.* Individual *J* has an individual health insurance policy through Issuer *V* that covers a yearly mammogram for participants starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *J* is 33 years old and has the BRCA2 mutation. *J* undergoes a mammogram and promptly submits a claim to *V* for reimbursement. *V* asks *J* for evidence of increased risk of breast cancer, such as the results of a genetic test, before the claim for the mammogram is paid.

(ii) *Conclusion.* In this *Example 2*, *V* does not violate paragraphs (e) or (f) of this section. Under paragraph (e), an issuer is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the issuer requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the covered individual's genetic makeup, the minimum amount of information necessary includes the results of the genetic test. Similarly, *V* does not violate paragraph (f) of this section because an issuer is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and the genetic information is not used for underwriting purposes).

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

(ii) *Conclusion.* In this *Example 3*, *W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K*'s undergoing a genetic test to determine the genetic markers *K* has for making the CYP_2D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *K*.

(h) *Applicability date.* The provisions of this section are effective with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

[74 FR 51693, Oct. 7, 2009]

Subpart D—Preemption; Excepted Benefits

§ 148.210 Preemption.

(a) *Scope.* (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's

authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers.* The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

§ 148.220 Excepted benefits.

The requirements of this part do not apply to individual health insurance coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

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

(8) Coverage for on-site medical clinics.

(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), or hospital indemnity or other fixed indemnity insurance (for example, $100/day) if the policies meet the requirements of §146.145(b)(4)(ii)(B) and (b)(4)(ii)(C) of this subchapter regarding noncoordination of benefits.

(4) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act. 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance). The requirements of this part 148 (including genetic nondiscrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic nondiscrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at *http://www.naic.org.*).

(5) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(6) 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]

Subpart E—Grants to States for Operation of Qualified High Risk Pools

SOURCE: 68 FR 23414, May 2, 2003, unless otherwise noted.

§ 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (PHS Act). It extends grants to States that have qualified high risk pools that meet the specific requirements described in § 148.310. It also provides specific instructions on how to apply for the grants and outlines the grant review and grant award processes.

[73 FR 22285, Apr. 25, 2008]

§ 148.308 Definitions.

For the purposes of this subpart, the following definitions apply:

Bonus grants means funds that the Secretary provides from the appropriated grant funds to be used to provide supplemental consumer benefits to enrollees or potential enrollees in qualified high risk pools.

CMS stands for Centers for Medicare & Medicaid Services.

Loss means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and the premiums collected by the pool.

Qualified high risk pool as defined in sections 2744(c)(2) and 2745(g) of the PHS Act means a risk pool that—

(1) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, except that it may provide for enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 2744 of the PHS Act) that includes a high risk pool as a component; and

(2) Provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act that was in effect at the time of the enactment of the Health Insurance Portability and Accountability Act of 1996 (August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

Standard risk rate means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard rate may be adjusted based upon age, sex, and geographical location.

State means any of the 50 States and the District of Columbia and includes the U.S. Territories of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State fiscal year, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.310 Eligibility requirements for a grant.

A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in § 148.308.

(b) The pool restricts premiums charged under the pool to no more than 200 percent of the premium for applicable standard risk rates for the State.

(c) The pool offers a choice of two or more coverage options through the pool.

(d) The pool has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State after the end of each fiscal year for which the State applies for Federal Funding in fiscal year (FY) 2005 through FY 2010 in connection with the operation of the pool.

(e) The pool has incurred a loss in a period described in § 148.314.

(f) In the case of a qualified high risk pool in a State that charges premiums that exceed 150 percent of the premium for applicable standard risks, the State will use at least 50 percent of the amount of the grant provided to the

State to reduce premiums for enrollees.

(g) In no case will the aggregate amount allotted and made available to the U.S. Territories for a fiscal year exceed $1,000,000 in total.

(h) Bonus grant funding must be used for one or more of the following benefits:

(1) Low income premium subsidies;

(2) Reduction in premium trends, actual premium or other cost-sharing requirements;

(3) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules;

(4) Less stringent rules or additional waiver authority with respect to coverage of pre-existing conditions;

(5) Increased benefits; and

(6) The establishment of disease management programs.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.312 Amount of grant payment.

(a) An eligible State may receive a grant to fund up to 100 percent of the losses incurred in the operation of its qualified high risk pool during the period for which it is applying or a lesser amount based on the limits of the allotment under the formula.

(b) Funds will be allocated in accordance with this paragraph to each State that meets the eligibility requirements of §148.310 and files an application in accordance with §148.316. The amount will be divided among the States that apply and are awarded grants according to the allotment rules that generally provide that: 40 percent will be equally divided among those States; 30 percent will be divided among States and territories based on their number of uninsured residents in the State during the specified year as compared to all States that apply; and 30 percent will be divided among States and territories based on the number of people in State high risk pools during the specified year as compared to all States that apply.

For purposes of this paragraph:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau during the period for which it is applying. The 3-year average will be calculated using numbers available as of March 1 of each year.

(2) The number of individuals enrolled in health care coverage through the qualified high risk pool of the State will be determined by attestation by the State in its grant application and verified for reasonability by the Secretary through acceptable industry data sources.

(c) The amount awarded to each eligible State will be the lesser of the 50 percent of losses incurred by its qualified risk pool for the fiscal year in question or its allotment under the formula.

(d) One-third of the total appropriation will be available for the bonus grants. In no case will a State for a fiscal year receive bonus grants that exceed 10 percent of the total allotted funds for bonus grants.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.314 Periods during which eligible States may apply for a grant.

(a) *General rule.* A State that meets the eligibility requirements in §148.310 may apply for a grant to fund losses that were incurred during the State's FYs 2005, 2006, 2007, 2008 and 2009 in connection with the operation of its qualified high risk pool. Funding for FY 2007 through FY 2010 under the Extension Act requires subsequent enactment of appropriations authority. States will be unable to apply for grants unless and until such funding becomes available. Grants funding is on a retrospective basis and applies to the States previous fiscal year. If a State becomes eligible for a grant in the middle of its fiscal year, a State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Only losses that are incurred after eligibility is established will qualify for a grant.

(b) *Maximum number of grants.* An eligible State may only be awarded a maximum of five grants, with one grant per fiscal year. A grant for a partial fiscal year counts as a full grant.

(c) *Deadline for submitting grant applications.* The deadlines for submitting grant applications are stated in § 148.316(d).

(d) *Distribution of grant funds.* States that meet all of the eligibility requirements in § 148.310 and submit timely requests in accordance with paragraph (c) of this section will receive an initial distribution of grant funds using the following methodology: Grant applications for losses will be on a retrospective basis. For example, grant applications for 2006 funds are based on the State's FY 2005 incurred losses. Grant funding was appropriated for Federal FY 2006 and is authorized to be appropriated for Federal FYs 2008 through 2010.

(e) *Grant allocations.* Grant allocations for each fiscal year will be determined by taking all grant applications during the period for which States are applying and allocating the funds in accordance with § 148.312.

(1) In no case will a State receive funds greater than 100 percent of their losses.

(2) If any excess funds remain after the initial calculation, these excess funds will be proportionately redistributed to the States whose allocations have not exceeded 100 percent of their losses.

[73 FR 22285, Apr. 25, 2008]

§ 148.316 Grant application instructions.

Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority. Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(a) *Application for operational losses.* Each State must compile an application package that documents that it has met the requirements for a grant. If a risk pool entity applies on behalf of a State, it must provide documentation that it has been delegated appropriate authority by the State. At a minimum, the application package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool.* Provide a detailed description of the qualified high risk pool that includes the following:

(i) Brief history, including date of inception.

(ii) Enrollment criteria (including provisions for the admission of eligible individuals as defined in § 148.103) and number of enrollees.

(iii) Description of how coverage is provided administratively in the qualified high risk pool (that is, self-insured, through a private carrier, etc.).

(iv) Benefits options and packages offered in the qualified high risk pool to both eligible individual (as defined in § 148.103) and other applicants.

(v) Outline of plan benefits and coverage offered in the pool. Provide evidence that the level of plan benefits is consistent with either Alternative One or Alternative Two in Section 8 of the NAIC Model Health Plan for Uninsurable Individuals Act. See appendix for the text of Section 8 of the NAIC Model.

(vi) Premiums charged (in terms of dollars and in percentage of standard risk rate) and other cost-sharing mechanisms, such as co-pays and deductibles, imposed on enrollees (both eligible individuals (as defined in § 148.103) and non-eligible individuals if a distinction is made).

(vii) How the standard risk rate for the State is calculated and when it was last calculated.

(viii) Revenue sources for the qualified high risk pool, including current funding mechanisms and, if different, future funding mechanisms. Provide current projections of future income.

(ix) Copies of all governing authorities of the pool, including statutes, regulations and plan of operation.

(2) *Accounting of risk pool losses.* Provide a detailed accounting of claims paid, administrative expenses, and premiums collected for the fiscal year for which the grant is being requested. Indicate the timing of the fiscal year upon which the accounting is based. Provide the methodology of projecting

losses and expenses, and include current projections of future operating losses (this information is needed to judge compliance with the requirements in §148.310(d)).

(3) *Bonus grants for supplemental consumer benefits.* Provide detailed information about the following supplemental consumer benefits for which the entity is applying:

(i) A narrative description of one or more of the following of the supplemental consumer benefits to be provided to enrollees and/or potential enrollees in the high risk pool:

(A) Low income premium subsidies;

(B) Reduction in premium trends, actual premium or other cost-sharing requirements;

(C) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment;

(D) Less stringent rules, or additional waiver authority with respect to coverage of pre-existing conditions;

(E) Increased benefits; and

(F) The establishment of disease management programs.

(ii) A description of the population or subset population that will be eligible for the supplemental consumer benefits.

(iii) A projected budget for the use of bonus grant funds using the SF 424 A.

(4) *Contact person.* Identify the name, position title, address, e-mail address, and telephone number of the person to contact for further information and questions.

(b) Standard form application kit—(1) Forms. (i) The following standard forms must be completed with an original signature and enclosed as part of the application package:

SF–424 Application for Federal Assistance.

SF–424A Budget Information.

SF–424B Assurances Non-Construction Programs.

SF–LLL Disclosure of Lobbying Activities Biographical Sketch.

(ii) These forms can be accessed from the following Web site: *http://www.grants.gov.*

(2) *Other narrative.* All other narrative in the application must be submitted on 8½ x 11 inches white paper.

(c) *Application submission.* Submission of application package is through *http://www.grants.gov.* Submissions by facsimile (fax) transmissions will not be accepted.

(d) *Application deadlines.* (1) The deadline for States to submit an application for losses incurred in a State fiscal year is June 30 of the next Federal fiscal year that begins after the end of the State fiscal year. Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority. Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(2) *Deadline for States to submit an application for losses incurred in their fiscal year 2005.* States had to submit an application to CMS no later than June 30, 2006.

(3) *Deadline for States to submit an application for losses incurred in their fiscal year 2006.* States must submit an application to CMS by no later than June 30, 2007.

(4) *Deadline for States to submit an application for losses incurred in their fiscal year 2007.* States must submit an application to CMS by no later than June 30, 2008.

(5) *Deadline for States to submit an application for losses incurred in their fiscal year 2008.* States must submit an application to CMS by no later than June 30, 2009.

(6) *Deadline for States to submit an application for losses incurred in their fiscal year 2009.* States must submit an application to CMS by no later than June 30, 2010.

(e) *Where to submit an application.* Applications must be submitted to *http://www.grants.gov.* Submissions by facsimile (fax) transmissions will not be accepted.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15701, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§148.318 Grant application review.

(a) *Executive Order 12372.* This grant program is not listed by the Secretary

under §100.3 of this title, and therefore the grant program is not subject to review by States under part 100 of this title, which implements Executive Order 12372, ''Intergovernmental Review of Federal Programs'' (see part 100 of this title).

(b) *Review team.* A team consisting of staff from CMS and the Department of Health and Human Services will review all applications. The team will meet as necessary on an ongoing basis as applications are received.

(c) *Eligibility criteria.* To be eligible for a grant, a State must submit sufficient documentation that its high risk pool meets the eligibility requirements described in §148.310. A State must include sufficient documentation of the losses incurred in the operation of the qualified high risk pool in the period for when it is applying.

(d) *Review criteria.* If the review team determines that a State meets the eligibility requirements described in §148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State's pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after each fiscal year for which it is applying for grant funds.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§148.320 Grant awards.

(a) *Notification and award letter.* (1) Each State applicant will be notified in writing of CMS's decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

(iii) The grantee will be required to submit quarterly progress and financial reports under part 92 of this title and in accordance with section 2745(f) of the Public Health Service Act, requiring the Secretary to make an annual report to Congress that includes information on the use of these grant funds by States.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS' Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

PART 149—REQUIREMENTS FOR THE EARLY RETIREE REINSURANCE PROGRAM

Subpart A—General Provisions

Sec.

Subpart B—Requirements for Eligible Employment-based Plans

Subpart C—Reinsurance Amounts

Subpart D—Use of Reimbursements

Subpart E—Reimbursement Methods

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 employment-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 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 primary 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;

(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 concessions, 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.

§ 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 section. 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 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.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce HIPAA Requirements

Subpart C—CMS Enforcement With Respect to Issuers and Non-Federal Governmental Plans—Civil Money Penalties

Subpart D—Administrative Hearings

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 2722 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group heath plans.* The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures described in §150.301 *et seq.*

(2) *Enforcement with respect to health insurance issuers.* The States have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a State is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in part 146 and part 148 of this subchapter, CMS enforces them under subpart C of this part.

§ 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.

HIPAA requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

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 part 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 part 146 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.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce HIPAA Requirements

§ 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces HIPAA requirements 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 HIPAA requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with §148.128 of this subchapter instead of complying with the guaranteed availability requirements of §148.120, CMS's determination focuses on the following:

(1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§148.101 through 148.126 and §148.170 of this subchapter.

§ 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 HIPAA 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 HIPAA 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.

§ 150.207 Procedure for determining that a State fails to substantially enforce HIPAA requirements.

Sections 150.209 through 150.219 describe the procedures CMS follows to determine whether a State is substantially enforcing HIPAA requirements.

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If CMS receives a complaint or other information indicating that a State is failing to enforce HIPAA 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.

§ 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 HIPAA 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.

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

(a) Identifies the HIPAA 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 HIPAA 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.

§ 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 HIPAA 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.

§ 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 HIPAA requirements that CMS is enforcing.

(b) The effective date of CMS's enforcement.

§ 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 HIPAA requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to ensure that a transition is effected with respect to the following:

(1) Consumer complaints and inquiries.

(2) Instructions to issuers.

(3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that will assume enforcement responsibility.

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 HIPAA requirements, it may be subject to a civil money penalty as described in this subpart.

§ 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 HIPAA 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.

(3) Any other information that indicates potential noncompliance with HIPAA 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 HIPAA 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.

§ 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 HIPAA 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 HIPAA 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 HIPAA requirements.

(d) *Actions or inactions of agent*. A principal is liable for penalties assessed for the actions or inactions of its agent.

§ 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 HIPAA requirements.

§ 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 HIPAA requirements. The following are examples of documentation that a potential responsible entity may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any individual policy, group policy, certificate of insurance, application, rider, amendment, endorsement, certificate of creditable coverage, advertising material, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the responsible entity to refute the complaint or allegation.

(b) Any other evidence that refutes an alleged noncompliance.

(c) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(d) Documentation that the policies, certificates of insurance, or non-Federal governmental plan documents have been amended to comply with HIPAA 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 HIPAA 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 HIPAA 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]

§ 150.313 Market conduct examinations.

(a) *Definition.* A market conduct examination means the examination of health insurance operations of an issuer, or the operation of a non-Federal governmental plan, involving the review of one or more (or a combination) of a responsible entity's business or operational affairs, or both, to verify compliance with HIPAA 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 HIPAA requirements.

§ 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 HIPAA requirements.

(2) Documentation that the responsible entity has submitted its policy forms to CMS for compliance review.

(3) Evidence that the responsible entity has never had a complaint for noncompliance with HIPAA 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.

§ 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 HIPAA 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 HIPAA 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 HIPAA requirements that were violated so that, to the extent practicable, that employer, employee, individual, or non-Federal governmental entity is in the same position that he, she, or it would have been in had the violation not occurred.

(iv) The adjustments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 150.321 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 150.323 Determining the amount of penalty—other matters as justice may require.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

§ 150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable

cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 150.343 Notice of proposed penalty.

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the HIPAA 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.

§ 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 postmarked 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 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 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) The request for hearing must identify the relevant notice of assessment by date and attach a copy of the notice.

§ 150.409 Amendment of notice of assessment or request for hearing.

The ALJ may permit CMS to amend its notice of assessment, or permit the respondent to amend a request for hearing that complies with § 150.407(a), if the ALJ finds that no undue prejudice to either party will result.

§ 150.411 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by § 150.405(a) or any extension of time granted by the ALJ pursuant to § 150.405(b).

(b) The request for hearing fails to meet the requirements of § 150.407.

(c) The entity that filed the request for hearing is not a respondent under § 150.401.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 150.413 Settlement.

CMS has exclusive authority to settle any issue or any case, without the consent of the administrative law judge at any time before or after the administrative law judge's decision.

§ 150.415 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor or the IRS may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

§ 150.417 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Applies the factors that are identified in § 150.317.

(2) May consider evidence of record relating to any factor that CMS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that CMS assessed.

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, 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 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 withholding the entire document must state why the nonprivileged part is not segregable.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§150.437 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in §150.431, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document (respondent's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 150.439 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 150.437 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 150.441 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 150.437 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 150.441 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 150.437 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person 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 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 transcript cost is to be paid for by the intervenor.

§ 150.451 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§ 150.453 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 150.457.

§ 150.455 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate

reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§ 150.457 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this subsection may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 150.453.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 150.459 Judicial review.

(a) *Filing of an action for review.* Any responsible entity against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to CMS.

(b) *Certification of administrative record.* CMS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review.* The findings of CMS and the ALJ may not be set aside

unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 150.461 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 150.463 Final order not subject to review.

In an action brought under § 150.461, the validity and appropriateness of the final order described in § 150.459 is not subject to review.

§ 150.465 Collection and use of penalty funds.

(a) Any funds collected under § 150.461 are paid to CMS.

(b) The funds are available without appropriation until expended.

(c) The funds may be used only for the purpose of enforcing the HIPAA requirements for which the penalty was assessed.

PART 151 [RESERVED]

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

Subpart A—General Provisions

Subpart B—PCIP Program Administration

Subpart C—Eligibility and Enrollment

Subpart D—Benefits

Subpart E—Oversight

Subpart F—Funding

Subpart G—Relationship to Existing Laws and Programs

Subpart H—Transition to Exchanges

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.

Subpart B—PCIP Program Administration

§ 152.6 Program administration.

(a) *General rule.* Section 1101(b)(1) of the Affordable Care Act requires that HHS carry out the Pre-Existing Condition Insurance Plan program directly or through contracts with eligible entities, which are States or nonprofit private entities.

(b) *Administration by State.* A State (or its designated non-profit private entity) may submit a proposal to enter into a contract with HHS to establish and administer a PCIP in accordance with section 1101 of the Affordable Care Act and this part.

(1) At the Secretary's discretion, a State may designate a nonprofit entity or entities to contract with HHS to administer a PCIP.

(2) As part of its administrative approach, a State or designated entity may subcontract with either a for-profit or nonprofit entity.

(c) *Administration by HHS.* If a State or its designated entity notifies HHS that it will not establish or continue to administer a PCIP, or does not submit an acceptable or timely proposal to do so, HHS will contract with a nonprofit private entity or entities to administer a PCIP in that State.

(d) *Transition in administration.* The Secretary may consider a request from a State to transition from administration by HHS to administration by a State or from administration by a State to administration by HHS. Such transitions shall be approved only if the Secretary determines that the transition is in the best interests of the PCIP enrollees and potential PCIP enrollees in that state, consistent with §152.7(b) of this part.

§ 152.7 PCIP proposal process.

(a) *General.* A proposal from a State or nonprofit private entity to contract with HHS shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

(b) *Special rules for transitions in administration.* (1) Transitions from HHS administration of a PCIP to State administration must take effect on January 1 of a given year.

(2) A State's proposal to administer a PCIP must meet all the requirements of this section.

(3) Transitions from State administration to HHS administration must comply with the termination procedures of the PCIP contract in effect with the State or its designated entity.

(4) The Secretary may establish other requirements needed to ensure a seamless transition of coverage for all existing enrollees.

Subpart C—Eligibility and Enrollment

§ 152.14 Eligibility.

(a) *General rule.* An individual is eligible to enroll in a PCIP if he or she:

(1) Is a citizen or national of the United States or lawfully present in the United States;

(2) Subject to paragraph (b) of this section, has not been covered under creditable coverage for a continuous 6-month period of time prior to the date on which such individual is applying for PCIP;

(3) Has a pre-existing condition as established under paragraph (c) of this section; and

(4) Is a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP. A PCIP may not establish any standards with regard to the duration of residency in the PCIP service area.

(b) *Satisfaction of 6-month creditable coverage requirement when an enrollee leaves the PCIP service area.* An individual who becomes ineligible for a PCIP on the basis of no longer residing in the PCIP's service area as described in paragraph (a)(4) of this section is deemed to have satisfied the requirement in paragraph (a)(2) of this section for purposes of applying to enroll in a PCIP in the new service area.

(c) *Pre-existing condition requirement.* For purposes of establishing a process for determining eligibility, and subject to HHS approval, a PCIP may elect to apply any one or more of the following criteria in determining whether an individual has a pre-existing condition for purposes of this section:

(1) *Refusal of coverage.* Documented evidence that an insurer has refused, or a clear indication that the insurer would refuse, to issue coverage to an individual on grounds related to the individual's health.

(2) *Exclusion of coverage.* Documented evidence that such individual has been offered coverage but only with a rider that excludes coverage of benefits associated with an individuals' identified pre-existing condition.

(3) *Medical or health condition.* Documented evidence of the existence or history of certain medical or health condition, as approved or specified by the Secretary.

(4) Other. Other criteria, as defined by a PCIP and approved by HHS.

§ 152.15 Enrollment and disenrollment process.

(a) *Enrollment process.* (1) A PCIP must establish a process for verifying eligibility and enrolling an individual that is approved by HHS.

(2) A PCIP must allow an individual to remain enrolled in the PCIP unless:

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual obtains other creditable coverage;

(iii) The PCIP program terminates, or is terminated; or

(iv) As specified by the PCIP program and approved by HHS.

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

(i) Verifying the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security as applicable; or

(ii) By requiring the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(iii) The PCIP must provide an individual who is applying to enroll in the PCIP with a disclosure specifying if the information will be shared with the Department of Health and Human Services, Social Security Administration, and if necessary, Department of Homeland Security for purposes of establishing eligibility.

(b) *Disenrollment process.* (1) A PCIP must establish a disenrollment process that is approved by HHS.

(2) A PCIP may disenroll an individual if the monthly premium is not paid on a timely basis, following notice and a reasonable grace period, not to exceed 61 days from when payment is due, as defined by the PCIP and approved by HHS.

(3) A PCIP must disenroll an individual in any of the following circumstances:

(i) The individual no longer resides in the PCIP service area.

(ii) The individual obtains other creditable coverage.

(iii) Death of the individual.

(iv) Other exceptional circumstances established by HHS.

(c) *Effective dates.* A PCIP must establish rules governing the effective date of enrollment and disenrollment that are approved by HHS. A complete enrollment request submitted by an eligible individual by the 15th day of a month, where the individual is determined to be eligible for enrollment, must take effect by the 1st day of the following month, except in exceptional circumstances that are subject to HHS approval.

(d) *Funding limitation.* A PCIP may stop taking applications for enrollment to comply with funding limitations established by the HHS under section 1101(g) of Public Law 111–148 and § 152.35 of this part. Accordingly, a PCIP may employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, and other measures, as defined by the PCIP and approved by HHS, including measures specified under § 152.35(b).

Subpart D—Benefits

§ 152.19 Covered benefits.

(a) *Required benefits.* Each benefit plan offered by a PCIP shall cover at least the following categories and the items and services:

(1) Hospital inpatient services

(2) Hospital outpatient services

(3) Mental health and substance abuse services

(4) Professional services for the diagnosis or treatment of injury, illness, or condition

(5) Non-custodial skilled nursing services

(6) Home health services

(7) Durable medical equipment and supplies

(8) Diagnostic x-rays and laboratory tests

(9) Physical therapy services (occupational therapy, physical therapy, speech therapy)

(10) Hospice

(11) Emergency services, consistent with § 152.22(b), and ambulance services

(12) Prescription drugs

(13) Preventive care

(14) Maternity care

(b) *Excluded services.* Benefit plans offered by a PCIP shall not cover the following services:

(1) Cosmetic surgery or other treatment for cosmetic purposes except to restore bodily function or correct deformity resulting from disease.

(2) Custodial care except for hospice care associated with the palliation of terminal illness.

(3) In vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy.

(4) Abortion services except when the life of the woman would be endangered or when the pregnancy is the result of an act of rape or incest.

(5) Experimental care except as part of an FDA-approved clinical trial.

§ 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.

(a) *Pre-existing condition exclusions.* A PCIP must provide all enrollees with health coverage that does not impose any pre-existing condition exclusions (as defined in §152.2) with respect to such coverage.

(b) *Waiting periods.* A PCIP may not impose a waiting period with respect to the coverage of services after the effective date of enrollment.

§ 152.21 Premiums and cost-sharing.

(a) *Limitation on enrollee premiums.* (1) The premiums charged under the PCIP may not exceed 100 percent of the premium for the applicable standard risk rate that would apply to the coverage offered in the State or States. The PCIP shall determine a standard risk rate by considering the premium rates charged for similar benefits and cost-sharing by other insurers offering health insurance coverage to individuals in the applicable State or States. The standard risk rate shall be established using reasonable actuarial techniques, that are approved by the Secretary, and that reflect anticipated experience and expenses. A PCIP may not use other methods of determining the standard rate, except with the approval of the Secretary.

(2) Premiums charged to enrollees in the PCIP may vary on the basis of age by a factor not greater than 4 to 1.

(b) *Limitation on enrollee costs.* (1) The PCIP's average share of the total allowed costs of the PCIP benefits must be at least 65 percent of such costs.

(2) The out-of-pocket limit of coverage for cost-sharing for covered services under the PCIP may not be greater than the applicable amount described in section 223(c)(2) of the Internal Revenue code of 1986 for the year involved. If the plan uses a network of providers, this limit may be applied only for in-network providers, consistent with the terms of PCIP benefit package.

§ 152.22 Access to services.

(a) *General rule.* A PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees.

(b) *Emergency services.* In the case of emergency services, such services must be covered out of network if:

(1) The enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and

(2) The services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted.

Subpart E—Oversight

§ 152.26 Appeals procedures.

(a) *General.* A PCIP shall establish and maintain procedures for individuals to appeal eligibility and coverage determinations.

(b) *Minimum requirements.* The appeals procedure must, at a minimum, provide:

(1) A potential enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding PCIP eligibility, including a determination of whether the individual is a citizen or national of the United States, or is lawfully present in the United States.

(2) An enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding the coverage of a service or the amount paid by the PCIP for a service.

(3) An enrollee with the right to a timely reconsideration of a redetermination made under paragraph (b)(2)

of this section by an entity independent of the PCIP.

§ 152.27 Fraud, waste, and abuse.

(a) *Procedures.* The PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse, and to appropriate law enforcement authorities instances of fraud. Such procedures shall include identifying situations in which enrollees or potential enrollees (or their family members) are employed, and may have, or have had, access to other coverage such as group health coverage, but were discouraged from enrolling.

(b) *Cooperation.* The PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report to appropriate authorities situations in which enrollment in other coverage may have been discouraged.

§ 152.28 Preventing insurer dumping.

(a) *General rule.* If it is determined based on the procedures and criteria set forth in paragraph (b) of this section that a health insurance issuer or group health plan has discouraged an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status, if the individual subsequently enrolls in a PCIP under this part, the issuer or health plan will be responsible for any medical expenses incurred by the PCIP with respect to the individual.

(b) *Procedures and criteria for a determination of dumping.* A PCIP shall establish procedures to identify and report to HHS instances in which health insurance issuers or employer-based group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. Such procedures shall include methods to identify the following circumstances, either through the PCIP enrollment application form or other vehicles:

(1) Situations where an enrollee or potential enrollee had prior coverage obtained through a group health plan or issuer, and the individual was provided financial consideration or other rewards for disenrolling from their coverage, or disincentives for remaining enrolled.

(2) Situations where enrollees or potential enrollees had prior coverage obtained directly from an issuer or a group health plan and either of the following occurred:

(i) The premium for the prior coverage was increased to an amount that exceeded the premium required by the PCIP (adjusted based on the age factors applied to the prior coverage), and this increase was not otherwise explained;

(ii) The health plan, issuer or employer otherwise provided money or other financial consideration to disenroll from coverage, or disincentive to remain enrolled in such coverage. Such considerations include payment of the PCIP premium for an enrollee or potential enrollee.

(c) *Remedies.* If the Secretary determines, based on the criteria in paragraph (b) of this section, that the rule in paragraph (a) of this section applies, an issuer or a group health plan will be billed for the medical expenses incurred by the PCIP. The issuer or group health plan also will be referred to appropriate Federal and State authorities for other enforcement actions that may be warranted based on the behavior at issue.

(d) *Other.* Nothing in this section may be construed as constituting exclusive remedies for violations of this section or as preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers.

Subpart F—Funding

§ 152.32 Use of funds.

(a) *Limitation on use of funding.* All funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program.

(b) *Limitation on administrative expenses.* No more than 10 percent of available funds shall be used for administrative expenses over the life of the contract with the PCIP, absent approval from HHS.

§ 152.33 Initial allocation of funds.

HHS will establish an initial ceiling for the amount of the $5 billion in Federal funds allocated for PCIPs in each State using a methodology consistent with that used to established allocations under the Children's Health Insurance Program, as set forth under 42 CFR Part 457, Subpart F, Payment to States.

§ 152.34 Reallocation of funds.

If HHS determines, based on actual and projected enrollment and claims experience, that the PCIP in a given State will not make use of the total estimated funding allocated to that State, HHS may reallocate unused funds to other States, as needed.

§ 152.35 Insufficient funds.

(a) *Adjustments by a PCIP to eliminate a deficit.* In the event that a PCIP determines, based on actual and projected enrollment and claims data, that its allocated funds are insufficient to cover projected PCIP expenses, the PCIP shall report such insufficiency to HHS, and identify and implement necessary adjustments to eliminate such deficit, subject to HHS approval.

(b) *Adjustment by the Secretary.* If the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit.

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General.* A State that enters into a contract with HHS under this part must demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts.* In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

PART 153 [RESERVED]

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Disclosure and Review Provisions

AUTHORITY: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

SOURCE: 76 FR 29985, May 23, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope.* This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid Services (CMS). This part further establishes the process by which it will be determined whether the rate increases are unreasonable rate increases as defined in this part.

§ 154.102 Definitions.

As used in this part:

CMS means the Centers for Medicare & Medicaid Services.

Effective Rate Review Program means a State program that CMS has determined meets the requirements set forth in §154.301(a) and (b) for the relevant market segment in the State.

Federal medical loss ratio standard means the applicable medical loss ratio standard for the State and market segment involved, determined under subpart B of 45 CFR part 158.

Health insurance coverage has the meaning given the term in section 2791(b)(1) of the PHS Act.

Health insurance issuer has the meaning given the term in section 2791(b)(2) of the PHS Act.

Individual market has the meaning given the term under the applicable State's rate filing laws, except that where State law does not define the term, it has the meaning given in section 2791(e)(1)(A) of the PHS Act.

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.

Rate increase means any increase of the rates for a specific 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 under the applicable State's rate filing laws, except that where State law does not define the term, it has the meaning given in section 2791(e)(5) of the PHS Act; provided, however, that for the purpose of this definition, ''50'' employees is substituted for ''100'' employees in the definition of ''small employer'' under section 2791(e)(4).

State has the meaning given the term in section 2791(d)(14) of the PHS Act.

Unreasonable rate increase means:

(1) When CMS is conducting the review required by this part, a rate increase that CMS determines under §154.205 is:

(i) An excessive rate increase;

(ii) An unjustified rate increase; or

(iii) An unfairly discriminatory rate increase.

(2) When CMS adopts the determination of a State that has an Effective Rate Review Program, a rate increase that the State determines is excessive, unjustified, unfairly discriminatory, or otherwise unreasonable as provided under applicable State law.

EFFECTIVE DATE NOTE: At 76 FR 54976, Sept. 6, 2011, §154.102 was amended by revising the definitions of ''individual market'' and ''small group market'', effective . For the convenience of the user, the revised text is set forth as follows:

§ 154.102 Definitions.

* * * * *

Individual market has the meaning given the term under the applicable State's rate filing laws, except that:

(1) Where State law does not define the term, it has the meaning given in section 2791(e)(1)(A) of the PHS Act; and

(2) Coverage that would be regulated as individual market coverage (as defined in section 2791(e)(1)(A)) if it were not sold through an association is subject to rate review as individual market coverage.

* * * * *

Small group market has the meaning given under the applicable State's rate filing laws, except that:

(1) Where State law does not define the term, it has the meaning given in section 2791(e)(5) of the PHS Act; provided, however, that for the purpose of this definition, ''50'' employees applies in place of ''100'' employees in the definition of ''small employer'' under section 2791(e)(4); and

(2) Coverage that would be regulated as small group market coverage (as defined in section 2791(e)(5)) if it were not sold through an association is subject to rate review as small group market coverage.

* * * * *

§ 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 on or after September 1, 2011, or effective on or after September 1, 2011, 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 September 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 September 1, as calculated under paragraph (c) of this section, determined by the Secretary. In establishing a State-specific threshold, the Secretary shall consult with the State and may consider relevant information provided by other interested parties. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that data relating to such State-specific factors is available.

(b) The Secretary will publish a notice no later than June 1 of each year concerning whether a threshold under paragraph (a)(1) or (2) of this section applies to a 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 the average increase for all enrollees weighted by premium volume 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.

§ 154.205 Unreasonable rate increases.

(a) When CMS reviews a rate increase subject to review under §154.210(a), CMS will determine that the rate increase is an unreasonable rate increase if the increase is an excessive rate increase, an unjustified rate increase, or an unfairly discriminatory rate increase.

(b) The rate increase is an excessive rate increase if the increase causes the

premium charged for the health insurance coverage to be unreasonably high in relation to the benefits provided under the coverage. In determining whether the rate increase causes the premium charged to be unreasonably high in relationship to the benefits provided, CMS will consider:

(1) Whether the rate increase results in a projected medical loss ratio below the Federal medical loss ratio standard in the applicable market to which the rate increase applies, after accounting for any adjustments allowable under Federal law;

(2) Whether one or more of the assumptions on which the rate increase is based is not supported by substantial evidence; and

(3) Whether the choice of assumptions or combination of assumptions on which the rate increase is based is unreasonable.

(c) The rate increase is an unjustified rate increase if the health insurance issuer provides data or documentation to CMS in connection with the increase that is incomplete, inadequate or otherwise does not provide a basis upon which the reasonableness of an increase may be determined.

(d) The rate increase is an unfairly discriminatory rate increase if the increase results in premium differences between insureds within similar risk categories that:

(1) Are not permissible under applicable State law; or

(2) In the absence of an applicable State law, do not reasonably correspond to differences in expected costs.

§ 154.210 Review of rate increases subject to review by CMS or by a State.

(a) Except as provided in paragraph (b) of this section, CMS will review a rate increase subject to review to determine whether it is unreasonable, as required by this part.

(b) CMS will adopt a State's determination of whether a rate increase is an unreasonable rate increase, if the State:

(1) Has an Effective Rate Review Program as described in § 154.301; and

(2) The State provides to CMS, on a form and in a manner prescribed by the Secretary, its final determination of whether a rate increase is unreasonable, which must include a brief explanation of how its analysis of the relevant factors set forth in § 154.301(a)(3) caused it to arrive at that determination, within five business days following the State's final determination.

(c) CMS will post and maintain on its Web site a list of the States with market segments that meet the requirements of paragraph (b) of this section.

§ 154.215 Submission of disclosure to CMS for rate increases subject to review.

(a) For each rate increase subject to review, a health insurance issuer must submit a Preliminary Justification for each product affected by the increase on a form and in the manner prescribed by the Secretary.

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

(1) Rate increase summary (Part I), as described by paragraph (e) of this section;

(2) Written description justifying the rate increase (Part II), as described by paragraph (f) of this section; and

(3) When CMS is reviewing the rate increase under § 154.210(a), rate filing documentation (Part III), as described by paragraph (g) of this section.

(c) A health insurance issuer must complete and submit Parts I and II of the Preliminary Justification described in paragraphs (b)(1) and (2) of this section to CMS and, as long as the applicable State accepts such submissions, to the applicable State for any rate increase subject to review. If a rate increase subject to review is for a product offered in the individual market or small group market and CMS is reviewing the rate increase under § 154.210(a), then the health insurance issuer must also complete and submit Part III of the Preliminary Justification described in paragraph (b)(3) of this section to CMS only.

(d) The health insurance issuer may submit a single, combined Preliminary Justification for rate increases subject to review affecting multiple products, if the claims experience of all products has been aggregated to calculate the rate increases and the rate increases are the same across all products.

(e) Content of rate increase summary (Part I): The rate increase summary 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; and

(6) Three year history of rate increases for the product associated with the rate increase.

(f) 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 include 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; and

(2) Brief description of the overall experience of the policy, including historical and projected expenses, and loss ratios.

(g) Content of rate filing documentation (Part III): (1) The rate filing documentation must be sufficient for CMS 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.

(2) If the health insurance issuer is also required to submit a rate filing to a State in connection with the rate increase under State law, CMS will accept a copy of the filing provided that the filing includes all of the information described in paragraph (g)(1) of this section.

(h) If the level of detail provided by the issuer for the information under paragraph (g) of this section does not provide sufficient basis for CMS to determine whether the rate increase is an unreasonable rate increase, 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.

(i) 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 Parts I and II of each Preliminary Justification.

(2) CMS will make available to the public on its Web site the information contained in Part III of each Preliminary Justification that is not a trade secret or confidential commercial or financial information as defined in CMS'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 Preliminary Justification.

(j) CMS will include information on its Web site concerning how the public can submit comments on the proposed rate increases that CMS reviews.

§154.220 Timing of providing the Preliminary Justification.

A health insurance issuer must submit a Preliminary Justification for all rate increases subject to review that are filed in a State on or after September 1, 2011, or effective on or after September 1, 2011 in a State that does not require the rate increase subject to review to be filed, as follows:

(a) 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 Preliminary Justification on the date on which the health insurance issuer submits the proposed rate increase to the State.

(b) For all other States, the health insurance issuer must submit to CMS and the State the Preliminary Justification prior to the implementation of the rate increase.

§154.225 Determination by CMS or a State of an unreasonable rate increase.

(a) When CMS receives a Preliminary 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.

§154.230 Submission and posting of Final Justifications for unreasonable rate increases.

(a) If a health insurance issuer receives from CMS a final determination by CMS or a State that a rate increase is an unreasonable rate increase, and the health insurance issuer declines to implement the rate increase or chooses to implement a lower increase, the health insurance issuer must submit to CMS timely notice that it will not implement the rate increase or that it will implement a lower increase on a form and in the manner prescribed by the Secretary.

(b) If a health insurance issuer implements a lower increase as described in paragraph (a) of this section and the lower increase does not meet or exceed the applicable threshold under §154.200, such lower increase is not subject to this part. If the lower increase meets or exceeds the applicable threshold, the health insurance issuer must submit a new Preliminary 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 Preliminary 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.

Subpart C—Effective Rate Review Programs

§154.301 CMS's determinations of Effective Rate Review Programs.

(a) *Effective Rate Review Program.* In evaluating whether a State has an Effective Rate Review Program, CMS will apply the following criteria for the review of rates for the small group market and the individual market, and

also, as applicable depending on State law, the review of rates for different types of products within those markets:

(1) The State receives from issuers data and documentation in connection with rate increases that are sufficient to conduct the examination described in paragraph (a)(3) of this section.

(2) The State conducts an effective and timely review of the data and documentation submitted by a health insurance issuer in support of a proposed rate increase.

(3) The State's rate review process includes an examination of:

(i) The reasonableness of the assumptions used by the health insurance issuer to develop the proposed rate increase and the validity of the historical data underlying the assumptions; and

(ii) The health insurance issuer's data related to past projections and actual experience.

(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;

(iv) The impact of benefit changes;

(v) The impact of changes in enrollee risk profile;

(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; and

(xii) The health insurance issuer's capital and surplus.

(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.* In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide access from its Web site to the Parts I and II of the Preliminary Justifications of the proposed rate increases that it reviews and have a mechanism for receiving public comments on those proposed rate increases.

(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.

PARTS 155–157 [RESERVED]

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

Sec.

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.

Contract reserves means reserves that are established by an issuer which, due to the gross premium pricing structure at issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

Direct paid claims means claim payments before ceded reinsurance and excluding assumed reinsurance except as otherwise provided in this Part.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this title, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year.

Experience rating refund means the return of a portion of premiums pursuant to a retrospectively rated funding arrangement when the sum of incurred losses, retention and margin are less than earned premium.

Group conversion charges means the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability.

Health Plan means health insurance coverage offered through either individual coverage or a group health plan.

Individual market has the meaning given the term in section 2791(e)(1) of the PHS Act and section 1304(a)(2) of the Affordable Care Act.

Large Employer has the meaning given the term in 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.

Multi-State 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 two or more States.

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.

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.

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.

Subpart A—Disclosure and Reporting

§ 158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this Part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

(b) *Timing and form of report.* (1) Except as provided in paragraph (b)(2) of this section, the report for each MLR reporting year 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.

(2) An issuer that reports its experience separately under §158.120(d)(3) or (4) of this subpart must submit a report for each quarter of the 2011 MLR reporting year, on the same form and in the same manner as described in paragraph (b)(1) of this section, as follows:

(i) By May 1 for the quarter ending March 31;

(ii) By August 1 for the quarter ending June 30; and

(ii) By November 1 for the quarter ending September 30.

(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.

§ 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, 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, the experience of the issuer must be included in the State report for the State where the employer or the association has its principal place of business.

(3) For the 2011 MLR reporting year, 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) For the 2011 MLR reporting year, an issuer with group policies that provide coverage for employees working outside their country of citizenship, employees working outside of their country of citizenship and outside the employer's country of domicile, and non-U.S. citizens working in their home country, must aggregate the experience from these policies but report the experience from such policies separately from other policies.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010]

§ 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:

(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 paid or received, excluding any rebate paid based upon an issuer's MLR.

(4) Account for unearned premium.

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 of this subpart 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 claim portion of lawsuits, and any experience rating refunds paid or received. Reimbursement for clinical services as defined in this section are referred to as ''incurred claims.''

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. If an issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting,

these amounts must be added to or subtracted from incurred claims.

(2) Incurred claims must include the current year's unpaid claims reserves, including claims reported in the process of adjustment, percentage withholds from payments made to contracted providers, claims that are recoverable for anticipated coordination of benefits (COB), and claim recoveries received as a result of subrogation.

(3) Incurred claims must include claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(4) Incurred claims must include changes in other claims-related reserves.

(5) Incurred claims must include 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.

(2) Adjustments that must be included in incurred claims:

(i) Market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments.

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

(iii) The amount of incentive and bonus payments made to providers.

(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.

(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) [Reserved]

(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 will be defined prior to January 1, 2011, 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. An issuer that chooses to use such an adjustment must use it for a minimum of three MLR reporting years.

(ii) [Reserved]

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010]

§ 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.

(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 3606 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.

(B) [Reserved]

(ii) Prevent hospital readmissions through a comprehensive program for hospital discharge. Examples include:

(A) Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;

(B) Patient-centered education and counseling.

(C) Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

(D) Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and lower infection and mortality rates.

(A) Examples of activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates include:

(*1*) The appropriate identification and use of best clinical practices to avoid harm.

(*2*) Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

(*3*) Activities to lower the risk of facility-acquired infections.

(*4*) Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

(*5*) Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

(*6*) Health information technology to support these activities.

(B) [Reserved]

(iv) Implement, promote, and increase wellness and health activities:

(A) Examples of activities primarily designed to implement, promote, and increase wellness and health activities, include—

(*1*) Wellness assessments;

(*2*) Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;

(*3*) Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition;

(*4*) Public health education campaigns that are performed in conjunction with State or local health departments;

(*5*) 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 (for example, costs of implementing new administrative simplification standards and code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended, including the new ICD–10 requirements);

(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 (c) 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.

§158.151 Expenditures related to Health Information Technology and meaningful use requirements.

(a) *General requirements.* An issuer may include as activities that improve

health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in §158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

(1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their ''meaningful use'' as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in §158.140 of this subpart;

(2) Implementing systems to track and verify the adoption and meaningful use of certified electronic health records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;

(3) Providing technical assistance to support adoption and meaningful use of certified electronic health records technologies;

(4) Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.

(5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.

(6) Advancing the ability of enrollees, providers, issuers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care, which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient's medical history and to support care management.

(7) Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.

(8) Provision of electronic health records, patient portals, and tools to facilitate patient self-management.

(b) [Reserved]

§158.160 Other non-claims costs.

(a) *General requirements.* The report required in §158.110 of this subpart must include non-claims costs described in paragraph (b) of this section and must provide an explanation of how premium revenue is used, other than to provide reimbursement for clinical services covered by the benefit plan, expenditures for activities that improve health care quality, and Federal and State taxes and licensing or regulatory fees as specified in this part.

(b) *Non-claims costs other than taxes and regulatory fees.* (1) The report required in §158.110 of this subpart must include any expenses for administrative services that do not constitute adjustments to premium revenue as provided in §158.130 of this subpart, reimbursement for clinical services to enrollees as defined in §158.140 of this subpart, or expenditures on quality improvement activities as defined in §§158.150 and 158.151 of this subpart.

(2) Expenses for administrative services include the following:

(i) Cost-containment expenses not included as an expenditure related to an activity at §158.150 of this subpart.

(ii) Loss adjustment expenses not classified as a cost containment expense.

(iii) Direct sales salaries, workforce salaries and benefits.

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

§ 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, 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]

§ 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) One of the following types of payments:

(A) Payments to a State, by not-for-profit health plans, of premium tax exemption values in lieu of State premium taxes limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large group;

(B) Payment by not-for-profit health plans for community benefit expenditures as described in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large group. These payments must be made due to a State based requirement to qualify for inclusion in this line item; or

(C) Payments made by (Federal income) tax exempt health plans for community benefit expenditures as defined in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group, and large group.

(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.* (1) A not-for-profit issuer exempt from

Federal or State taxes and assessments, but required to make community benefit expenditures in lieu of taxes, must report to the Secretary such community benefit expenditures, multiplied by the allocated premiums earned for individual, small group and large group, but not to exceed the amount of the taxes they would otherwise be required to pay. Each expenditure must not be reported more than once, but may be split between Federal and State taxes as applicable.

(2) 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:

(i) Are available broadly to the public and serve low-income consumers;

(ii) 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);

(iii) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;

(iv) Leverage or enhance public health department activities such as childhood immunization efforts; and

(v) 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.]

§ 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 of this subpart.

(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.

§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, pursuant to section 1312(c)(3) of the Affordable Care Act, a State requires the small group market and individual market to be merged, then the data reported separately under subpart A for the small group and individual market in that State may 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 paragraph (c) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in §158.221 of this subpart and aggregating the data reported under this Part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) *Requirements for MLR reporting years 2011 and 2012.* (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this Part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year—

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this Part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in §158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year and the 2012 MLR reporting year.

§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 2011 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 two.

(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 for the 2011 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 two.

(c) *Denominator.* The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in §158.130, minus 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) of this part.

§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.

(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.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010]

§ 158.232 Calculating the credibility adjustment.

(a) *Formula.* An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the deductible factor, as determined under paragraph (c) of this section.

(b) *Base credibility factor.* (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under §158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

TABLE 1 TO §158.232: BASE CREDIBILITY FACTORS

Life-years	Base credibility factor
< 1,000	No Credibility.
1,000	8.3%.
2,500	5.2%.
5,000	3.7%.
10,000	2.6%.
25,000	1.6%.
50,000	1.2%.
≥ 75,000	0.0% (Full Credibility).

(c) *Deductible factor.* (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under §158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be calculated as follows: The lesser of the sum of the individual family members' deductibles or the overall family deductible for the subscriber and subscriber's family, shall be divided by the total number of individuals covered through the subscriber (including 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.* For 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.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010]

§ 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 received by the issuer from the enrollee after subtracting Federal and State taxes and licensing and regulatory fees as provided in § 158.161(a), § 158.162(a)(1) and § 158.162(b)(1) of this part, multiplied by the difference between the MLR required by § 158.210 or § 158.211 of this subpart, and the issuer's MLR as calculated under § 158.221 of this subpart.

(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 small group 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 small group 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 premium and subtracting taxes and fees as provided in paragraph (c) of this section. In this example, an enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.161(a), § 158.161(a)(1) and § 158.162(b)(1) of this subpart are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of 5 percent of $1,850, or $92.50.

(d) *Timing of rebate.* An issuer must provide any rebate owing to an enrollee no later than August 1 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.

§ 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) 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.

(b) *Former enrollees.* Rebates owing to former enrollees must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

§ 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.* An issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the enrollee, in amounts proportionate to the amount of premium the policyholder and each subscriber paid.

(1) *Arrangement with policyholder to distribute rebates.* An issuer may meet its obligation to provide any rebate owing to a large group or small group enrollee by entering into an agreement with the group policyholder to distribute the rebate on behalf of the issuer, subject to all of the following conditions:

(i) The issuer must remain liable for complying with all of its obligations under this part.

(ii) The issuer must obtain and retain records and documentation evidencing accurate distribution of any rebate owing, sufficient to demonstrate compliance with its obligations under this subpart, subpart D, and subpart E. Such records and documentation include:

(A) The amount of the premium paid by each subscriber;

(B) The amount of the premium paid by the group policyholder;

(C) The amount of the rebate provided to each subscriber;

(D) The amount of the rebate retained by the group policyholder; and

(E) The amount of any unclaimed rebate and how and when it was distributed.

(2) [Reserved]

§ 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, if the total rebate owed to the policyholder and the subscribers is less than $5 per subscriber covered by the policy for a given MLR reporting year.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) *Distribution.* (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee's rebate by $0.20.

§ 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.

For each MLR reporting year, at the time any rebate of premium is provided in accordance with this Part, an issuer

must provide each enrollee who receives a rebate the following information in a form prescribed by the Secretary:

(a) A general description of the concept of an MLR;

(b) The purpose of setting a MLR standard;

(c) The applicable MLR standard;

(d) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(e) The issuer's aggregate premium revenue as reported in accordance with §158.130, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §§158.161(a) and 158.162(a)(1) and (b)(1); and

(f) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

§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 and percentage of enrollees who received a rebate;

(2) Number and amount of rebates provided:

(i) As premium credit; and

(ii) As lump sum check or lump-sum reimbursement to a subscriber's credit card or direct payment to a subscriber's bank account;

(3) Amount of rebates that were provided to enrollees, including a breakdown of the amounts provided based upon the portion of premiums paid by group policyholders and amounts provided based upon the portion of premium paid by subscribers;

(4) Amount of rebates that were *de minimis,* as provided in §158.243, and a detailed description of how these rebates were disbursed; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a detailed description of how the unclaimed rebates were disbursed.

(d) *Timing and form of report.* The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under §158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under §158.110 for the subsequent MLR reporting year.

§158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this Part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in 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.

§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 implementation 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 and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with § 158.240(d) of this part.

§ 158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E—Additional Requirements on Issuers

§ 158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§ 158.502 Maintenance of records.

(a) *Basic rule.* Each issuer subject to the requirements of this part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this part comply with the definitions and criteria set forth in this part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under §158.501 of this subpart.

Subpart F—Federal Civil Penalties

§ 158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties, as described in this subpart, may be imposed.

§ 158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in § 158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this Part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§ 158.603 Notice to responsible entities.

If HHS learns of a potential violation described in § 158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§ 158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in § 158.602 of this subpart.

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of

compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§ 158.606 Amount of penalty—general.

A civil monetary penalty for each violation of §158.602 of this subpart may not exceed $100 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 noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by §158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in §158.607 of this subpart, HHS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under §158.603 of this subpart, implemented and followed a compliance plan as described in §158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this Part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she, or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this Part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 158.611 Settlement authority.

Nothing in § 158.606 through § 158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 158.603 of this subpart or to compromise on any penalty provided for in §§ 158.606 through 158.610 of this subpart.

§ 158.612 Limitations on penalties.

(a) *Circumstances under which a civil monetary penalty is not imposed.* HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this Part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this Part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in § 158.607 through § 158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with § 158.615 of this subpart.

(b) *Delivery of Notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§ 158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this Part may appeal that penalty in accordance with § 150.400 *et seq.*

§ 158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in § 158.613 of this subpart, HHS may assess the proposed civil monetary penalty indicated in such notice and may impose additional penalties as described in § 158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this subchapter, unless the responsible entity can show good cause, as determined at § 150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

PART 159—HEALTH CARE REFORM INSURANCE WEB PORTAL

Sec.

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.